American Conference Institute's
7th Annual

ACI's HATCH-WAXMAN SERIES

Paragraph IV Disputes

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

Earn CLE ETHICS Credits

May 7–8, 2013 | Crowne Plaza Times Square Manhattan | New York City

Preeminent patent litigators representing brand name and generic drug makers will provide insights on every facet of Paragraph IV litigation from pre-litigation concerns to commencement of suit through final adjudication, including the latest legal challenges affecting parties on both sides. They will help you:

- **ASSESS** how new **PTO proceedings** will influence the course of Hatch-Waxman litigation
- **UNDERSTAND** how **new 271(e) (1)** controversies under ***Claussen*** and ***Momenta*** will affect ANDA filings
- **DECIPHER** the impact of new **obvious considerations** in the **courts** and **PTO** on **primary compound** and **composition** claims
- **ASSESS** the implications of new regulatory considerations under **FDASIA, the GAIN Act,** and **Generic User Fees Act on Paragraph IV proceedings**
- **EXPLORE inducement** and **divided infringement** in the context of Orange Book-listed **method patents**
- **IDENTIFY** new **challenges** to **market** as well as **regulatory exclusivities**
- **EXAMINE** possible **damages quantifications** for **launching at risk**

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Guy Donatiello
Vice President, Intellectual Property
Endo Pharmaceuticals


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

Judicial Insights on Federal Practice, Parallel and Alternate Proceedings:

U.S. Court of Appeals for the Federal Circuit


Hon. Paul R. Michel, Chief Judge (ret.)

U.S. Federal District Court
The District of New Jersey


Hon. Garrett E. Brown, Chief Judge (ret.)


Hon. Stanley R. Chesler


Hon. Joel A. Pisano


Hon. Tonianne Bongiovanni


Hon. Joseph A. Dickson

District of Delaware


Hon. Gregory M. Sleet, Chief Judge


Hon. Mary Pat Thynge

USPTO's Patent Trial and Appeal Board


Hon. James Donald Smith
Chief Judge (invited)

US International Trade Commission


Hon. Robert K. Rogers, ALJ

Industry Insights from:

BioDelivery Sciences International, Inc.
Boehringer Ingelheim
Bristol-Myers Squibb
Endo Pharmaceuticals
Gilead Sciences
Impax Laboratories, Inc.
Merck & Co.
Mylan
Novartis
Sandoz, Inc.
Pfizer Inc.
Sun Pharmaceutical Industries Inc.

Spotlight on Pay-For-Delay Settlements:


Markus H. Meier
Assistant Director of the Health Care Division
Bureau of Competition
Federal Trade Commission


James 'Mit' Spears
Executive Vice President and General Counsel
PhRMA


Robert Billings
Senior V.P. for Finances
Planning and Special Programs, GPhA

Customized Working Groups, Workshops & Master Classes

May 6, 2013 - Hatch-Waxman and BPCIA 101 — A Primer on IP Basics and Regulatory Fundamentals

May 6, 2013 - Working Group Session: Assessing The Impact of New PTO Procedures Under the AIA on Paragraph IV Litigation

May 9, 2013 - The Master Class on Settling Paragraph IV Disputes: Drafting and Negotiating Strategies for Brand-Name and Generics – A Hands-On, Practical Approach

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By 2016, the pharmaceutical industry will encounter total patent losses of nearly $150 billion.[1]

Master the litigation strategies that your company needs to successfully scale the legal intricacies of this next crag of the patent cliff.

Many thought that 2012 with its record patent losses of nearly $70 billion would mark the worst year of the pharmaceutical industry's patent cliff.[2] However, the worse escarpments of the cliff may yet to be encountered. By some estimates, the industry will experience patent losses approaching $150 billion within the next three years.[3] This will undoubtedly test the balance of power created by the Hatch-Waxman Act and lead to dramatic new litigation challenges for brand names and generics.

Come to this conference and meet with the leading legal minds in this area as you acquire the skills needed for the new era of extreme Hatch-Waxman litigation.

Now in its seventh iteration, **American Conference Institute's (ACI's) Paragraph IV Disputes** conference is the only event which helps both brand name and generic pharmaceutical companies make sense of changing industry dynamics precipitated by the patent cliff and other factors such as patent reform, regulatory shifts and recent and pending case law. This is the conference that not only sets the standards for Paragraph IV litigation, but also serves as the annual meeting place for the "who's who" of pharmaceutical patent litigation.

Our faculty of respected and renowned counsel for branded and generic pharmaceutical companies will provide insights on all facets of Paragraph IV litigation: pre-litigation concerns — the commencement of suit — final adjudication and every step in between. Sessions will address the key elements of Paragraph IV litigation in addition to some of the most pressing and recent controversies in this area, including:

- The impact of patent reform on Hatch-Waxman litigation
- The boundaries of 271(e)(1) relative to infringing pre vs. post market activities
- New obviousness considerations in light of recent decisions and the AIA
- The potential effects of FDASIA and the GAIN Act on Paragraph IV Challenges
- Exclusivity concerns for brands as well as generics
- New rulings in divided infringement and inducement of infringement
- Damages theories relative to launching at risk
- The further evolution of the inequitable conduct ruling post-*Therasense*

[1] http://www.fiercepharma.com/story/beware-patent-losses-climb-back-56b-2015/2012-06-20

[2] Id.

