**West Coast Edition**

ACI'S HATCH-WAXMAN SERIES

American Conference Institute's

# Paragraph IV Disputes

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

December 8-9, 2010 | San Francisco | Sheraton Fisherman's Wharf

### Conference Co-Chairs:

*Martin A. Voet*
Consultant in Intellectual Property and Pharmaceutical Product Exclusivity
*(Former Senior Vice President, Chief IP Counsel for Allergan)*

*Jan P. Weir*
Shareholder
Stradling Yocca Carlson & Rauth

### Industry Insights from:

**Facet Biotech**

**Impax Laboratories**

**InterMune**

**Medicis**

**Spectrum**

**Trubion**

### FTC Keynote on Pay-For-Delay Settlements:

*J. Thomas Rosch, Commissioner*
**Federal Trade Commission**

**Preeminent patent litigators representing brand name and generic drug makers will provide insights on the latest legal challenges affecting Paragraph IV litigation for parties on both sides and help you:**

- **IDENTIFY patents** for – **small molecules and small proteins** – that may be **ripe** for a Paragraph IV challenge
- **RECOGNIZE** an **ANDA** applicant's initial **obligations** and **REVALAUATE Orange Book** tactics
- **INCORPORATE post-*KSR* obviousness** considerations into your Paragraph IV litigation strategies
- **COMPREHEND** the procedural and substantive requirements for the **contents** and **delivery** of the **Notice Letter**
- **DEVELOP a plan to use** the **45 day post-Notice Letter receipt period** more effectively and **KNOW** when it makes sense to file suit
- **MASTER** techniques for **drafting** the initial Paragraph IV **pleadings** and **FACTOR-IN considerations** relative to **venue, jurisdiction, local rules** and **cost**
- **UNDERSTAND** the criteria for **180-day exclusivity** and the circumstances under which it may be **forfeited**
- **APPRECIATE** the significance of **generic v. generic actions** for brand names and generics
- **NAVIGATE** the intricacies of litigation with **multiple ANDA filers**
- **SPEARHEAD** discovery dilemmas, **OPTIMIZE** the use of **experts** and **PERFECT Markman** timing
- **ANALYZE** the **CAFC's** latest findings on **declaratory judgments, inequitable conduct, preliminary injunctions** and **Rule 11 sanctions** vis-à-vis Paragraph IV cases
- **WEIGH** the options over an **at risk launch**

**Workshop A:** December 7, 2010 – Hatch-Waxman and BPCIA 101 – A Primer on IP Basics and Regulatory Fundamentals

**Workshop B:** December 10, 2010 – The Master Class on Settling Paragraph IV Disputes: Brand Name and Generic Perspectives

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American Conference Institute

# The Undisputed Source for Hatch-Waxman Litigation Strategies for Brand Name and Generic Drug Companies

**ACI's *Paragraph IV Disputes*** – the first and original conference of its kind – is **the most trusted source** for the 'ins and outs' of Paragraph IV litigation. We are proud to bring this event – which serves as the essential litigation playbook for brand name and generic drug companies in the high stakes arena of Hatch-Waxman litigation – to California to best serve our West Coast delegates.

The inherent intensity of Paragraph IV litigation has been magnified of late by the seemingly unending repercussions of the Hatch-Waxman reforms of the MMA, proposed Patent Reform legislation, the approval of an abbreviated pathway for follow-on biological products and threat of pending legislation, which may make settlements of these matters near impossible – let alone illegal. These factors have added to the complexity of this litigation, and have also raised the monetary ante to unprecedented heights. In this environment, it is imperative that brand name and generic pharmaceutical companies and their counsel, have the *offensive moves and defensive plays* that they need to meet the challenges of pharmaceutical patent endgame litigation.

**ACI's *Paragraph IV Disputes*** conference has been designed to give counsel for both **brand name** and **generic** companies the critical up-to-the minute information that they need to plan their Hatch-Waxman litigation strategies.

An experienced faculty comprised of respected and renowned counsel for both brand name and generic pharmaceutical companies will provide insights on every facet of Paragraph IV litigation from pre-litigation concerns to the commencement of suit through to final adjudication – and every step in between. This conference will also provide you with access to a **renowned FTC Commissioner.** You will learn firsthand what the FTC deems fair and foul in the settlement of Paragraph IV disputes.

