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

ACI's HATCH-WAXMAN SERIES

April 25 & 26, 2016 | The Conrad – New York | New York City
April 27, 2016: Post-Conference Workshops

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10TH ANNUAL Paragraph IV Disputes

Industry Insights from:

- Amneal Pharmaceuticals
- ARIAD Pharmaceuticals, Inc.
- Boehringer Ingelheim
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- Depomed
- Endo Pharmaceuticals
- Gilead Sciences
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- Novartis Pharmaceuticals Corporation
- Pfizer Inc
- Sandoz Inc.
- Teva Pharmaceuticals

Judicial Insights from:

District Court


Honorable Ruben Castillo
Chief Judge, United States District Court
Northern District of Illinois


Honorable Tonianne Bongiovanni, U.S.M.J.
United States District Court
District of New Jersey


Honorable Christopher J. Burke, U.S.M.J.
United States District Court
District of Delaware


Honorable Roy Payne, U.S.M.J.
United States District Court
Eastern District of Texas

PTAB


Honorable Jackie Wright Bonilla (invited)
Lead Administrative Patent Judge
Patent Trial and Appeal Board, USPTO


Honorable Brian P. Murphy (invited)
Lead Administrative Patent Judge
Patent Trial and Appeal Board, USPTO

FTC Keynote on Commission Activity Post-*Actavis*


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

Preeminent patent litigators representing brand name and generic drug makers, leading in-house counsel, esteemed jurists and government representatives will provide insights on recent developments impacting Paragraph IV litigation, including:

- Ongoing **jurisdictional challenges** in the aftermath of ***Daimler*** and ***Mylan***
- The latest **safe harbor** and related **271(g)** controversies in view of the new ***Momenta*** decision
- **On-sale bars** in in light of *Angiomax*
- The continuing impact of **101 invalidity findings**
- Strategies for navigating **parallel proceedings**
- Current jurisprudential thought on **induced** and **indirect** infringement via the latest *Akamai* ruling
- **Obviousness discord** in the District Courts and PTAB
- The repercussions of ***Teva*** and implications of ***Cuozzo***
- New influences on **damages calculations** and at-risk launches

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The **ONE** and **ONLY** Forum which Shapes the Law, Policy and Proceedings of *Paragraph IV Litigation*

Dear Colleague:

This year marks the 10th anniversary of ACI's industry-leading **Paragraph IV Disputes** conference. From the time of our first Paragraph IV Disputes conference through to its present iteration, we have witnessed the ongoing evolution of the Hatch-Waxman pharmaceutical patent endgame. The rules of this endgame which once seemed straight forward have been reframed by the Medicare Modernization Act, America Invents Act, and to some extent the Affordable Care Act. There are now questions about where you can file suit and which forum to file in. There is still little if no clarity on how to settle one of these cases and not run the risk of government scrutiny despite a Supreme Court decision.

However, through this metamorphosis and continuing evolution, one thing has remained certain: each spring, the who's who of Hatch-Waxman litigators, industry decision makers and stakeholders, as well as Judges — now from two different forums — and government representatives will gather in New York City to attend **ACI's Paragraph IV Disputes** event. They will come to confer with one another, discuss, evaluate and assess new and evolving jurisprudence, the latest crags of the patent cliff, and related legal and economic consequences. This conference remains the constant. It is the only event which shapes the law, policy and proceedings of Paragraph IV litigation.

In this 10th anniversary year, we will continue to bring you up-to-the minute information on the latest developments impacting Paragraph IV disputes and how it will impact every facet of this complex type of litigation from pre-suit considerations, case filings, final adjudication and every step in between. We will examine victories and vanquishments before the District Court and PTAB, the ongoing jurisdictional debate, new *Momenta* controversies which reach beyond the safe harbor to the to the "making" provisions of 271 (g)(1), the on sale bar controversy of *Angiomax*, further opinions on divided and induced infringement, new twists on obviousness, claim construction and damages. Against this backdrop, we will explore how the economic losses of nearly $130 billion will affect the balance of power between brand name and generic companies when drugs such as Humira, Crestor, Benicar, Cubicin and Kaletra go off patent this year.