[3] Id.

Hear from leading Jurists, the PTO, FDA and the FTC.

We are also pleased to bring you the opportunity to hear from **eleven** renowned Jurists from the Federal Circuit; Federal District Court (Districts of Delaware and New Jersey); and Administrative Law Judges from the PTO's Patent Trial and Appeals Board and International Trade Commission. Do not miss this opportunity to learn firsthand how the bench analyzes the theories of your case and how to effectively navigate alternative forums.

Additionally, a key official from the Federal Trade Commission will be on hand to discuss the latest in the 'Pay for Delay' debate and representatives from PhRMA and GPhA will also be present to share their opinions on the matter.

Benefit from Training Sessions, Working Groups and Master Classes Designed to Give You the Edge in the New Hatch-Waxman Landscape.

We are pleased to offer you informative and hands-on workshops which will complete your conference and networking experience:

- **Hatch-Waxman and BPCIA 101 — A Primer on IP Basics and Regulatory Fundamentals** will provide you with the patent and regulatory backdrop for the more in-depth Hatch-Waxman litigation controversies discussed in the main conference;
- **A Working Group Session on Assessing The Impact of New PTO Procedures Under the AIA on Paragraph IV Litigation** will address how new pre- and post-issuance procedures may alter certain components of Paragraph IV litigation and lead to parallel proceedings before the Federal Courts and PTO; and
- **The Master Class on Settling Paragraph IV Disputes: Drafting and Negotiating Strategies for Brand-Name and Generics** will give you practical and hands-on strategies for drafting and negotiating settlement agreements that will pass muster with the FTC

In this costly and ruthless endgame, not a moment can be lost. Register now by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563** or logging on to **www.AmericanConference.com/PIVDisputesNYC.**

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

Huong Nguyen
Senior Director, Intellectual Property
Impax Laboratories (Hayward, CA)

Stephen Payne
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Schiff Hardin LLP (San Francisco, CA)

Moderator:

Jonathan A. Harris
Partner
Axinn Veltrop Harkrider LLP (Hartford, CT)

This hands-on workshop will provide you with an in-depth review of the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act of 2009 (BPCIA) (including the FDA draft regulations on biosimilars) as well as other IP and regulatory basics relative to small molecules and biologics. 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 will help you fully appreciate the complexities of the Hatch-Waxman litigation challenges presented during the main conference as well as anticipated conundrums under the new biosimilar schematic. 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)

- 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

BLAs

- 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"?

Biosimilars

- What does the approval process for a 'biosimilar' under BPCIA entail and how is it different from the BLA approval process?

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 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
  - exclusivity (180 day market exclusivity)
  - 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 the Biologics Price Competition and Innovation Act of 2009 (BPCIA), i.e., biosimilar legislation
  - Title VII of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148)
  - Section 35k of the Public Health Services Act
  - status of Pending FDA regulations for biosimilars
- 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

* Luncheon will be provided to delegates attending both workshops beginning at 11:30.

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

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Moderator:

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

On September 16, 2012, certain procedures under The America Invents Act (AIA) including Third Party Pre-Issuance Submissions, Supplemental Examination, Post-Grant Review and Inter-Partes Review went into effect. This date also marked the end of Inter-Partes Re-examination. These new and amended PTO Procedures have created a parallel and/or alternate administrative avenue to certain components of Paragraph IV litigation in the District Courts. These procedures go directly to the heart of an invalidity challenge and also provide administrative mechanisms, in certain instances to 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 use of these mechanisms carries with them consequences which may bring about the opposite of the intended result.

The workshop leaders will address these procedures as well as specific concerns for brands and generics. Points of discussion will include:

Third Party Pre-issuance Submissions

- Understanding when pre-issuance submission of prior art to the PTO as outlined by this procedure would be used in a Hatch-Waxman scenario
- Examining scenarios in which the application of the pending pharmaceutical patent might actually be strengthened as opposed to diminished by the invocation of this procedure
- Considerations relative to the transition from 'first to invent' to "first to file" in March 2013

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)
  - question of prior art
- Exploring relationship between supplemental proceedings and inequitable conduct
  - circumstances in which supplemental reexam can be used as a means to circumvent questions of inequitable conduct
  - failure to disclose - presence of mind
    - intent v. mistake
  - findings of fraud in aftermath of proceedings and possibility of criminal prosecution
    - materiality