By popular demand – and in light of current legislative developments, we will once again offer our exclusive **Master Class on Settling Paragraph IV Disputes: Brand-Name and Generic Perspectives.** This in-depth workshop will offer valuable up-to-the minute insights and strategies on and from both sides as to what may now well be the most critical aspect of a Paragraph IV challenge.

Also, this year, in response to your requests, we have added the following specialized class: **Hatch-Waxman and BPCIA 101 – A Primer on IP Basics and Regulatory Fundamentals.**

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 **1-877-927-1563**, or logging on to **www.AmericanConference.com/ParagraphIV**.

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## Distinguished Faculty

**Co-Chairs:**

***Martin A. Voet***
Consultant in Intellectual Property and Pharmaceutical Product Exclusivity, (Mission Viejo, CA / Amsterdam, NE)
*(Former Senior Vice President, Chief IP Counsel for Allergan)*

***Jan P. Weir***
Shareholder, Stradling Yocca Carlson & Rauth (Newport Beach, CA)

**Speakers:**

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

***John Bendrick***
Principal/Owner, PharmExtend Consulting (Belmont, CA) (Former Vice President, Intellectual Property, InterMune (San Francisco, CA))

***Paul H. Berghoff***
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***Vincent L. Capuano, Ph.D.***
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***Janine A. Carlan***
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***Douglas H. Carsten***
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***George Ng***
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***J. Thomas Rosch, Commissioner***
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***Robin M. Silva***
Partner, Morgan, Lewis & Bockius LLP (San Francisco, CA)

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

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

***Jennifer J. Swan***
Of Counsel, Finnegan, Henderson, Farabow Garrett & Dunner, LLP (Palo Alto, CA)

***Jennifer A. Trusso***
Partner, Sheppard Mullin Richter & Hampton LLP (Costa Mesa, CA)

***Samuel E. Webb***
Partner, Stoel Rives LLP (Seattle, WA)

***Hill B. Wellford***
Partner, Bingham McCutchen LLP (Washington, DC)

***Jessica Wolff***
Partner, Cooley Godward Kronish LLP (San Diego, CA)

# Tuesday, December 7, 2010

## Workshop A | Hatch-Waxman and BPCIA 101 • A Primer on IP Basics and Regulatory Fundamentals

(Registration opens at 9:00 – Continental Breakfast will be served)

This hands-on workshop will provide you with an in-depth review of the Hatch-Waxman schematic and other IP and regulatory basics relative to small molecules and biologics, as well as critical insights into the commercialization and the pre-approval processes for these products. The workshop leaders will lay the necessary foundation for you to comprehend thoroughly the dynamics of the IP and regulatory backdrop underlying each Paragraph IV dispute. They also will help you fully appreciate the complexities of the Hatch-Waxman litigation challenges presented during the main conference.

### 10:00 A Guide to the Essentials of the FDA Approval Process for Drugs and Biologics for Life Sciences Patent Lawyers

*Martin A. Voet*
Consultant in Intellectual Property and Pharmaceutical Product Exclusivity *(Former Senior Vice President, Chief IP Counsel for Allergan)*

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

**Rx Drugs (new drugs)**

- Identifying the application process for the approval of a new drug, i.e., small molecule, new chemical entities, etc.
- NDA (New Drug Application)
  - what information does it contain?
  - labeling, patent information, trade name
  - filing requirements
  - the FDA review process
- INDA (Investigational New Drug Application) aka "IND"
  - how does it differ from an NDA?
  - filing requirements
  - what does it entitle you to do?
- Accelerated approvals
  - defining eligibility criteria for accelerated approval and priority reviews
  - what portions of approval submissions might FDA release and when?
- Using advisory committees in the approval process

**Biologics**

- Understanding the approval process for a biologic
  - how does the approval process for a biologic differ from that of a drug?
- BLA (Biological Licensing Application)
  - how does a biologic differ from a drug?
  - what application needs to be filed and with whom is it filed?
  - which products require BLAs instead of NDAs?
  - what does a BLA look like?
- Why is it a "license," rather than an "approved application"?
- What does the approval process for a 'biosimilar' under BPCIA entail and how is it different from the BLA approval process?

