American Conference Institute's *3rd West Coast Edition*

ACI's HATCH-WAXMAN SERIES

Paragraph IV Disputes

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

December 4 – 5, 2012 • Hotel Nikko • San Francisco, CA

FTC Keynote on Pay-For-Delay Settlements

Understand the repercussions of the recent 3rd Circuit decision *In re K-Dur*

Markus H. Meier
Assistant Director, Health Care Division
Bureau of Competition
Federal Trade Commission
(Washington, DC)

Judicial insights from:

Honorable Tonianne Bongiovanni, U.S.M.J.
United States Federal District Court
District of New Jersey (Trenton, NJ)

Honorable Garrett E. Brown, Jr., U.S.D.J. (Ret.)
Arbitrator, Mediator, and Special Master, JAMS
Former Chief Judge
United States Federal District Court
District of New Jersey (Trenton, NJ)

Honorable David Folsom, U.S.D.J. (Ret.)
Partner, Jackson Walker L.L.P.
Arbitrator and Mediator, Federal Arbitration, Inc.
Former Chief Judge
United States Federal District Court
Eastern District of Texas (Texarkana, TX)

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

Industry Insights From: Distinguished Co-Chairs:

Carmen M. Shepard
Mylan Pharmaceuticals

Karen Brown
Ironwood Pharmaceuticals

Plus counsel from 5 other leading companies

Veteran counsel from branded and generic drug makers and the FTC as well as experienced jurists will provide insights into how the latest developments in Hatch-Waxman case law will affect your Paragraph IV litigation strategies and long term business and product portfolio plans. They will discuss the latest legal challenges affecting parties on both sides and help you:

- **NAVIGATE** the evolving case law surrounding obvious-type double patenting and **FORMULATE** litigation strategies based on prior art obviousness analysis
- **EXAMINE** method of treatment claims in view of recent and pending decisions regarding inducement of infringement and divided infringement
- **COMPREHEND** the impact of *Therasense* on the standard for inequitable conduct and its implications for Hatch-Waxman cases
- **EVALUATE** new trends in validity challenges including extended and delayed release formulations
- **WEIGH** the risks and benefits of at-risk launches and **ASSESS** potential damages

December 3, 2012:

Workshop A: **Hatch-Waxman and BPCIA 101** — A Primer on IP Basics and Regulatory Fundamentals will provide the patent and regulatory foundation for the high-level Hatch-Waxman litigation discussions of the main conference

Workshop B: **Working Group Session — Assessing the Impact of New PTO Procedures Under the AIA on Paragraph IV Litigation** will address how new pre- and post issuance procedures affecting Paragraph IV suits and parallel proceedings between the Federal Courts, PTO. **Also features insights from Janet Gongola, Patent Reform Coordinator, U.S. Patent and Trademark Office.**

December 5, 2012

Workshop C: **Working Group Session — Biosimilars: Product Development Strategies, Regulatory Review, and Anticipated Litigation Through A Hatch-Waxman Lens** will create a map by which to traverse this novel and uncertain terrain

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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 numerous blockbuster drugs go off patent between now and 2014, Hatch-Waxman litigation will only intensify. Brand name manufacturers are struggling to fill a drying pipeline and extend patent life through other statutory and regulatory conventions. Meanwhile, generics eye the ultimate Hatch-Waxman prize of 180-day exclusivity — knowing that such opportunities in the future may be short-lived as there will be few patented drug products worth coveting.

The monetary ante combined with constantly evolving case law including *Caraco, Therasense, In re Cyclobenzaprine, Akamai* and *McKesson* and legislative developments such as the America Invents Act create more questions which will inevitably spawn more litigation.

At **American Conference Institute's 3nd Annual West Coast Edition** of its acclaimed **Paragraph IV Disputes** conference, an experienced faculty of renowned litigators, judges and government officials will guide you through every stage of a Paragraph IV challenge. They will 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 the Commission's approval.

Obtain the tools that you need to advance a novel claim or defense at this West Coast edition of our industry-leading conference. You will have access to the expertise of trial leading patent counsel from generic and branded companies. You will also have the opportunity to hear from 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 provide strategies from both brand name and generic perspectives to help you 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.