Post Grant Review

- Weighing considerations for when challenge should be brought under post grant review (PGR) in a Hatch-Waxman challenge
- Exploring start dates, timing and basis of the application – questions to ask
  - is the challenge brought within nine months of patent issuance?
  - what is the basis of the invalidity challenge
    - prior art
    - 112 deficiency under written description
    - lack of enablement
    - obviousness; inherent anticipation
  - fate of best mode
- Estoppel considerations relative to Paragraph IV litigation
- Examining the mechanics, protocols and procedures for PGR
  - filing of petition
  - analogous nature of proceeding to district court litigation
  - discovery
    - hearings; motions; settlement
  - appearing before the Patent Trial and Appeals Board (PTAB)
- Analyzing the petitioner's burden of proof
- Procedures for appeal

Inter Partes Review

- Understanding the fine points of the new inter partes review procedure
  - comparing current inter partes review protocols under AIA to prior inter partes reexamination protocols
  - considerations for choosing this new forum
    - timing, cost, speed of resolution
- Examining the patent challenger's burden of proof under new inter partes review procedures
  - how does it compare to prior standard under inter partes reexamination?
    - reasonable likelihood that the petitioner will prevail on claim vs. substantial new question of patentability
  - understanding the immediate repercussions of this shift relative to pending inter partes reexam filings
    - which standard will be utilized for inter partes reexamination petitions filed prior to the September 16th date?
- Exploring the scope of review for pending prior and new procedures under 102 and 103
  - patents (prior art) and publications
  - comprehending the relationship between scope of review and estoppel
- Transition and phase out
  - examining the transition for post grant review and inter partes review
  - transition in presiding forums
    - Central Reexam Unit (CRU) vs. Patent Trial and Appeal Board (PTAB)
    - appeal to CAFC
- Comparing the utilization of past inter partes reexamination procedures for both patent challengers and patent holders in Hatch Waxman scenarios to the use of inter partes review

MAIN CONFERENCE – DAY 1
Tuesday, May 7, 2013

7:15 **Registration and Continental Breakfast**

Sponsored by: GIBSON DUNN

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

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

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

Pre-Suit Due Diligence Strategies

8:30 **Anticipating A Paragraph IV Challenge: New Considerations in Light of AIA and the Patent Cliff**

Scott Brown
Assistant General Counsel – Patent Litigation
Bristol-Myers Squibb (Princeton, NJ)

Wendy Petka, Ph.D., J.D.
Director & Senior Counsel II IP
Boehringer Ingelheim Pharmaceuticals, Inc. (Ridgefield, CT)

Barbara R. Rudolph Ph.D.
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (Washington, DC)

Moderator:

Pablo D. Hendler
Partner
Ropes & Gray LLP (New York)

Brand Name Side

- Evaluating the strength of the patents in your current portfolio
  - assessing the impact of the patent cliff on this analysis
  - blockbusters vs. smaller products
    - determining vulnerabilities
      - IP and economic
      - small molecules vs. small proteins
- Understanding how changes in the US Patent System under the AIA will influence Orange Book listing strategies
  - first to file
  - third party pre-issuance submissions
  - provisional applications
  - prior user rights
- Examining the Orange Book 'to list or not list' conundrum
  - which types of patents should you list?
  - alternatives to compound patents
    - methods
  - propriety of the utilization of use codes in the aftermath of *Caraco*
    - polymorphs
  - listing considerations for small proteins post-BPCIA
- Gauging when to reasonably expect a Paragraph IV filing by a generic competitor in light of new industry dynamics created by the AIA and patent cliff
- PTA and PTE considerations
  - possible impact of *Exelixis v. Kappos* (E.D.Va 2012)
- Factoring in challenges from generics and regulatory bodies to brand name exclusivities in your due diligence analysis
  - NCE
  - new use or indication
  - new formulation
  - orphan drug
  - pediatric
- Claim construction concerns relative to the patent holder's due diligence assessments
  - broad vs. narrow readings
    - *Retractable Technologies*
    - *Cybor*
- 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
- Anticipating new forums and litigants for pharmaceutical patent challenges – PIV and beyond
  - PTO proceedings
  - ITC actions
  - NPEs
- Preventing a Paragraph IV challenge
  - entering an authorized generics agreement
  - claiming the label
  - filing a citizen's petition
  - OTC switches
  - use of supplemental proceedings before the PTO as a proactive strategy to cure any allegations of inequitable conduct

9:30 **Asserting Invalidity or Non- Infringement Under Paragraph IV: Exploring the ANDA Applicant's Pre- Litigation Obligations and Options**

Douglass Hochstetler
Partner
Kelley Drye & Warren LLP (Chicago, IL)

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

George Ng
Senior Vice President & General Counsel
BioDelivery Sciences International, Inc. (Raleigh, NC)

Moderator:

Tedd Van Buskirk
Shareholder
Polsinelli Shughart P.C. (New York, NY

Generic Side

- Comprehending the initial obligations of the ANDA applicant under Paragraph IV, re: invalidity and non-infringement
  - revisiting the "clear and convincing" standard
  - *Sciele Pharma Inc. v. Lupin Ltd.* (Fed. Cir. 2012)
    - reaffirmation of *Microsoft v. i4i* (131 S. Ct. 2238 (2011)
  - assessing the consequences of not meeting this burden of proof
  - understanding circumstances in which the burden may shift