### 11:15 Patent and IP Overview for Drugs and Biologics: Hatch-Waxman, Trade Dress, and More

*Ann M. Caviani Pease*
Partner, Dechert LLP (Mountain View, CA)

**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?
  - listings and de-listings
- The patent end game (Hatch-Waxman Overview)
  - overview of Hatch-Waxman and reforms under MMA
  - the role of Orange Book under Hatch-Waxman vis-à-vis the MMA
  - exclusivity (180 day)
    - regulatory exclusivity
      - NCE (new chemical entity)
        - 5 years marketing exclusivity
        - 5 years data exclusivity
      - indication (new indication or use)
        - 3 years marketing exclusivity
      - NDF (new dosage formulation)
      - ODE (orphan drug exclusivity)
      - PED (pediatric exclusivity)
  - 30-month stay
  - patent extensions
  - the safe harbor
- FD&C 505b2 (an alternate pathway to an ANDA)

**Biologics**

- Overview of recent biosimilar legislation
  - Title VII of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), *i.e.,* Biologics Price Competition and Innovation Act of 2009 (BPCIA)
- Identifying biologics that fall within the purview of Hatch-Waxman
  - why are other biologics outside of the Hatch-Waxman rubric?
- The rationale for safety and efficacy concerns surrounding second generation biologics

**Trademark Issues**

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

### 12:30 Networking Luncheon

### 1:45 Patent and Non-Patent Exclusivity

*Samuel E. Webb*
Partner, Stoel Rives LLP (Seattle, WA)

- Patent exclusivity v. non-patent, i.e., regulatory exclusivity
- The concept of market exclusivity under the Hatch-Waxman Act
- Understanding which drug products are eligible for regulatory exclusivity
  - small biologics v. biologics
- The different modes and methods of regulatory exclusivity (non-patent)
  - NCE (new chemical entity): 5 years marketing exclusivity/ 5 years data exclusivity
  - indication (new indication or use): 3 years marketing exclusivity
  - NDF (new dosage formulation)
  - ODE (orphan drug exclusivity); PED (pediatric exclusivity)
- FD&C 505b2 (alternate pathway to ANDA) a/k/a paper NDA
- What role does the FDA play in regulating these modes of exclusivity?
- When are each of these methods sought?
- Using trade dress as means of exclusivity

### 2:45 Afternoon Refreshment Break

## 3:00 Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability

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

*Robin M. Silva*
Partner, Morgan, Lewis & Bockius LLP (San Francisco, CA)

- Defining bioequivalence in drugs and biologics
  - drugs v. biologics
- What an ANDA-filer must demonstrate for bioequivalence?
  - bioequivalence and dosage form – oral tablet/capsule, injection, nasal sprays, topical, nasal sprays
- How does bioequivalence relate to patents?
  - patenting of bioequivalence characteristics – extended-release drug products
  - bioequivalence v. Doctrine of Equivalents – what is the difference?
  - arguments about bioequivalence raised in Paragraph IV patent litigation
    - infringement, copying (non-obviousness)

## 3:45 Exploring Pharmaceutical Patent Extensions: Patent Term Adjustment and Patent Term Restoration

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

*John Bendrick*
Principal/Owner, PharmExtend Consulting (Belmont, CA) (Former Vice President, Intellectual Property, InterMune (San Francisco, CA))

- Extension of patent term under 35 U.S.C. § 156 and 37 CFR 1.710 – 1.791
- Exploring the viability of extension applications to:
  - basic and combination compounds; secondary patents
- Important benchmarks in the drug's development and patent timelines
- Eligibility for patent term extension
- Regulatory review period determinations
- How to calculate the patent term restored
  - respective roles of the FDA and PTO in granting patent extensions
  - third-party challenges — "diligence"
- Patent term extensions outside the U.S.
- Examining patent term adjustment due to delays in prosecution before the USPTO
  - strategies for:
    - diligence in prosecution by the patent applicant
    - calculating the adjustment period
- Understanding the link between patent extensions and exclusivity
  - extensions obtained through FDA Pediatric Exclusivity and Orphan Drug Exclusivity
- Obtaining patent coverage for pharmaceuticals through the use of second-generation patents, e.g.,
  - maintaining patent position for second-generation products
  - approaches taken by pharmaceutical companies in obtaining second-generation patents
  - enforcement of second-generation patents
- Assessing the impact of the PTO Rule regarding elimination of continuation practice on pharmaceutical patent extensions