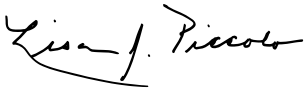
Also, by popular demand this year's event will feature mock parallel proceedings before the District Court and PTAB, in addition to a keynote by the FTC and two Judicial Roundtables — one with District Court Judges and the other with PTAB Judges. There will also be an IPR Master Class and a Biosimilars Boot Camp.

In short, this year's conference will help you rewrite your Hatch-Waxman patent playbook for the next decade by helping you develop strategies for the *defensive moves and offensive plays* of this very complicated and high stakes endgame

Clearly, there is not a moment to lose in this ruthless endgame of no-holds bar litigation. Do not be left behind. Register today by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563** or logging onto **www.AmericanConference.com/PIVDisputesNYC.**

We look forward to seeing you this spring in New York City.

Very truly yours,



Lisa J. Piccolo
Senior Industry Manager, Life Sciences and Health Care
American Conference Institute

Monday, April 25, 2016
Main Conference – Day One

7:00 *Registration and Continental Breakfast*
Sponsored by: Taft/

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 (Ridgefield, CT)

8:15 Pharmaceutical Patent Invalidity Challenge Score Card: District Courts v. The PTAB

Vincent L. Capuano, Ph.D.
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Peter Waibel
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Novartis Pharmaceuticals Corporation (East Hanover, NJ)

Moderator:

Gregory A. Morris, Ph.D.
Partner, Leader, Life Sciences Litigation Practice Group
Honigman Miller Schwartz and Cohn LLP
(Chicago, IL)

In the nearly four years since their inception and implementation, IPRs have offered an increasingly popular alternate route to invalidate a pharmaceutical patent outside of mainstream Hatch-Waxman litigation. In a sense, IPRs have now become an expected, although ancillary part of Hatch-Waxman litigation. However, all is not quiet at the District Court. As practitioners become more skilled in the IPR playing fields, they have realized that despite seeming cost savings, not all things are properly suited for an IPR and sometimes District Court makes the most sense. This panel will examine victories and vanquishments, procedural and substantive comparisons, and strategic and economic considerations for both the District Courts and PTAB. Point of discussion will include:

- Evaluating the pros, cons and costs of PTO proceedings and District Court litigation in a Hatch-Waxman setting
- Survey of notable pharmaceutical patent invalidity wins and losses at the PTAB
- Determining which pharmaceutical patents are the most vulnerable to an IPR petition
- Examining circumstances in which an IPR should be bypassed for traditional ANDA litigation in the District Court
- Comparing procedural and substantive legal options in both forums to evaluate best options
  - standard of review
    - rules package remedy
  - *Teva* applicability
  - obviousness, prior art and double patenting
  - impact of so-called reverse patent trolls
  - real parties of interest implications
- Analyzing the latest legislative and administrative developments impacting Paragraph IV litigation at the PTAB and District Courts

9:15 Paragraph IV Jurisdictional Show-Down at the Federal Circuit: Determining Where a Hatch-Waxman Case Can Be Filed in the Aftermath of *Daimler* and *Mylan*

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

Gary E. Hood
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Staci Julie
SVP and Chief IP Counsel
Teva Pharmaceuticals (Dresher, PA)

Jeffrey N. Myers, Ph.D.
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Bruce M. Wexler
Partner
Paul Hastings LLP (New York, NY)

Moderator:

Steven M. Coyle
Partner and Pharmaceutical Litigation Group Leader
Cantor Colburn LLP (Hartford, CT)

In the last year, several jurisdictional challenges in Hatch-Waxman settings have been made in various District Courts, most notably in Delaware. While these cases have been brought under the auspices of the Supreme Court's ruling in *Daimler,* they present a unique scenario given that the act of infringement is artificially brought into being by the filing of an ANDA. This panel will take a new look at these cases and the *Mylan* appeals currently pending before the Federal Circuit.