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Boehringer Ingelheim
(Ridgefield, CT)

Who You Will Meet

✓ **Patent attorneys and litigators (in-house & law firm) who represent:**

- Brand name pharmaceutical companies
- Generic pharmaceutical companies
- Biopharmaceutical companies

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Pre-Conference Workshops – Monday, December 3, 2012

A Hatch-Waxman and BPCIA 101 — A Primer on IP Basics and Regulatory Fundamentals

9:00 AM – 12:30 PM (Registration begins at 8:00 AM)

Kurt R. Karst
Partner
Hyman, Phelps & McNamara, P.C. (Washington, D.C.)

Laura Lydigsen
Co-chair, Appellate Practice Group
Brinks Hofer Gilson & Lione (Chicago, IL)

This workshop will provide you with an in-depth review of the Hatch-Waxman Act as well as other IP and regulatory basics relative to small molecules. The workshop leaders will lay the necessary foundation for you to comprehend the dynamics of the IP and regulatory backdrop underlying each Paragraph IV dispute. They will help you fully appreciate the complexities of the Hatch-Waxman litigation challenges presented during the main conference. Points of discussion will include:

Regulatory Essentials Relative to Hatch-Waxman

- Understanding the link between the FDA approval process and the patenting of drugs and biologics

Rx Drugs (new drugs)

- Analysis of effects of the User Fee Authorization Act on the timing of generic approvals
- Identifying the application process for the approval of a new drug, i.e., small molecule, new chemical entities, etc.
- NDA (New Drug Application)
- INDA (Investigational New Drug Application) aka "IND"
- Accelerated approvals
- Using advisory committees in the approval process

Biologics

- Understanding the approval process for a biologic
- BLA (Biological Licensing Application)
- Why is it a "license," rather than an "approved application"?

IP Protection for Drugs and Biologics

- Analyzing the patenting process for drugs and biologics
- Seeking patent protection during the pre-approval process
- IP and regulatory redress for time lost during the pre-approval process
- Distinguishing the patenting process for drugs from that of biologics - which biologics are treated as drugs and why?
- Identifying the respective roles of the FDA and the PTO in the patenting of drugs and biological products

Drugs

- Exploring the differences between a NDA and an ANDA (Abbreviated New Drug Application)
- ANDA: what does it require?
- Paragraph IV Certifications and Notice Letters
- Bioequivalence defined
- The Orange Book: what is it and why is it Orange?

Biologics

- Identifying biologics that fall within the purview of Hatch-Waxman

The Pharmaceutical Patent Endgame: Hatch-Waxman Explained

- Overview of Hatch-Waxman and reforms under the Medicare Modernization Act (MMA)
- The role of Orange Book under Hatch-Waxman vis-à-vis the MMA
- Exploring different concepts in exclusivity
- 30-month stay
- Patent extensions
- The safe harbor
- FD&C 505b2 (an alternate pathway to an ANDA)

Trademark and Trade Dress Issues

- Identifying the PTO and FDA clearances necessary for trade name/ trademark approval on your product

** Networking Luncheon will be available for attendees registered for Workshops A and B beginning at 12:45*

B AIA/PTO Working Group: Assessing the Impact of New PTO Procedures Under the AIA on Paragraph IV Litigation

2:00 PM – 5:30 PM (Registration begins at 1:15 PM)

Adda Gogoris
Partner
Merchant & Gould (New York, NY)

Janet Gongola
Patent Reform Coordinator
U.S. Patent and Trademark Office

Keeto Sabharwal
Director
Sterne Kessler Goldstein Fox (Washington, DC)

Matthew A. Smith
Partner, Chair of Patent Office Trials Group
Foley & Lardner LLP (Washington, DC)

Patricia M. Thayer
Partner
Sidley Austin (San Francisco, CA)

The America Invents Act (AIA) has created, and in some instances amended PTO Procedures which would create a parallel and/or alternate administrative avenue to certain components of Paragraph IV litigation in the District Courts. These procedures would go directly to the heart of an invalidity challenge and also provide administrative mechanisms which in some instances could cure errors in the file history. There are also mechanisms that could stop the issuance of a patent during the pendency of its application. However, the employ of these mechanisms may carry consequences which may bring about the opposite effect of which was the intended purpose. The workshop leaders will address these procedures as well as specific concerns to brands and generics. Points of discussion will include:

Third Party Pre-Issuance Submissions

- Understanding when pre-issuance submission of prior art to the PTO by a third party challenger as outlined by this procedure would be used in a Hatch-Waxman scenario
- Examining scenarios in which the application of a pending pharmaceutical patent might actually be strengthened as opposed to diminished by the invocation of this procedure

Supplemental Proceedings

- Exploring Paragraph IV scenarios in which it makes sense for a patent holder to pursue supplemental reexamination
- Protocols and procedures for supplemental proceedings
- Defining a substantial new question of patentability (SNQP)
- Exploring relationship between supplemental proceedings and inequitable conduct

Post Grant Review

- Weighing considerations for when a challenge should be brought under post grant review (PGR) in a Hatch-Waxman setting
- Exploring start dates, timing and basis of the application – questions to ask
- Estoppel considerations relative to Paragraph IV litigation
- Examining the mechanics, protocols and procedures for PGR
- Analyzing the petitioner's burden of proof
- Procedures for appeal

Inter Partes Review

- Comparing current inter partes reexamination protocols to inter partes review protocols under AIA
- Examining how current inter partes reexamination procedures are being employed by both patent challengers and patent holders in Hatch Waxman scenarios
- Understanding the fine points of the new inter partes review procedure
- Revisions to patent challenger's burden of proof under current inter partes reexamination and new inter partes review procedures
- Exploring the scope of review for current and new procedures under 102 and 103
- Transition and phase out

Joinder of Accused Infringers

- Potential impact of 299 on Hatch-Waxman disputes

Main Conference Day 1
Tuesday, December 4, 2012

7:15 **Registration and Continental Breakfast**

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

Karen Brown
Senior IP Counsel
Ironwood Pharmaceuticals (Cambridge, MA)

Carmen M. Shepard
Senior VP, Global Policy and Regulatory
Mylan Pharmaceuticals (Washington, DC)

8:15 **Anticipating and Reassessing Paragraph IV Challenges in the Era of the Patent Cliff**

Jamison Lynch
Senior Counsel, Intellectual Property
Gilead Sciences, Inc. (Foster City, CA)

Jennifer Fox
Counsel
Brinks Hofer Gilson & Lione (Research Triangle Park, NC)

Michael V. O'Shaughnessy
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (Washington, DC)

Brand Name Side

- Understanding how the arrival of the 'patent cliff' has changed a patent holder's Paragraph IV due diligence strategies
- Evaluating the strength of the patents in your current portfolio in light of the new industry dynamics created by the patent cliff
  - Orange Book and non-Orange Book eligible patents
- Examining the Orange Book 'to list or not list' dilemma
  - alternatives to compound patents
    - methods
      - employment of use codes
    - polymorphs
    - basic chemical patents; formulation patents
    - products by process
  - special listing considerations for small proteins filed through an NDA as opposed to a BLA in light BPCIA biosimilar provisions
    - what is the protein's method of manufacture
      - chemical vs. biotechnical
- Gauging when to reasonably expect a Paragraph IV filing by a generic competitor in the era of the 'patent cliff'
- Learning to look beyond the 'blockbuster patents'
  - understanding why patents on smaller products may be more vulnerable to challenge in some instances
- Exploring brand name exclusivities and their correlation to the start of a Paragraph IV challenge
  - NCE
    - possible extension of NCE exclusivity from 5 to 12 years?
  - new use or indication; new formulation
  - orphan drug; pediatric
- Preparing for litigation
  - developing discovery check-lists
    - implementation of document retention policy
    - when is a litigation hold put on all documents which may be discoverable
  - e-discovery
    - possible e-discovery restraints in various jurisdictions
    - "call back" rule for inadvertent disclosure
  - where have courts upheld/invalidated patents and what factors seem to be important in those outcomes?
- Preventing a Paragraph IV challenge
  - entering an authorized generics agreement
  - claiming the label; filing a citizen's petition
  - OTC switches
- Understanding how changes in the US Patent System under the AIA may influence Orange Book listing strategies