## 5:00 Workshop Ends



# Day One: Wednesday, December 8, 2010

## 7:15 Registration and Continental Breakfast

## 8:00 Co-Chairs' Opening Remarks

*Martin A. Voet*
Consultant in Intellectual Property and Pharmaceutical Product Exclusivity, (Mission Viejo, CA/Amsterdam, NE)
(Former Senior Vice President, Chief IP Counsel for Allergan)

*Jan P. Weir*
Shareholder, Stradling Yocca Carlson & Rauth (Newport Beach, CA)

## 8:30 Pre-Suit Due Diligence Strategies in Anticipation of the Paragraph IV Challenge

**Branded Side**

*Dale Rieger, Ph.D.*
Partner, Jones Day LLP (San Diego, CA)

*George Ng*
Senior Corporate Counsel & Director of Intellectual Property
Spectrum Pharmaceuticals, Inc. (Irvine, CA)

*Jan P. Weir*
Shareholder, Stradling Yocca Carlson & Rauth (Newport Beach, CA)

- Predicting and preparing for Paragraph IV litigation
- Examining the Orange Book: the "to list or not list" quandary
  - which types of patents should you list?
    - special listing considerations for small proteins filed through an NDA as opposed to a BLA in light of new FOB legislation
  - which are the most likely targets of an eventual Paragraph IV challenge?
- Evaluating the strength of the patents in your current portfolio
- Gauging when to reasonably expect a Paragraph IV filing by a generic competitor
- Looking at the different types of brand name exclusivities and their tie the start of a Paragraph IV challenge
  - NCE
  - new use or indication
  - new formulation
  - orphan drug
  - pediatric
- Preparing for litigation
  - preparing for discovery
    - implementation of document retention policy
    - when is a litigation hold put on all documents which may be discoverable
    - e-discovery considerations
- Considerations for heading off a Paragraph IV challenge at the pass
  - entering an authorized generics agreement
  - claiming the label
  - filing a citizen's petition
- Biological patents: anticipating new challenges and how they may compare to a Paragraph IV dispute
- Coordinating with outside counsel on these matters

## 9:30 Assessing the ANDA Applicant's Initial Obligations

**Generic Side**

*Jennifer A. Trusso*
Partner, Sheppard Mullin Richter & Hampton LLP (Costa Mesa, CA)

- Deciphering the ANDA applicant's Orange Book strategy
  - how to choose 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
  - API
  - new considerations/strategies for biological products in light of proposed FOB legislation
  - Identifying the initial obligations of the ANDA applicant under Paragraph IV

Generic Side

- Getting a legal opinion on invalidity and non-infringement
  - assessing when opinions are needed
  - opinion of in-house v. outside counsel
- Tactics for identifying the best art
- Attempting to influence where and when the suit will occur
- 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

10:30 **Morning Coffee Break**

## 10:45 New Takes on Obviousness: Pre-Suit Considerations for Brand-Names and Generics

*Robert J. Goldman*
Partner, Ropes & Gray LLP (East Palo Alto, CA)

*Jeffrey C. Pepe, Ph.D.*
Associate General Counsel, Intellectual Property
Trubion Pharmaceuticals Inc. (Seattle, WA)

- Analyzing the major post-*KSR* obviousness decisions in the District Courts and Federal Circuit
  - *Sanofi v. Apotex* (Plavix) (Fed Cir. Dec. 2008)
  - *Aventis v. Lupin* (Ramipril) (Fed Cir 2007)
  - *Forest Labs v. Ivax* (Celexa )(Fed Cir. 2007)
  - *Ortho McNeil v. Mylan Labs* (Topomax) (Fed Cir 2008)
  - *Takeda v. Alpharma* (Actos) (Fed. Cir. 2008)
- Incorporating the post-*KSR* obviousness precedent into brand name and generic Paragraph IV litigation strategies
  - how have these decisions rendered primary compound and pharmaceutical composition claims more vulnerable to generic challenge?
  - understanding how these decisions have impacted the patentability of secondary patents:
    - enantiomers; isomers
    - new formulations; new indications
    - crystallization; salts
  - determining when and how secondary patents should be pursued/challenged in light of this jurisprudence
- What judicial trends can be discerned from these decisions?
- *In re Kubin:* what can the pharmaceutical industry learn from this case vis-a-vis a Paragraph IV challenge

## 11:30 Throwing Down the Gauntlet: The Paragraph IV Notice Letter – Delivery and Receipt

*Douglas H. Carsten*
Partner, Foley & Lardner LLP (San Diego/De Mar, CA)

*Stephen M. Hankins*
Partner, Schiff Hardin LLP (San Francisco, CA)

**Generic Side**

The ANDA filer must notify the patent owner and the NDA owner of its actions within twenty days of the ANDA filing. This section will explore the procedural and substantive requirements for the Paragraph IV Notice Letter and related filings.