- Choosing which Orange Book patents to challenge
  - compounds
  - formulations
  - process
  - methods of use
  - polymorphs
- Weighing your options in light of the burden: should you file a Paragraph IV certification or choose an alternate ANDA route?
- 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
- Assessing safe harbor protections relative non-infringing activity
- Other considerations for your Orange Book strategy
  - forfeiture
  - questions of skinny labeling and carve-outs post-*Caraco*
  - obviousness assessments
- 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
  - assessing when opinions are needed
  - opinion of in-house v. outside counsel
  - questions of privilege
    - Rule 26 (b) (4)
- 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 Networking Break**

Sponsored by: Steptoe
STEPTOE & JOHNSON LLP

10:45 Safe Harbor or Stormy Port?: Analyzing How New 271 (e) (1) Controversies Will Impact Paragraph IV Disputes

Mark I. Bowditch
Head, US Product Support, Intellectual Property
Sandoz, Inc. (Princeton, NJ)

Kathleen B. Carr
Partner
Edwards Wildman Palmer LLP (Boston, MA)

D. Christopher Ohly
Partner
Schiff Hardin LLP (Washington, DC)

Michael A. Sitzman
Partner
Gibson, Dunn & Crutcher LLP (San Francisco, CA)

Moderator:

Stephen R. Auten
Member
Cozen O'Connor (Chicago, IL)
(Formerly Vice President, IP, Sandoz, Inc.)

- Understanding the implications of *Classen v. Biogen* (Fed. Cir. 2011) and *Momenta v. Amphastar* (Fed. Cir. 2012) for Paragraph IV challenges relative to the boundaries of 271(e)(1)
- Deciphering how the dichotomy of these opinions will impact ANDA filings
  - when and to what activities does the safe harbor exception apply?
    - pre-market vs. post-market activity
  - infringing vs. non-infringing activity
    - "development and submission information under of a Federal law" vs. "information that may be routinely reported to the FDA, long after marketing approval has been obtained"
- Exploring Judge Rader's contention in the *Momenta* dissent that the majority's "interpretation of 271(e)(1) would essentially render manufacturing method patents worthless"
  - how may this jurisprudence impact the relationship between brands and generics as established by the Hatch-Waxman Act

11:45 Throwing Down the Gauntlet: The Paragraph IV Notice Letter

For the Brand Name Side:

Lisa M. Ferri
Partner
Mayer Brown LLP (New York, NY)

Peter Waibel
Head, US Patent Litigation
Novartis Pharmaceuticals Corporation
(East Hanover, NJ)

For the Generic Side:

Thomas D. Hoffman, Ph.D. , J.D.,
Of Counsel
Sandoz Inc. IP/Legal (East Hanover, NJ)

Shashank Upadhye
Partner
Seyfarth Shaw LLP (Chicago, IL)
(Formerly Vice President - Global Intellectual Property, Apotex, Inc.)

Moderator:

Earl Austin
Partner; Head, Life Sciences Practice & Co-Chair Pharmaceutical Litigation Practice
Baker Botts L.L.P. (New York, NY)

Generic Side

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

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
- Examining the detailed statement and questions of confidentiality
- Exploring the use of opinion letters in relation to the Notice Letter

- details and other requirements
- sanctions
- are they still needed in view of Patent Reform

Branded Side

The response

- Making productive use of the 45 day period
- Information gathering techniques strategies
  - 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
    - suing for damages
    - declaratory judgment actions
    - no contest letter

1:00 **Networking Luncheon**

Sponsored by: EDWARDS WILDMAN

2:15 **Obviousness in Retrospect: Making Sense of Prior Art, Obvious-Type Double Patenting, Inherency and New AIA Controversies**

Dominick A. Conde
Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

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

Martin B. Pavane
Member
Cozen O'Connor (New York, NY)

Bruce Wexler
Partner
Paul Hastings LLP (New York, NY)

Moderator:

Denise L. Loring
Partner
Ropes & Gray LLP (New York, NY)

In 2007, the Supreme Court's decision in *KSR* left many patent holders wondering if any patent would be able to withstand an obviousness challenge. This became especially perplexing in the world of pharmaceutical patents as secondary patents appeared particularly vulnerable under the *KSR* ruling. The evolution of the obvious-type double patenting doctrine added another dimension of uncertainty. More recently, changes to the definition of prior art under Patent Reform have added a new concern to the obviousness conundrum.