9:15 **Analyzing Invalidity & Non-Infringement Assertions In Light of the ANDA Applicant's Pre-Litigation Obligations and Assertions**

Rochelle Dede
Patent Attorney
Sandoz Inc. (Princeton, NJ)

Anders Aannestad
Partner
Morrison Foerster (San Diego, CA)

Paul Tully
Partner
McDonnell Boehnen Hulbert & Bergoff LLP (Chicago, IL)

Generic Side

- Reexamining the initial obligations oNDA applicant under Paragraph IV in light of the Supreme Court's ruling in Microsoft v. i4i
  - when is there "clear and convincing" evidence that patent is invalid and therefore not infringed
  - assessing the consequences of not meeting this burden of proof
- Weighing your options in light of the burden: should you file a Paragraph IV certification or choose another ANDA route?
- Choosing which Orange Book patents to challenge
  - compounds; formulations
  - reformulations
    - *The Research Foundation of State University of New York v. Mylan Pharmaceuticals, Inc.*
    - *AstraZeneca AB et al v. Hanmi USA, Inc.*
  - process; methods of use
  - polymorphs
  - extended release
    - *In re Cyclobenzaprine*
    - *Cyntora*
    - *AstraZeneca Pharmaceuticals LP v. Torrent Pharmaceuticals Ltd.*
  - enantiomers
    - *Sunovian Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*
  - factoring "forfeiture" into your Orange Book strategy
  - skinny labeling and carve-out considerations via *Caraco*
  - obviousness assessments
- How Patent Reform may impact Orange Book patent challenges
  - elimination of Best Mode defense
  - prior user rights
  - exploring new Post Grant Review and Inter Partes Review as another mechanism for invalidating an Orange Book patent
- Understanding the role of non-Orange Book patents in your PIV ANDA strategies
  - innovator / non-innovator
  - API
- Procuring legal opinions on invalidity and non-infringement
  - performing cost effective due diligence and freedom to operate analysis before filing an ANDA
  - assessing when opinions are needed
  - opinion of in-house v. outside counsel
  - questions of privilege
    - Rule 26 (b) (4) revisions regarding expert opinions
- Filing the ANDA
  - fulfilling requirements for FDA approval:
    - pharmaceutically equivalent; bioequivalent
  - identifying triggers which may necessitate new bioequivalence studies
- Contents of the Paragraph IV certification

10:15 **Morning Coffee Break**

10:30 **Prior Art Obviousness and Obviousness-Type Double Patenting: Legal Analysis and Practical Applications for Brand Names and Generics**

Karen Brown
Senior IP Counsel
Ironwood Pharmaceuticals (Cambridge, MA)

Meg Snowden
VP, Intellectual Property at Impax Laboratories
Impax Pharmaceuticals (San Francisco, CA)

Mark E. Waddell
Partner and Chair, Patent Litigation and Counseling
Loeb & Loeb LLP (New York, NY)

- Prior Art Obviousness
  - exploring the reaffirmation of *KSR* through *In re Kao* (Fed. Cir. 2011)
  - how establishing secondary considerations earlier in the game could save your patent
  - examining questions of "secret prior art" and "inherent anticipation"
  - assessing the impact of the AIA's prior art provisions in Paragraph IV related obvious challenges
- Obvious-Type Double Patenting
  - analyzing the evolving state of the law on obviousness-type double patenting and its impact on Paragraph IV litigation
    - *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*
  - new theories on the double patenting defense
    - 103(c) safe harbor and its implications for secret art
- Practical Applications
  - how portfolio building is affected
  - strategies for invoking and responding to an obviousness challenge in concurrence with current law
  - summary judgment assessments
  - discover approaches
  - experts
    - using the same expert for both infringement and invalidity opinions
    - new expert report provisions under Rule 26(b)(4)

12:00 **Networking Luncheon**

1:15 Labels, Patents and Use Codes: Understanding the Significance of *Novo Nordisk v. Caraco* to Hatch-Waxman Challenges

James Hurst
Partner & Chair of Intellectual Property Practice
Winston & Strawn (Chicago, IL)

Terry Mahn
Principal
Fish & Richardson (Washington, DC)

Michael Sitzman
Partner
Gibson Dunn (San Francisco, CA)