**Procedural requirements**

- Perfecting the Paragraph IV Certification
- Contents of the Notice letter
- Delivery/service of Notice Letter
- Perfecting the Paragraph IV Certification
- Making necessary amendments to the ANDA
  - sending the notice letter
  - receipt of notice letter

**Substantive requirements**

- Identifying the proposed product covered by the ANDA
- Identifying the patent of the corresponding branded product which is the subject of the Paragraph IV letter
- Legal and factual basis
- Exploring the use of opinion letters in relation to Notice letter

**Branded Side**

Upon receipt of the Notice Letter, the patent holder has 45 days to commence suit. If a law suit is filed, a 30-month stay on the FDA's approval of the ANDA is granted. If suit is not commenced within the 45 day period, the 30-month stay is forfeited and the ANDA filer may be entitled to 180 days of market exclusivity on its ANDA product. This session will delve into the strategies and deliberations of the 45 day period.

- Using the 45 day period productively
- Information gathering techniques for the 45 day period
  - confidentiality agreements and document requests
    - obtaining the ANDA
    - terms
    - scope of information that can reasonably expected
    - negotiations
- Extending the 45 day period
  - 21 CFR 314.95 (f)
- When should a patent owner file suit?
  - other options to explore
  - license
    - authorized generic
- Strategies to consider with multiple ANDA filers

**Questions for both sides to consider:**

- Options to explore if suit is not commenced in 45 days
  - pros, cons and consequences of:
    - forfeiture of 30 month stay
    - sue for damages
    - declaratory judgment actions
    - no contest letter
- Factoring in the potential impact of possible Patent Reform legislation

12:45 **Networking Luncheon**

## 2:00 Let the Games Begin: The Start of the Paragraph IV Law Suit – Pleadings and Considerations

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

*Paul H. Berghoff*
Partner, McDonnell Boehnen Hulbert & Berghoff LLP (Chicago, IL)

**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
    - E.D. Texas
    - Michigan
- Question of jury trial: exploring circumstances that may put you in front of a jury
- Cost considerations
- Factoring-in corporate/organizational changes, *e.g.,* mergers

**Crafting the initial Paragraph IV 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
  - the generic point of view:
    - attorneys fees
    - 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**

- Commencement of the statutory 30 month stay
  - understanding the scope and limits of the 30 month stay under the MMA
- The 30-month stay in the course of litigation
  - options and strategies for the patent holder if the stay expires during the course of litigation
    - early termination of the stay

3:30 **Afternoon Refreshment Break**

3:45 **Exploring Exclusivity and Forfeiture Dilemmas Relative to Paragraph IV Litigation**

*Jessica Wolff*
Partner, Cooley Godward Kronish LLP (San Diego, CA)

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

- Identifying the qualifying criteria for 180-day exclusivity
- How can an ANDA applicant determine who is "first-to-file"?
- Spotting triggers for the running of the 180-day exclusivity period
- 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"
- Assessing the impact of "authorized generics" in Paragraph IV 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?
- 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
- Survey and analysis of recent FDA forfeiture rulings
  - *Kytril*
  - *Altace*
  - *Precose*
  - *Cosopt*
  - *Camptosar*
- Exploring the FTC/DOJ stance on forfeiture

4:30 **Conference Adjourns to Day Two**

## Day Two: Thursday, December 9, 2010

7:30 **Continental Breakfast**

8:15 **Co-Chairs' Opening Remarks and Recap of Day One**

8:45 **A Closer Look at Generic v. Generic Law Suits**

*Teresa Stanek Rea*
Partner, Crowell & Moring LLP (Washington, D.C.) Immediate Past President, American Intellectual Property Lawyers Association

- Understanding the impetus for generic/generic litigation
  - 180 day exclusivity
  - protecting market share or something more?
- Identifying factors making this type of litigation more prevalent
  - how have authorized generics changed the playing field?
  - generic innovation? /R & D?
- 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

9:45 **Litigating with Multiple ANDA Filers: Brand Name and Generic Perspectives**

*Janine A. Carlan*
Partner, Arent Fox LLP (Washington, D.C.)