This panel will explore the evolution of *KSR* and its progeny and discuss new developments impacting obviousness (both prior art and obvious-type double patenting) and related concepts in the federal courts and PTO. Points of discussion will include:

- *Otsuka v. Sandoz* (Abilify) (Fed. Cir. 2012)
  - obviousness analysis for lead compounds
    - obviousness vs. obviousness-type double patenting
    - reaffirmation of the clear and convincing standard
  - "a poster child for impermissible hindsight reasoning"
- Deciphering the impact of this decision and *KSR*'s other progeny on primary compound and composition claims vis-à-vis a Paragraph IV challenge
  - impact on methods and compositions
    - *Pozen Inc. v. Par Pharmaceutical, Inc* (Fed. Cir. 2012)
  - impact on secondary patents
    - enantiomers
    - isomers
    - polymorphs
    - new formulations
    - new indications
    - crystallizations
    - salts
- Re-visiting questions of inherency and its relation to obviousness
  - determining when a new use for an old composition is not obvious and therefore patentable
  - *In re Montgomery* (Fed. Cir. 2012)
  - exploring the significance of Judge Newman's dissent in *Hoffmann-La Roche Inc. v. Apotex Inc.* (Fed. Cir. 2012) concerning 'unpredictable results' and its relation to inherency
- Assessing the impact of the AIA's prior art provisions in Paragraph IV related obvious challenges
  - examining secondary considerations before the PTO under current procedures
    - under new Post Grant Review Procedure
- Exploring how PTO procedures may be used to overturn finding of non-obviousness in the federal courts
  - *In Re Baxter International* (Fed. Cir. 2012)
    - *In Re Swanson* (Fed. Cir. 2008)
  - assessing how the different burdens of proof in the federal courts and PTO relative to obviousness challenges may impact litigation strategies
    - clear and convincing vs. preponderance standards
    - exploring questions of collateral estoppel and stays of litigation
    - examining the matter of federal court authority vs. administrative authority
  - can the PTO's review authority rightfully trump a federal appellate court's decision regarding validity?
  - possible Supreme Court review?
    - impact on tactics of generic first and second filers in Paragraph IV disputes

3:15 **Afternoon Networking Break**

Sponsored by: Steptoe
STEPTOE & JOHNSON LLP

3:30 **Let the Games Begin: The Start of the Paragraph IV Law Suit - Pleadings and Other Initial Considerations and Analyses**

For the Brand Name Side

David P. Frazier Ph.D.
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (Washington, DC)

Jeffrey N. Myers, Ph.D.
Vice President & Assistant General Counsel
Pfizer Inc. (New York, NY)

For the Generic Side

John L. Dauer, Jr.
Chief Patent Counsel
Sun Pharmaceutical Industries Inc.(Cranbury, NJ)

Kelly J. Eberspecher
Shareholder
Brinks Hofer Gilson & Lione (Chicago, IL)

Moderator:

Kerry B. McTigue
Member & Co-Chair, IP Practice Group
Cozen O'Connor (Washington, DC)

Initial Considerations

- Where should suit be filed?
  - attempting to influence where and when the suit will occur
  - evaluating transfer motions and writs of mandamus relative to venue/jurisdiction
  - examining joinder provisions and Hatch-Waxman exceptions under AIA relative to venue
- Assessing subject matter jurisdiction
  - *Dey v. Sunovion* (Fed. Cir. 2012)
  - Seattle Children's Hospital and *Novartis v. Akorn, Inc.* (N.D. Ill 2012)
- Questions of standing
  - considerations for multinationals and subsidiaries
    - which entity is the patent holder and where does it reside?
  - weighing probability for motions to dismiss
- Handicapping of judges and jurisdictions
- Surveying local patent rules
  - knowing which district rules favor patent holders and patent challengers
    - New Jersey; E.D. Texas; Delaware
- Question of jury trial: exploring circumstances that may put you in front of a jury
- Examining parallel proceedings before the PTO in view of Patent Reform

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
  - the generic point of view:
    - attorneys fees; Rule 11

Considerations with Multiple ANDA Filers

Branded Side

- Choosing who to sue
  - ANDA filers; others?
  - when does it make sense to only sue the first filer or a few as opposed to all ANDA filers?
    - what are the consequences of not suing all ANDA filers?
- Special forum selection considerations for multiples
- Amending pleadings for later ANDA filers

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

Generic Generic Law Suits

- Exploring circumstances in which the generic on the pleadings behaves as an innovator
- Pleading protection of market exclusivity

Declaratory Judgments

- Understanding the MMA declaratory judgment provisions and the CAFC's interpretation of these provisions
- 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

4:45 **A View From the Bench**

Honorable Paul R. Michel, Chief Judge (ret.)
U.S. Court of Appeals for the Federal Circuit (Washington, DC)

Honorable Gregory M. Sleet, U.S.D.J.
Chief Judge
United States Federal District Court
District of Delaware (Wilmington, DE)

Honorable Stanley R. Chesler, U.S.D.J.
United States Federal District Court
District of New Jersey (Newark, NJ)

Honorable Joel A. Pisano, U.S.D.J.
United States Federal District Court
District of New Jersey (Trenton, NJ)

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

Moderators:

Honorable Garrett E. Brown, U.S.D.J. (ret.)
Chief Judge, United States Federal District Court
District of New Jersey (Trenton, NJ)
Neutral, JAMS, The Resolution Experts
(New York, NY)

Brian P. Murphy
Partner
Edwards Wildman LLP (New York, NY)

Renowned jurists with some of the most active Paragraph IV litigation dockets in the country will share their thought and insights on some of the most

compelling issues facing both patent holders and patent challengers. Come prepared with your most pressing questions.