- Exploring the relationship between a drug's label, patents, use codes and Orange Book listings relative to Hatch-Waxman litigation
  - *Bayer Schering Pharma AG v. Lupin, Ltd. (Fed. Cir. 2012)*
  - *Bone Care International, L.L.C. v. Roxane Laboratories, Inc.*
- Deciphering therapeutic equivalence evaluation codes
  - what are the roles of AB ratings and OB use codes in the Orange Book
- Defining Section viii carve–outs and understanding their significance to Orange Book listings and Paragraph IV challenges
  - skinny labeling
    - off-label uses
- Examining how the Supreme Court's ruling in *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.* has altered the landscape in this area with respect to:
  - the interpretation of the counterclaim provision challenging method of use patents per the MMA amendments
    - counterclaims for and against the FDA
  - delisting strategies based on use codes and labeling controversies
    - when can use codes be altered?
    - seeking permission from the FDA to carve-out patent protected language to allow for generic entry
    - possible consequences of narrowing vs. expanding the use code narrative
- Discussion of predictions of more Section viii related litigation as an alternative to P4
  - counterclaims for and against FDA

2:30 **Afternoon Refreshment Break**

2:45 Reassessing Paragraph IV Strategies for Method Treatment Patents in View of Recent and Pending Decisions Regarding Inducement and Divided Infringement

Shashank Upadhye
Independent Consulting & Mediation
Shashank Upadhye Consulting (Oakville, Ontario, Canada)

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

Jason G. Winchester
Partner
Jones Day (Chicago, IL)

Moderator:
Jeffry M. Nichols
Intellectual Property Attorney, Co-chair of the Biotechnology & Pharmaceutical Practice Group
Brinks Hofer Gilson & Lione (Chicago, IL)

- Defining inducement of infringement and divided infringement under current law
  - how the Supreme Court's ruling in *Global Tech v. SEB* has altered the standard for inducement findings
    - mens rea requirements
      - willful blindness vs. deliberate indifference
      - *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc. (Fed. Cir. 2012)*
    - indirect vs. direct infringement
  - the concept of divided and joint infringement vis-à-vis *Akamai Technologies, Inc. v. Limelight Networks, Inc. (Fed. Cir. 2011)* and *McKesson Technologies Inc. v. Epic Systems Corp. (Fed. Cir. 2011)*
- Exploring the relationship between inducement actions and divided infringement allegations and how they apply to methods of treatment claims in pharmaceutical patents
- Examining inducement and divided infringement challenges to methods of treatment claims listed in the Orange Book
  - *AstraZeneca LP v. Apotex, Inc.*: exploring the role of Section viii carve-outs and the inducement controversy
- How may the Federal Circuit's en banc rulings in *Akamai* and *McKesson* influence Paragraph IV challenge of these types of Orange Book listed patents going forward?
- How to craft claims and draft the label to prevent allegations of inducement of infringement

Judges' Roundtable

4:00 A View From the Bench

Honorable Tonianne Bongiovanni, U.S.M.J.
United States Federal District Court
District of New Jersey (Trenton, NJ)

Honorable Garrett E. Brown, Jr. (Ret.)
Mediator and Arbitrator, JAMS
Former Chief Judge
United States Federal District Court
District of New Jersey (Trenton, NJ)

Honorable David Folsom (Ret.)
Partner, Jackson Walker L.L.P.
Arbitrator and Mediator, Federal Arbitration, Inc.
Former Chief Judge
United States Federal District Court
Eastern District of Texas (Texarkana, TX)

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

Moderator:
Sandra A. Bresnick
Partner
Quinn Emanuel Urquhart & Sullivan, LLP (New York, NY)

Sitting and retired jurists having vast experience with Paragraph IV litigation will share their thoughts and insights on some of the most pressing issues facing both patent holders and patent challengers. Come prepared to ask the questions you would never have a chance to put forth in court.