*Vincent L. Capuano, Ph.D.*
Partner, Duane Morris LLP (Boston, MA)

**Branded Side**

- Choosing who to sue
  - ANDA filers; others?
  - when does it make sense to only sue one or a few as opposed to all ANDA filers?
    - suing the first filer
  - what are the consequences of not suing all ANDA filers?
    - non-party ANDA filers and dealing with the repercussions of "at risk" launches
- Choosing where to sue: special considerations for multiples
  - risks and opportunities regarding forum selection
  - evaluating MDL options
- Dealing with later ANDA filers
  - consolidate, stay or keep separate: analyzing the alternatives and selecting strategy

**Generic Side**

- The generic's position in the queue
  - general considerations for first to file
  - thoughts for second and later filers
- Consolidation vs. separate cases
  - dealing with your co-defendants
- Taking advantage of the multiple defendant situation
  - strategies during fact discovery
  - scenarios arising from experts
- Achieving a successful outcome with multiple players
- Maintaining or improving your scenario by the end of discovery

10:45 **Morning Coffee Break**

11:00 **FTC Keynote: Pay For Delay Settlements**

*J. Thomas Rosch, Commissioner*
Federal Trade Commission

The Federal Trade Commission continues to vigorously use its enforcement and policy tools to prevent anticompetitive business practices in the pharmaceutical industry. "Reverse settlement" or "pay-for-delay" agreements have been viewed by the FTC as a very anticompetitive practice. It now appears that the DOJ, and even Congress have taken a similar view and see these agreements as being in restraint of trade and causing great harm to the consumer.

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
- 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

12:00 **Networking Luncheon**

1:15 **Recent Decisions Impacting Paragraph IV Challenges and Motion Practice**

*S. Christian Platt*
Partner, Paul, Hastings, Janofsky & Walker LLP (San Diego, CA)

*Renee M. Kosslak Ph.D.*
General Patent Counsel, Facet Biotech (Redwood City, CA)

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

- Identifying and analyzing the latest judicial trends from the CAFC and District Courts concerning PIV challenges and understanding how they will affect your litigation strategies
- Inequitable conduct
  - *Therasense, Inc. v. Becton, Dickinson & Co.* (Fed. Cir. 2010)
  - *AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA, Inc.* (Fed. Cir. 2009)
  - *Aventis Pharma v. Amphastar and Teva,* No. 2007-1280 (Fed. Cir. 2008)
- Inducement of Infringement
  - *Eli Lilly v. Activis* (D.N. J. 2009)
  - *Wyeth v. Sandoz* (E. N. C. 2010)
- Declaratory Judgment actions
  - *Innovative Therapies, Inc. v. Kinetic Concepts, Inc., et al.,* 599 F.3d 1377 (Fed. Cir. 2010)
  - *Merck & Co. v. Apotex,* No. 2008-1133 (Fed. Cir. 2008)
  - *Prasco v. Medicis Pharm. Corp.,* No. 2007-1524 (Fed. Cir. 2008)
  - *GlaxoSmithKline v. Mutual Pharm.,* No. 08-549 (E.D. Pa. 2008)
  - *Impax Labs. v. Medicis Pharm.,* No. C-08-0253 MMC (N.D. Cal. 2008)
  - *Janssen v. Apotex* (Fed. Cir. 2008)
  - *Ivax v. AstraZeneca* (D.N. J. 2008)
  - *Dr. Reddy's v. Astra Zeneca* (D.N. J. 2008)
- Double Patenting
  - *Boehringer Ingleheim Int'l, et al. v. Barr Labs, Inc., et al.,* 592 F.3d 1340 (Fed. Cir. 2010)
- Covenants not to sue
  - *Caraco Pharm. Labs. v. Forest Labs.,* No. 2007-1404 (Fed. Cir. 2008)
- Preliminary/permanent injunctions
  - exploring the rise in at-risk launches
  - *AstraZeneca LP, et al., v. Apotex, Inc., et al.,* 623 F. Supp. 2d. 579 (D. N.J. May 14, 2009)
  - *King Pharmaceuticals, Inc., et al., v. Sandoz, Inc.,* 210 U.S. Dist. LEXIS - 48385 (D. N.J. May 17, 2010)
  - *King Pharmaceuticals, Inc., et al., v. Corepharma, LLC,* 2010 U.S. Dist. LEXIS 45660 (D. N.J. May 7, 2010)
  - *Eisai Co. v. Teva Pharms. USA,* No. 05-5727 (D.N.J. 2008)
  - *Altana Pharma and Wyeth v. Teva,* No. 2008-1039 (Fed. Cir. 2009)
  - *Eisai Co. v. Teva Pharms. USA,* No. 05-5727 (D.N.J. 2008)