- Examining personal and general jurisdiction as defined by *Daimler* in a Hatch-Waxman setting
  - consent jurisdiction vs. personal jurisdiction
- Survey of various Hatch-Waxman jurisdiction cases since *AstraZeneca AB v. Mylan Pharms, Inc.,* 72 F. Supp. 3d 549, 558 (D. Del. Nov. 5, 2014)., Fed. Cir. Docket No. 15-1460 and in *Acorda Therapeutics v. Mylan Pharms.* Inc., 78 F. Supp. 3d 572 (D. Del. Jan. 14, 2015)
- Status of interlocutory appeals for both *Mylan* cases before the Federal Circuit
- Predicting how the Federal Circuit may rule
- Devising interim jurisdictional strategies

10:15 *Networking Break*
Sponsored by: HONIGMAN

10:30 The Safe Harbor: Defining Boundaries and Preparing for New Ancillary Storms

Kathleen B. Carr
Member
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (Boston, MA)

Henry H. Gu
Assistant General Counsel, Intellectual Property
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Meg Snowden
VP, Intellectual Property
Impax Laboratories (Hayward, CA)

Moderator:

David L. Anstaett
Partner
Perkins Coie LLP (Madison, WI)

This past November, the Federal Circuit revisited the *Momenta* case and reversed itself as to its original safe harbor ruling. However, just as this decision calmed the proverbial waters, it also cleared the path for new controversy. This panel will discuss this latest tempest in the safe harbor teapot and what it means for Paragraph IV litigation

- Comparing the Federal Circuit's latest *Momenta* ruling to its prior one with respect to Hatch-Waxman safe harbor boundaries
- Knowing what's safe as per 271(e)(1) and this latest ruling
  - pre-marketing v. post-marketing approval activity
- Understanding the implications of this ruling to Hatch-Waxman litigation
  - future of research tool and analytical patents
- Examining the latest *Momenta* controversy relative to the Federal Circuit's ruling concerning 271(g)
  - analyzing the role of research tool and analytical patents within the 271(g) rubric
  - exploring the nexus between "making" and "testing" relative to the Federal Circuit's interpretation of 271 (g) (1)
  - understanding how the Federal Circuit's ruling with respect to the plain meaning of "made" as per the statute will impact infringement under both Hatch-Waxman and BPCIA litigation
  - examining "made" on a case by case basis as per Judge Dyke's partial dissent and understanding the implications of this dissent relative to offshore outsourcing of US process patents

11:30 On Sale Bar in a Hatch-Waxman Setting: Analyzing Patent Impediments Caused by Contract Manufacturing and Its Impact on Pharmaceutical Product Market Access

Richard Berman
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Richard T. Ruzich
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Taft Stettinius & Hollister LLP (Chicago, IL)

This past November, the Federal Circuit granted a petition for a re-hearing en banc in *The Medicines Company v. Hospira,* Inc., *i.e.,* the *Angiomax* case which held that placing an order with a contract manufacturer for a pharmaceutical product could invalidate a subsequently issued patent for that product. Given the role of contract manufacturing in the pharmaceutical industry — all eyes are now on this case which began as a Hatch-Waxman dispute and its possible implications for Paragraph IV litigation. Points of discussion will include:

- Review of *Angiomax* case and 35 U.S.C. § 102(b) prior to AIA
  - 35 U.S.C. § 102(b) post AIA
- Examining the "no supplier exception rule" and its applicability in the *Angiomax* scenario
- Understanding the implications of this ruling in a Hatch-Waxman scenario
  - experimental use exception
- Possible repercussions to subsequent patents for contract manufactured pharmaceutical products
- Exploring consequences for patent loss under scope of post-AIA 35 U.S.C. § 102(b) and its impact in a Hatch-Waxman scenario

12:15 *Networking Luncheon Sponsored by:* Knobbe Martens INTELLECTUAL PROPERTY LAW

1:30 The Evolving 101 Challenge: How Subject Matter Patentability Has Become the "Next Big Thing" in Hatch-Waxman Related Invalidity Challenges

Neal K. Dahiya
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Keith J. Grady
Practice Chair & Shareholder
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Husch Blackwell (Chicago, IL)

Since the Supreme Court issued its *Prometheus* and *Myriad* decisions in 2012 and 2013, there has been growing fears in the industry that these cases would have far reaching implications for 101 patent subject eligibility that would eventually reach the Hatch-Waxman arena. This panel will examine how these fears are now through recent developments turning to reality. Points of discussion will include:

- Understanding the implications of the Federal Circuit's recent denial for a rehearing in *Ariosa v. Sequenom* (Fed. Cir. 2015) for the pharmaceutical industry relative to 101 rejections and patent invalidity
- Analyzing the implications of the 101 invalidity trend through the District of Delaware's recent ruling in *Endo Pharmaceuticals Inc. v. Actavis Inc., C.A.* No. 14-1381-RGA (D. Del. Nov. 17, 2015)
- Exploring the widespread implications of these decisions and related jurisprudence on method of use patents in a Hatch-Waxman setting
- Devising new due diligence and patent prosecution strategies for small molecules in light of this evolving body of case law