5:15 **Conference Adjourns to Day 2**

5:15 **Cocktail Reception** ***Hosted by:*** LOEB & LOEB LLP

Wednesday, December 5, 2012

7:15 **Registration and Continental Breakfast**

8:00 **Co-Chairs Opening Remarks and Recap of Day One**

Antitrust Update

8:15 **FTC Keynote: Pay-for-Delay Update**

Markus H. Meier
Assistant Director, Health Care Division
Bureau of Competition
Federal Trade Commission (Washington, DC)

The FTC continues to vigorously use its enforcement and policy tools to prevent anticompetitive business practices in the pharmaceutical industry. Over the last several years, the Commission has used much of this arsenal on the matter of "reverse settlement" or "pay-for-delay" agreements which it views as a very anticompetitive practice. The FTC is not alone in this view, as the DOJ and some members of Congress have also come to the conclusion that these agreements are in restraint of trade and cause great harm to the consumer.

Markus Meier of the FTC's Bureau of Competition's Health Care Division will discuss the current status of the FTC's efforts to end "pay-for-delay" settlements and address such matters as:

- The significance of the recent 3rd Circuit decision *In re K-Dur*
- The status of pending FTC litigation concerning patent settlements
- The enforcement of the MMA reporting requirements
- The status of pending legislation regarding "pay-for-delay" settlements
- The findings of the FTC's authorized generic's study

9:00 **Settling Paragraph IV Disputes: Drafting and Negotiation Strategies for Brand-Names and Generics**

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

Steven A. Maddox
Partner
Knobbe Martens (Washington, DC)

This session will explore best practices to achieve successful settlement agreements while minimizing unnecessary antitrust risk. Points of discussion will include:

- How to draft and structure an agreement that will receive FTC approval Identifying and avoiding red flags that may lead to FTC scrutiny
- Negotiating settlement agreements while Supreme Court review is pending in *AndroGel* and *K-Dur*
- The potential nationwide ramifications of California antitrust law in *In re Cipro*
- Anticipating possible requirements under proposed legislation
- Understanding the role of authorized generics in these agreements and the FTC's view on this topic
- Incorporating elements that emphasize the competitive nature of the agreement
- Devising strategies to employ pending completion of the FTC's review How FTC enforcement may affect your product development and licensing

10:00 **Morning Coffee Break**

10:15 **Exclusivities and Forfeitures: New Developments, Controversies and Concerns Relative to Paragraph IV Litigation**

Frank Grassler
Corporate Counsel (Contract)
Genentech, Inc. (San Francisco, CA)

Kerry McTigue
Partner, Co-Chair IP Practice Group
Cozen O'Conner (Washington, DC)

Preston K. Ratliff, II
Partner
Paul, Hastings LLP (New York, NY)

- Deciphering the FDA stance on pre and post-MMA 180-day exclusivity
  - orphan drug and marketing exclusivity and how it interplays with litigation
  - data exclusivity
- 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
- When can a brand "park" a generic's exclusivity?
- Defining "shared exclusivity"
- How have authorized generics changed the playing field relative to 180-day exclusivity?
- Exploring regulatory bars to exclusivity
  - GMP regulations; SEC
- Forfeiture provisions: circumstances under which exclusivity is forfeited
- Interpreting the "earlier of," "later of" language in making a forfeiture determination
- Evaluating the strength of "the failure to market" provisions post-Lipitor
- Exploring simultaneous qualification for and forfeiture of exclusivity for failure to obtain tentative approval
- Evaluating the impact of "delisting" on forfeiture
- Forfeiture relative to patent expiration
- Understanding the relationship between forfeiture and the increase in generic/generic litigation
- Revisiting the relationship between exclusivity, forfeiture, and the 30 month stay

11:00 **Controversies Surrounding Damages and Injunctions Relative to At Risk Launches**

Kenneth L. Dorsney
Counsel
Morris James (Wilmington, DE)

Adam G. Kelly
Partner
Loeb & Loeb LLP (Chicago, IL)

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

Moderator:

Mark T. Jansen
Partner
Crowell & Moring (San Francisco, CA)

- Launching at risk during litigation or the appeal period
  - benefits and risks analysis

Injunctions

- Examining the inconsistencies between the Federal Circuit and the Supreme Court relative to the granting of a preliminary injunction
  - intra-Circuit split
  - *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC, Case No. 10-1382 (Fed. Cir., Sept. 29, 2011)*
    - *eBay Inc. v. MercExchange, LLC, 547 U.S. 388 (2006)*
  - *Boniva; Cephalon*
  - considerations by the District Courts in light of this inconsistency
- Practical strategies for brand names and generics in dealing with this discord before the District Courts and Federal Circuit
  - proving irreparable harm
- 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