2:30 **Afternoon Refreshment Break**

## 2:45 Discovery Strategies and Pre-Trial Maneuvering Tactics for Brand Names and Generics

*Jeremy C. Lowe*
Partner, Axinn Veltrop & Harkrider LLP (Hartford, CT)

*Mark H. Remus*
Shareholder, Brinks Hofer Gilson & Lione (Chicago, IL)

**Documents**

- Exploring brand and generic perspectives on document review
  - what is legitimately discoverable by generics?
  - at what point is a discovery request overburdensome?
  - finding a way to balance the perceived inequities between document requests made by brand-names and generics
- Assessing the impact of e-discovery and revisions to the FCPR on paper discovery in Paragraph IV matters

**Experts**

- Optimizing the use of experts in paragraph IV proceedings
- Identifying key points on which the opinion of an expert is sought by both sides
  - inherent anticipation
  - obviousness
  - infringement and invalidity
  - what is the nature of the claims?
    - compound
    - formulation
    - method of treatment

**Questions of Privilege**

- Addressing questions of attorney-client privilege with respect documents and witnesses in Paragraph IV cases
- Determining whether the attorney-author of an opinion or Paragraph IV Certification letter can be deposed?

**Markman Hearings**

- Understanding and perfecting the timing of Markman hearings in a Paragraph IV case
- Should Markman hearings be before or after expert reports and discovery?
- Analyzing the nature of the claims presented
- Deciding which claims should be presented in a Markman hearing and which should be saved for trial

## 4:00 Assessing Danger and Mitigating Liabilities Associated with Injunctions and "At Risk Launches"

*Jennifer J. Swan*
Of Counsel, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (Palo Alto, CA)

- 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
- Re-assessing the meaning of irreparable harm as per *Winter v. Natural Resources Defense Council*
- Launching at risk during litigation or the appeal period
  - weighing of benefits and risks
- How do authorized generics impact the decision to launch at risk?
- Calculating damages for launching at risk

5:00 **Conference Adjourns**

# Workshop B

**Friday, December 10, 2010 • 9:00 a.m. - 12:30 p.m.**

**Registration opens at 8:00 | Continental Breakfast will be served**

## The Master Class on Settling Paragraph IV Disputes: Brand-Name and Generic Perspectives

*Robert C. Funsten*
Partner, Bingham McCutchen LLP (Costa Mesa, CA)

*Hill B. Wellford*
Partner, Bingham McCutchen LLP (Washington, DC)

The MMA mandated that pharmaceutical companies provide the FTC with advance notice of proposed settlements of pharmaceutical patent disputes. The FTC and state attorneys general have challenged a number of settlements on antitrust grounds. Private litigation raising similar claims has followed. Additionally, the DOJ has now lent is support to the FTC in also challenging the legality of these settlements.

Both brand names and generic drug companies have expressed their frustration with the FTC in attempting to come to an agreeable resolution in this matter. In addition, there is mounting fear in the pharmaceutical industry concerning proposed legislation which may, in certain circumstances deem these types of settlements to be per se illegal.

This interactive workshop will examine how in the current environment, parties to a Paragraph IV dispute can resolve their differences and receive the government's blessing. The workshop leaders will explore best practices to reach and finalize settlements that the parties and the FTC can live with. Points of discussion will include:

**PIV Settlement Overview**

- What types of settlements have been found invalid or unenforceable?
  - "Pay for Delay" / "Reverse Payment Settlements"
- What are the options for parties who want to settle?
- How do authorized generics fit into settlement schemes?
- How pending legislation is currently affecting patent settlements

**Pending legislation concerning "pay for delay"**

** Review of recent activity in the House and Senate*
- Preserve Access to Affordable Generic Drugs Act

**Industry Considerations**

- Exploring your settlement options
- Which settlements have received approval and which have not?

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

**Workshop B:** December 10, 2010

The Master Class on Settling Paragraph IV Disputes: Brand-Name and Generic Perspectives

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