2:30 *Networking Break Sponsored by:* HONIGMAN

2:50 Parallel Proceedings Moot Court: District Court and PTAB Mock Pharmaceutical Patent Invalidity Hearing

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Tedd W. Van Buskirk
Partner
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Counsel, Gibbons P.C. (Newark, NJ)
(Former Vice President & Chief Patent Counsel, Hoffmann-La Roche)

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

Mock District Court Judge

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Connell Foley LLP (Newark, NJ)

Mock PTAB Judges

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Partner
Foley Hoag LLP (Washington, DC)

Honorable Teresa Rea
Partner
Crowell & Moring LLP (Washington, DC)
(Former Acting Under Secretary of Commerce for Intellectual Property and Former Acting Director of the United States Patent and Trademark Office)

Moderator:

David G. Conlin
Member
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C
(Boston, MA)

Setting

Parallel litigation between the District Court and PTAB in a Hatch-Waxman setting is becoming more and more commonplace and adds to the "no-holds" bar atmosphere of this high stakes type of litigation. The art of navigating proceedings between to these two forums has been described as akin to walking a tightrope. In this very interactive session we will illustrate the ins and outs of this balancing act through a mock pharmaceutical patent invalidity hearing running parallel in both the district court and PTAB.

We will provide the audience with a fact pattern. The case will play out as both mock patent challenger and patent holder duke it out before a moot district court judge and a moot PTAB panel.

Deliberations and Polling

At the end of the mock hearing and motion, delegates will deliberate and use polling devices to cast their votes as to the outcome in each forum.

4:05 The PTAB Live

Honorable Jackie Wright Bonilla (invited)
Lead Administrative Patent Judge
Patent Trial and Appeal Board, USPTO

Honorable Brian P. Murphy (invited)
Lead Administrative Patent Judge
Patent Trial and Appeal Board, USPTO

Moderator:

Ralph J. Gabric
Shareholder
Brinks Gilson & Lione (Chicago, IL)

IPRs have become an important component in the Hatch-Waxman arsenal. As such, knowing the "ins and outs" of PTAB practice is a critical competency for today's Hatch-Waxman petitioner. To help you with this task, Judges from the PTAB will discuss protocols and the art of appearance before this administrative body.

4:50 A View From the U.S. District Court Bench

Honorable Ruben Castillo
Chief Judge
United States District Court
Northern District of Illinois (Chicago, IL)

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

Honorable Christopher J. Burke, U.S.M.J.
United States District Court, District of Delaware
(Wilmington, DE)

Honorable Roy Payne, U.S.M.J.
United States District Court, Eastern District of Texas
(Marshall, TX)

Moderators:

Anne Shea Gaza
Partner
Young Conaway Stargatt & Taylor, LLP
(Wilmington, DE)

Barry P. Golob
Vice Chair, Intellectual Property Department
Cozen O'Connor (Washington, DC)

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 pressing 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

Tuesday, April 26, 2016
Main Conference – Day Two

7:00 *Continental Breakfast*
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8:00 Co-Chairs' Opening Remarks and Recap of Day One

8:15 In the *Limelight:* Examining *Lilly v. Teva* and Its Larger Implications for Divided and Induced Infringement in a Hatch-Waxman Setting

Andrew M. Alul
Partner
Taft Stettinius & Hollister LLP. (Chicago, IL)

Alan B. Clement
Partner
Locke Lord LLP (New York, NY)

Lars P. Taavola
Senior Director,
Senior Patent Counsel – Global Intellectual Property, Head of Patent Litigation
Amneal Pharmaceuticals (Bridgewater, NJ)

Jennifer Tempesta
Special Counsel
Baker Botts LLP (New York, NY)

Ha Kung Wong
Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

Last August, the United States District Court for the Southern District of Indiana, followed the lead of the Supreme Court and Federal Circuit's subsequent remand ruling in *Limelight v. Akamai* in rendering its decision in *Eli Lilly and Company v. Teva Parenteral Medicines, Inc., et. al.,* 1-10-cv-01376 (INSD). At time of press, a Notice of Appeal has been filed before the Federal Circuit. This panel will explore this case and its wider implications for divided and induced infringement rulings in a Hatch-Waxman setting. Points of discussion will include:

- Review of the *Limelight v, Akamai* appeals including Supreme Court's ruling and Federal Circuit's most recent en banc decision
  - exploring the relationship between induced and direct infringement
- Analyzing the Southern District's ruling in *Lilly* in light of the most *Limelight v. Akamai* rulings and its importance to Paragraph IV infringement litigation
  - role of doctor and patient as infringers
- Understanding the critical role of the label in the determination of divided and induced infringement via the *Lilly* ruling
- Predicting how this case may influence other allegations of direct and induced infringement in Hatch-Waxman litigation
- Status of proposed FDA rulemaking and other carve out and skinny labeling tactics relative to the latest *Limelight* cases and progeny

9:15 Revisiting Obviousness in the Hatch-Waxman Realm: Prior Art, Obvious-Type Double Patenting, Inherency by Anticipation and PTAB Findings

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

Stephen M. Hash
Partner
Baker Botts LLP (Austin, TX)

Mark Rachlin
Senior Patent Counsel-Litigation
GlaxoSmithKline (King of Prussia, PA)

Joseph M. Reisman
Partner
Knobbe, Martens, Olson & Bear, LLP (San Diego, CA)

Steven D. Roth
Partner
Locke Lord LLP (New York, NY)

Christina Schwarz
Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

- Applying prior art via secondary considerations and unexpected results
  - *Prometheus Laboratories, Inc. v. Roxane Laboratories, Inc. et al.,* No. 14-1634, -1635, slip op. (Fed. Cir. Nov. 10, 2015)
    - link to obvious-type double patenting
  - *Spectrum Pharmaceuticals Inc. v. Sandoz Inc.* (Fed. Cir. 2015)
- Re-examining the Federal Circuit's stance on obvious-type double patenting
  - *G.D. Searle LLC v. Lupin Pharmaceuticals, Inc.* (Fed. Cir. 2015)
- Reassessing inherency by anticipation
  - *Purdue Pharma L.P. et al v. Amneal Pharmaceuticals,* LLC (S.D.N.Y. 2015)
    - *Gilead v. Natco*
- Analyzing obvious findings at PTAB relative to pharmaceutical patents
- Exploring ongoing obviousness discord at PTAB and District Courts

10:15 *Networking Break*
Sponsored by: HONIGMAN

10:30 Re-Evaluating Claim Construction and Markman Strategies Post-*Teva*

Ronald M. Daignault
Shareholder
Polsinelli PC (New York, NY)

Michael R. Dzwonczyk
Partner
Sughrue Mion PLLC (Washington, DC)

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

Robert D. Rhoad
Partner
Dechert LLP (Princeton, NJ)

- Analysis of *Teva* and the Supreme Court's ruling with respect to de novo review vs. deferential review
- Survey of recent Federal Circuit and District Court opinions in Hatch-Waxman space addressing *Teva* applicability
- Addressing *Teva* applicability in IPR proceedings before the PTAB
  - BRI vs. Phillips standard
  - *In re Cuozzo Speed Technologies, LLC*
- Reassessing claim drafting in view of the *Teva* decision
  - clarity of claims in view of written description and enablement requirements
  - being mindful of indefiniteness findings
- Rethinking Markman strategies in Paragraph IV challenges in view of *Teva*
- Re-evaluating the use of witnesses in a Markman hearing in view of *Teva*

11:15 FTC Keynote: Reverse Payment Settlements and Other Antitrust Concerns Impacting Paragraph IV Litigation in the Wake of *Actavis*

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

The Supreme Court's decision in the *Actavis* case established the antitrust "rule of reason" as the standard for evaluating reverse payment settlement cases. The significance of the Supreme Court's decision, however, will only become clear as the lower courts grapple with its application to challenged reverse payment settlements.

As per the MMA, the FTC is required to continue to review Hatch-Waxman settlements, and it has publicly announced that it will continue challenging reverse payment settlement agreements, possibly including settlement agreements filed prior to the *Actavis* decision. Private plaintiffs certainly have stepped up their challenges, and there are currently fifteen reverse payment cases in litigation. Additionally, the FTC recently has questioned the legality under *Actavis* of a Hatch-Waxman settlement based on the brand's agreement not to launch an authorized generic. It is now anyone's guess as to how far the FTC and private plaintiffs will go.