6:00 **Conference Adjourns to Day Two**

Cocktail Reception

Hosted by: LOEB & LOEB LLP

MAIN CONFERENCE – DAY 2
Wednesday May 8, 2013

7:15 **Registration and Continental Breakfast**

Sponsored by: GIBSON DUNN

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

Focus on Reverse Payment Settlements

8:30 **Pay-for-Delay Update**

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

FTC Keynote

On December 7, 2012, the Supreme Court granted certiorari in *Federal Trade Commission v. Watson Pharmaceuticals, Inc.* This case marks a potentially significant turning point in the FTC's enforcement efforts in the area of settlements of pharmaceutical patent cases. The Commission has made no secret of its position that "reverse settlement" or "pay-for-delay" agreements are anticompetitive practices that harm competition and consumers. Over the last several years, the DOJ and some members of Congress have come to a similar conclusion, finding that these agreements restrain competition and harm consumers. The briefing in *FTC v. Watson* has been completed, and the oral argument has been heard. It remains to be seen as to what the Supreme Court ultimately will decide.

Markus Meier, Assistant Director in the FTC's Bureau of Competition will discuss the *FTC v. Watson* case and other matters such as:

- The MMA reporting requirements and findings from the FTC's annual reports concerning the MMA
- The status of other pending litigation concerning patent settlements, including *K-Dur* and *FTC v. Cephalon*
- The status of federal legislation regarding "pay-for-delay" settlements
- The findings of the FTC's authorized generic's study

9:15 **Settlement of Paragraph IV Law Suits: The Industry Perspective**

James 'Mit' Spears
Executive Vice President and General Counsel
PhRMA (Washington, DC)

Robert Billings
Senior V.P. for Finances,
Planning and Special Programs
GPhA (Washington, DC)

FTC enforcement actions concerning reverse payment settlements have been a concern as well as puzzlement for both brand name and generic drug companies for over a decade. Brand names and generics find agreement in their disagreement with the FTC's theories of anticompetitive behaviors relative to these settlements. They believe that they have a right to settle cases – even those involving pharmaceutical patents governed by the Hatch-Waxman law. Mitt Spears from PhRMA and Bob Billings from GPhA will outline the industry's perspective and provide a rebuttal to the FTC's keynote.

10:00 **Morning Networking Break**

Sponsored by: Steptoe
STEPTOE & JOHNSON LLP

10:15 **Parallel and Alternate Proceedings in Paragraph IV Disputes: Seeking Simultaneous or Sole Redress before the PTO, ITC and Other Alternative Forums**

Honorable Paul R. Michel
Chief Judge (ret.)
U.S. Court of Appeals for the Federal Circuit
(Washington, DC)

Honorable Garrett E. Brown, U.S.D.J. (ret.)
Chief Judge, United States Federal District Court,
District of New Jersey (Trenton, NJ)
Neutral, JAMS, The Resolution Experts
(New York, NY)

Honorable Mary Pat Thynge, U.S.M.J.
United States Federal District Court
District of Delaware (Wilmington, DE)

Honorable Joseph A. Dickson, U.S.M.J.
United States Federal District Court
District of New Jersey (Newark, NJ)

Honorable James Donald Smith (invited)
Chief Judge, Patent Trial and Appeal Board
United States Patent and Trademark Office
(Alexandria, VA)

Honorable Robert K. Rogers, ALJ
Administrative Law Judge
U.S. International Trade Commission
(Washington, DC)

Moderator:

Thomas J. Filarski
Partner
Steptoe & Johnson LLP (Chicago, IL)

The implementation of certain PTO Procedures under the America Invents Act and utilization of the ITC has brought the matter of parallel proceedings in Hatch-Waxman litigation into greater focus. There is also great interest in the use of mediation/arbitration and ADR in these matters. This panel will examine the different forums and proceedings before which Paragraph IV litigants may seek concurrent or sole redress. Points of discussion will include:

Overview of Alternate Forums

- Forums in which parallel Paragraph IV challenges may be brought
- Evaluating the types of proceedings which may run parallel relative to a Paragraph IV Dispute
  - traditional District Court litigation
  - new PTO proceedings
- ITC investigatory actions under section 337 of the Tariff Act of 1930
- Stays of various District Court and ITC proceedings in view of pending decisions from the PTO
- Use of arbitration and mediation in these proceedings

PTO Proceedings

- Specific concerns for joinder relative to District Court and PTO Procedures under the AIA
- Possible scenarios in which the following procedures would run parallel to district court proceedings
  - supplemental examination
  - post-grant review
  - inter-partes review
- Examining circumstances in which redress is only sought before the PTO