Damages Analysis

Gregory K. Bell
Group Vice President
Charles River Associates (Boston, MA)

Richard Manning, PhD
Partner
Bates White, LLC (Washington, DC)

Glenn S. Newman, CPA/ABV/CFF, MBA
Partner, Forensic Litigation & Valuation Services
ParenteBeard LLC (Philadelphia, PA)

Experts Panel

- The quantification of damages
  - brand–name vs. generic point of view
  - small v. large generic company concerns
- Lost profits:
  - Assessment of profit as a true measure of damages
    - is the drug profitable?
    - a question of sales
  - when is it the only thing that you can seek?
- Reasonable royalties:
  - basis for royalty
  - looking at market share
  - the point where infringement began
- Mitigating factors impacting damage award
- Lessons learned from *Sanofi v. Apotex (Plavix)* and predictions for Protonix

12:45 **Networking Luncheon**

1:45 **Updating the Standards in Inequitable Conduct Post-*Therasense*: Ethical Considerations for Paragraph IV Cases**

Scott B. Howard
Partner
Patterson Belknap Webb & Tyler LLP (New York, NY)

James K. Stronski
Partner
Crowell & Moring LLP (New York, NY)

Ethics

- Examining the Federal Circuit's tightening of the of the inequitable conduct standard in *Therasense*
  - intent to deceive
    - single most reasonable inference
  - materiality
    - 'but' for test
  - possible Supreme Court review?
- Exploring the legacy of *Therasense* in light of these rulings and their impact for future inequitable conduct filings
  - *Astor* case
  - *Apotex, Inc. v. Cephalon, Inc.*
  - *Pfizer v. Teva*
    - awarding sanctions for asserting unsubstantiated claims of inequitable conduct
  - repercussions of this ruling and its impact for future inequitable conduct filings
- Re-examining the relationship between inequitable conduct and corporate fraud
  - future question of corporate intent in a Hatch-Waxman setting
- Inequitable conduct and Patent Reform
  - supplemental proceedings under the AIA: an opportunity to cure inequitable conduct?

2:45 **Conference Ends**

Wednesday, December 5, 2012

Working Group Session – Biosimilars: Product Development Strategies, Regulatory Review, and Anticipated Litigation Through A Hatch-Waxman Lens

3:00 PM – 6:00 PM (Registration begins at 2:30 PM)

Deborah A. Martin, Ph.D.
Assistant General Counsel
Pfizer Inc. (San Francisco, CA)

David A. Manspeizer
Partner
WilmerHale (New York, NY)

Vicki Norton
Partner
Duane Morris (San Diego, CA)

Biosimilars are the new frontier. Many industry players see the potential for these new biological products and are positioning themselves to take advantage of this developing market space. Prepare now for life cycle management and the impending onslaught of litigation for these emerging and innovative products. A team of experts will lead you in discussion of this exciting and challenging new arena. Topics will include:

- Identifying major provisions of the act
- Understanding the Act's impact through early FDA guidelines and requirements
  - analyzing the FDA response to Abbott's citizen petition
- Preventing major mistakes early on by determining which patents must be named in the generic certification process
  - what happens if you omit listing a patent that should be listed?
  - is an omitted listing tantamount to forfeiting the right to sue on it?
- Examining the legislation with respect to:
  - proposed pathways; exclusivity and the interpretation of that word; patentability; interchangeability; no Orange Book listing
- Assessing the similarities and differences between Hatch-Waxman and how a Hatch-Waxman model will compare to an exclusivity model designed for biological products
- Abbreviated approval process differentiations for small vs. large proteins
- An update on biosimilars in Europe

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Workshop B: **Working Group Session — Assessing the Impact of New PTO Procedures Under the AIA on Paragraph IV Litigation**

December 5, 2012
Workshop C: **Working Group Session — Biosimilars: Product Development Strategies, Regulatory Review, and Anticipated Litigation Through A Hatch-Waxman Lens**

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