In this session, the FTC will address these matters, in addition to other anticompetitive concerns in the Hatch-Waxman space.

12:00 *Networking Luncheon*

1:00 Settlement Anthology: A Review of Pharmaceutical Patent Settlement Jurisprudence Since *Actavis* and Its Practical Applications

George G. Gordon
Partner
Dechert LLP (Philadelphia, PA)

M. Howard Morse
Partner
Cooley LLP (Washington, DC)

Seth C. Silber
Partner
Wilson Sonsini Goodrich & Rosati (Washington, DC)

In the three years since the *Actavis* decision, the pharmaceutical industry has anxiously watched both District and Appellate Courts weigh in on the continuing pay-for-delay controversy as these forums grapple with the Supreme Court's "rule of reason" test. While there is judicial activity and movement, answers to what precisely constitutes "pay for delay" remains unclear. This panel will explore the latest decisions and practical take aways for drafting settlement agreements. Points of discussion will include:

- Review of District Court and Appellate decisions in the pay for delay arena
- Defining what constitutes pay for delay as per the "rule of reason" test
- Antitrust determinations relative to
  - non cash payments
  - authorized generics provisions
    - *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp. (3rd Cir. 2015)*
  - licensing provisions
  - acceleration clauses
- Analysis of *Wellbutrin* case
- Status of indirect purchaser litigation
- Predicting outcome of Nexium antitrust suits
- Devising settlement strategies in light of this developing jurisprudence

2:00 FDA Update: Survey of Latest FDA Developments Impacting Paragraph IV Litigation

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

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

Shashank Upadhye
Partner
Amin Talati & Upadhye (Chicago, IL)
(Former Vice President – Global Intellectual Property, Apotex, Inc.)

- Status of FDA's proposed rule to implement the MMA
- Update on GDUFA and pre-GDUFA filing status
- Review of latest exclusivity challenges impacting brand names and generics
- Impact of Improving Regulatory Transparency for New Medical Therapies Act on exclusivity start dates for certain drugs
- Significance of new NDA classification codes
- Exploring FDA's stance on brand name and generic trade dress relative to recent trade dress law suits

2:45 *Networking Break Sponsored by:* HONIGMAN

3:00 Risky Business: Examining New Guidance for Calculating Damages in the Aftermath of an At-Risk Launch

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

Chris Gerardi
Senior Managing Director
FTI Consulting (New York, NY)

Bradley C. Graveline
Partner
Sheppard, Mullin, Richter & Hampton LLP (Chicago, IL)

Christopher J. Harnett
Partner
Ropes & Gray LLP (New York, NY)

Vince Thomas
Senior Managing Director
FTI Consulting (Chicago, IL)

- Review of most recent at-risk-launches and lessons learned
- Conducting a risk-benefits analysis of launching at risk during the trial or appeal period based on current at-risk outcomes
- Review of recent preliminary injunction determinations in Hatch-Waxman matters
  - examining trends and jurisdictional inconsistencies in these matters
- Asserting damages in an at-risk scenario
- Understanding the significance of *AstraZeneca AB v. Apotex Corp.* (Fed. Cir 2015) to damages calculations in the Hatch-Waxman sector
  - entire market value rule
  - question of damages eligibility for pediatric exclusivity
- Reasonable royalties:
  - establishing the basis for royalty
  - looking at market share
  - identifying the point in time when infringement began
  - question of prior art relative to damages calculation
- Lost profits
  - assessment of profit as a true measure of damages
    - questions of profitability and sales
  - circumstances under which lost profits can be denied
- Mitigating factors impacting damage award

4:00 Ethical Considerations in Paragraph IV Practice

Bradford J. Badke
Partner
Ropes & Gray LLP (New York, NY)

David H. Silverstein, M.S., J.D.
Partner
Axinn, Veltrop & Harkrider LLP (New York, NY)
(Former Senior Director, Intellectual Property, Par Pharmaceutical, Inc)

Laura A. Vogel
Counsel
Wolf, Greenfield & Sacks, P.C. (Boston, MA)