ITC Proceedings

- Exploring circumstances in which a 337 Complaint can be brought before the ITC in a Paragraph IV matter
  - lessons learned from *In the Matter of Certain Gemcitabine and Products Containing the Same* (Eli Lilly Section 337 Complaint)

Alternative Dispute Resolution

- Assessing the utilization of ADR in Paragraph IV controversies
  - when does ADR make sense in a Hatch-Waxman setting?
- Exploring validity determinations in an ADR setting
- Court sponsored ADR or private ADR?
  - pros and cons of each in a Paragraph IV matter

General considerations

- Factoring in new rules relating to:
  - how each type of proceeding will be conducted
  - scope of proceeding
  - scope of discovery in each type of proceeding
  - legal standards of review
- Estoppel effects
- Cost and time comparisons
  - which proceedings make the most economic sense in terms of time and money?
- Analyzing whether parallel proceedings make sense in view of particular circumstances

11:30 FDA Proceedings and Regulatory Developments Impacting Paragraph IV Litigation

David Fox
Partner
Hogan Lovells US LLP (Washington, DC)

Carmen M. Shepard
Sr. Vice President
Global Policy and Regulatory Counsel
Mylan(Washington, DC)

- Examining different provisions under the FDA Safety and Innovation Act ("FDASIA") that may impact the future of pharmaceutical patents and Paragraph IV litigation
  - The Generating Antibiotic Incentives Now Act ("GAIN Act")
    - identifying criteria for qualified infectious disease products or QIPDs
    - examining provisions for 5 years additional exclusivity for certain antibiotics
  - new form
  - new indication
  - rare disease/orphan status
    - how may this extension of patent term impact Hatch-Waxman litigation?
  - Generic Drug User Fee Amendments of 2012 ("GDUFA")
    - addressing FDA's ANDA backlog
    - understanding how incorrect payment or late payment of generic user fees will impact ANDA filings
    - assessing possible repercussions for first filer status and its impact on Paragraph IV disputes
- Understanding the significance of the Center for Drug Evaluation and Research's ("CDER's) Exclusivity Board
  - focus on clarity and consistency of decisions
  - review of NCE exclusivity, 3-year new clinical trial exclusivity, and exclusivity for biological products
  - potential impact on exclusivity challenges by brands after agency denial
- Citizens petitions revisited
  - examining the uptick in citizen's petitions filings in Hatch-Waxman matters
    - why are they on the rise?
  - when should they be filed
  - review of requirements for citizen's petitions under FDAAA
    - avoiding accusations the citizen petition is being filed as a delaying tactic
  - FDA response time/505(q)
  - citizens petitions relative to REMS and generic drugs
- Lawsuits against FDA
  - when should you consider suing the FDA relative to a Hatch-Waxman determination?

12:15 Networking Luncheon

Sponsored by: Knobbe Martens
INTELLECTUAL PROPERTY LAW

1:30 New Exclusivity Challenges: Brand Names Take Notice - It's Not Just a Concern for Generics Anymore

Greg Chopskie
Senior Counsel
Gilead Sciences (Foster City, CA)

Gary E. Hood
Shareholder
Polsinelli Shughart PC. (Chicago, IL)

Chad A. Landmon
Partner & Co-Chair of IP Practice Group;
Chair, FDA Practice Group
Axinn, Veltrop & Harkrider LLP (Washington, DC)

Irena Royzman
Partner
Patterson Belknap Webb & Tyler LLP
(New York, NY)

Moderator:

Kurt Karst
Director
Hyman, Phelps & McNamara, P.C.
(Washington, DC)

Brand Name Exclusivity Challenges

- Understanding why challenges to brand name regulatory exclusivities such as NCE and orphan drug are now under scrutiny by FDA
  - Veramyst
  - Torisel
  - Makena
- Status of lawsuits against FDA in regulatory exclusivity denials

180-day exclusivity challenges and forfeiture concerns

- Forfeiture provisions: circumstances under which exclusivity is forfeited under FDC Act § 505(j)(5)(D)(i)
- 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
- Taking a closer look at the failure to obtain timely tentative approval forfeiture provision
  - *Mylan v. FDA*
- Evaluating the strength of "the failure to market" provision post-*Lipitor*
- Assessing the impact of "delisting" on forfeiture
- Forfeiture relative to patent expiration
- Evaluating when the 180-day exclusivity period can be relinquished or transferred, and exploring the consequences
  - What impact does an ANDA amendment have on 180-day exclusivity?
- 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?
- Identifying regulatory bars to exclusivity
  - GMP violations
  - SEC actions
- Understanding the relationship between forfeiture and the increase in generic/generic litigation
- Exploring the possibility of new PTO proceedings being utilized to trigger a forfeiture
- Revisiting the relationship between exclusivity, forfeiture and the 30 month stay
  - circumstances under which a second stay may be granted
  - impact on grant of exclusivity

2:30 **Examining New Rulings in Inducement of Infringement and Divided Infringement and Their Application to Method Claims in Hatch-Waxman Litigation**

Joseph M. O'Malley, Jr.
Partner & Global Co-Chair, Intellectual Property
Paul Hastings (New York, NY)

Paul A. Ragusa
Partner
Baker Botts L.L.P. (New York, NY)

Jason W. Schigelone
Patent Attorney
Brinks Hofer Gilson & Lione (Chicago, IL)

Moderator:

Steven J. Moore
Partner
Kelley Drye & Warren LLP (Stamford, CT)

- Examining the Federal Circuit's en banc ruling on inducement of infringement and divided infringement in *Akamai Technologies, Inc. v. Limelight Networks, Inc.* (Fed. Cir. 2012) and *McKesson Technologies Inc. v. Epic Systems Corp.* (Fed. Cir. 2012)
- Analyzing the Federal Circuit's determination of multiple actor infringement relative to inducement of infringement
  - assessment of liability by inducement of one or more actors to perform all steps and methods
    - *Global Tech v. SEB* (U.S. 2012)
  - *mens rea* requirements (willful blindness vs. deliberate indifference)
  - indirect vs. direct infringement
- Exploring the relationship between inducement actions and divided infringement 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
  - implications of *Akamai* for Paragraph IV litigation

3:15 **Afternoon Networking Break**

Sponsored by: Steptoe
STEPTOE & JOHNSON LLP

3:30 **New Developments in Damages Theories and Injunctions Relative to At Risk Launches: Legal and Economic Assessments**

Yogesh Bahl
Partner, National Life Sciences Leader
Deloitte Financial Advisory Services LLP
(New York, NY)

Michael F. Buchanan
Partner
Patterson Belknap Webb & Tyler LLP
(New York, NY)

James F. Hurst
Partner & Chair, Litigation Practice
Winston & Strawn LLP (Chicago, IL)

Don J. Mizerk
Partner
Husch Blackwell LLP (Chicago, IL)

Moderator:

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

- 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
  - *Winter v. Natural Resources Defense Counsel, Inc.*, 555 U.S. 7 (2008)
    - *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006)
  - intra-Circuit split
    - *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, Case No. 10-1382 (Fed. Cir., Sept. 29, 2011)
  - considerations by the District Courts in light of this inconsistency
- Overview of recent Hatch-Waxman matters concerning preliminary injunctions
  - *Hoffmann-La Roche Inc. v. Apotex Inc.* (Fed, Cir. 2012)
  - *Valeant International (Barbados) SRL v. Watson Pharmaceuticals, Inc.* (S.D Fl. 2012)
  - *Sciele Pharma Inc. v. Lupin Ltd.* (Fed. Cir. 2012)
- Practical strategies for brand names and generics in dealing with this discord before the District Courts and Federal Circuit
- 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

- 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?
  - circumstances under which lost profits can be denied
    - *Sanofi v. Glenmark* (D.N.J. 2012)
    - question of authorized generic
- Reasonable royalties:
  - basis for royalty
  - looking at market share
  - the point where infringement began
- Mitigating factors impacting damage award

4:45 **Inequitable Conduct Developments in the Courts and at the PTO: Ethical Considerations for Paragraph IV Cases**

Meredith Martin Addy
Partner
Steptoe & Johnson LLP (Chicago, IL)

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

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

Anthony J. Viola
Partner
Edwards Wildman Palmer LLP (New York, NY)

Ethics Panel

- Exploring recent applications of Federal Circuit's *Therasense* ruling in a Paragraph IV scenario
  - *Santarus, Inc. v. Par Pharmaceutical, Inc.* (Fed. Cir. 2012)
    - *Pfizer v. Teva*
  - intent to deceive
    - single most reasonable inference
  - materiality
    - 'but' for test
  - possible Supreme Court review?
- What can we derive from these rulings for future inequitable conduct filings?
- Exploring the role of Paten t Reform in the inequitable conduct debate
  - supplemental proceedings under the AIA
    - an opportunity to cure inequitable conduct?

5:30 **Conference Ends**

THURSDAY, MAY 9, 2013

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

Continental Breakfast will be served

C The Master Class on Settling Paragraph IV Disputes: Drafting and Negotiating Strategies for Brand-Name and Generic – A Hands-On, Practical Approach

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

William R. Zimmerman
Partner
Knobbe Martens Olson & Bear 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 and private plaintiffs have challenged a number of settlements on antitrust grounds. The DOJ has also lent its support to the FTC in challenging the legality of these settlements. There is also pending legislation addressing the parameters 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 these matters concerning patent settlements. The Supreme Court's recent grant of certiorari in the *Watson* case may finally bring resolution to this controversy, but until such time, the issue remains a point of industry contention and anxiety.

This hands-on, 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 successful and sound settlements. Through use of a hypothetical, the workshop leaders will help you:

- Draft and structure an agreement that will receive FTC approval
- Identify and avoid red flags that may lead to FTC scrutiny
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