- Review of recent inequitable conduct cases impacting Hatch-Waxman litigation post-*Therasense*
- Willfulness and recklessness considerations in relation to ANDA filings
- Examining perceived abuses at the PTAB relative to so called reverse patent troll IPR filings
- Understanding the ethical implications for *Octane Fitness v. Icon Health & Fitness* (Supreme Court Docket Number 12-1184)

5:00 *Conference Ends*

Wednesday, April 27, 2016 | Post-Conference Workshops

8:30 AM – 12:00 PM
(Registration Begins at 8:00 – Continental Breakfast will be Served)

A

IPR Master Class for the Hatch-Waxman Patent Practitioner

IPRs: Avoiding Traps for the Unwary — Practice Tips for Both Petitioners and Patent Owners in Pharmaceutical Patent Arena

Honorable Teresa Rea
Partner
Crowell & Moring LLP (Washington, DC)
(Former Acting Under Secretary of Commerce for Intellectual Property and Former Acting Director of the United States Patent and Trademark Office)

Donna M. Meuth
Associate General Counsel, Intellectual Property
Eisai Inc. (Andover, MA)

In the three and a half years since their inception, over 3600 IPR petitions have been filed. While the vast majority of these petitions still remain in the tech sectors, petitions for the life sciences industries are increasing steadily. Of the 1843 petitions filed in fiscal years 2015 and 2016, approximately 17% have been filed in the life sciences sector. This is an almost 10% increase from previous fiscal years.

Patent practitioners in the Hatch-Waxman space are learning the ropes of this unique type of litigation and are not only honing in on best practices, but are also becoming aware of certain things to avoid in these procedures. In this workshop, we will explore best practice pointers in addition to traps to avoid in the pharmaceutical patent arena. Points of discussion will include:

- Formulating strategies based on type of pharmaceutical patent
- Examining IPR petition rejections, decisions and appeals for sound petition drafting and practice guidance
- Establishing jurisdiction at the PTAB
  - special considerations for ex-U.S. parties
- Ensuring all RPIs are properly named
- Developing sound discovery strategies relative to these proceedings
- Devising tactics for parallel litigation with the District Court
- Evaluating the pros and cons of using multiple experts
- Assessing split petition strategies
- Understanding when requests for joinder can be made and when they should be made
- Analyzing secondary considerations
- Managing desire and expectations of parties to settle despite PTAB's insistence on moving the petition forward

1:00 PM – 4:30 PM
(Registration Begins at 12:30 PM)

B

Biosimilars Boot Camp for the Paragraph IV Litigator

Christopher P. Borello
Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

Despite the fact that BPCIA litigation has been filed, it is still relatively new and uncharted territory, as we are only at the beginning of beginning. In this hands-on boot camp will walk you through the first of the biosimilars cases which have been filed and will also take a look, we at the approval process and other key points of regulation.

Legal and regulatory background:

- Comparing and contrasting the biosimilar pathway to 505(b)(2) and BLA pathways
  - determining whether research and development resources are best spent pursuing a biosimilar pathway or going the traditional BLA route
  - breakdown of relevant considerations with each route including timing, costs, and IP litigation considerations, and exclusivity
- Overview of the 2010 Biologics Price Competition and Innovation Act (BPCIA)
  - exclusivity provisions
  - criteria for biosimilarity and interchangeability
  - clinical trials and safety studies
  - patent litigation and exchange provisions: Understanding the major differences between Hatch-Waxman and biosimilars litigation as outlined in the statute

Litigation Update:

- Reviewing the BPCIA cases filed to date and analyzing the substantive arguments in the first cases
  - *Sandoz v. Amgen*
  - *Celltrion v. Janssen*
- Bringing declaratory judgment actions to invalidate patents pre-suit/post-District Court decision in *Sandoz*
  - will companies attempt to make this argument in other jurisdictions?
- Timing of patent filings: making the decision to file pre-suit, waiting out the lengthy legal process, or launching without the benefit of having discovery of the other party's patents and legal positions
- Analyzing the use of PTO Proceedings in biosimilars litigation
- Developing patent certainty: factoring the decisions in the BPCIA case into BLA versus biosimilar application analysis and into forum choice between District Courts, USPTO, and the ITC

**Luncheon will be served at 12:00 PM for Delegates who are attending both Workshop A and Workshop B.*

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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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Baker Botts is an international law firm with a global network of offices. Our Life Science lawyers are wellversed in all facets of the law impacting the industry, and our matters have included representation of proprietary pharmaceutical companies over a range of Hatch-Waxman issues, including ANDA litigation, patent portfolio review, product design and clearance, Orange Book inquiries, 505(b)(2) applications, paragraph IV certifications and notice letters, exclusivity inquiries, pre-litigation assessments, settlements and trial. **BakerBotts.com**

Brinks' Hatch-Waxman litigation practice group clears the legal and regulatory pathways for our generic pharmaceutical clients. We have handled dozens of Hatch-Waxman cases involving drugs from A (atomoxetine) to Z (zolpidem). These cases have covered virtually every type of drug technology, including compounds, formulations, polymorphs, and methods of treatment. We have been trial and appellate counsel on behalf of leading companies in successful ANDA litigations involving blockbuster drugs worth billions of dollars. With top-accolades received from leading legal directories and industry publications, Brinks Gilson & Lione Hatch-Waxman litigators are recognized leaders in Intellectual Property Law. Understanding our clients' top priorities, including responsiveness, efficiency and budgeting is how we help them navigate through complex legal issues surrounding their IP needs. We align our litigation tactics with their business objectives, enabling us to formulate a solid plan to achieve them.

Cozen O'Connor is an international law firm with more than 600 lawyers in 24 offices. Our intellectual property team is a national leader in Hatch-Waxman litigation with an impressive track record. In addition to top-tier patent litigation, we also counsel clients on a full range of regulatory issues and advocate on their behalf before key regulatory authorities. Our attorneys hold advanced degrees in the natural sciences and nearly all members have experience as research scientists in industry or academia for small molecules, biosimilars and hybrid products, such as smaller polysaccharides and peptides **(http://www.cozen.com/practices/intellectual-property/biologics-biosimilars).**

Dechert LLP is a global specialist law firm focused on sectors with the greatest complexities and highest regulatory demands. Leading global pharmaceutical companies rely on our trial lawyers, appellate lawyers and Ph.D.-level subject matter experts to protect their investment in R&D and take on ANDA challenges with them. Our legal services are distinguished by a high degree of technical and scientific sophistication. Taking an interdisciplinary approach, our strategies are designed to protect and maximize the value of our clients' pharmaceutical patents. Our deep bench of trial lawyers has extensive experience in the preparation for and litigation of ANDA disputes, and having taken on and won cases involving as many as a dozen ANDA filers, we are not afraid to take these disputes to trial. Likewise, our seasoned antitrust lawyers, which include former FTC personnel, are highly skilled in patent-antitrust and settlement issues.

Dechert's ability to see the entire ANDA picture from start to finish is a valuable perspective we bring to each Hatch-Waxman Act matter. Our team focuses on our clients' business needs from the day the Paragraph IV notice is received to the trial and appeal or FTC ANDA settlement review process. When necessary, our team is adept at handling follow-on antitrust litigation.

Our frequent, high-profile success on behalf of life sciences companies means our teams handle highly sensitive matters, including pre-litigation Orange Book reviews and product launch strategic assessments and, in one case, architecting what is likely the largest branded/generic settlement of all time and shepherding it through the FTC.

FTI Consulting has created and shaped its multi-faceted intellectual property practice with the express purpose of helping organizations deal with the inherent and emerging complexities of successful intellectual property management, including creation, strategy and governance, assessment of assets, licensing and acquisition, and protection, enforcement and defense. The Intellectual Property group at FTI Consulting consists of a prestigious, integrated team of highly trained professionals that can provide an unmatched breadth of in-depth consulting and expert witness assistance to corporations and their counsel across the entire intellectual property lifecycle.

Mintz Levin's Hatch-Waxman litigation group has a proven track record of trying cases to verdict and having those verdicts upheld on appeal. Our professionals bring technical and strategic knowledge to their work, which leads to the levels of satisfaction clients have come to expect from Mintz Levin. Our team guides clients from portfolio development tracking and analysis through to initial ANDA filings and the entire regulatory and litigation process. As part of an ongoing Paragraph IV litigation, Mintz Levin recently blocked institution of three inter partes review petitions filed against our client.

We recognize that each Hatch-Waxman litigation is different, and we put the time and resources into ensuring that each case is handled with the utmost attention to detail. Whether a single generic has filed an Abbreviated New Drug Application or a dozen have, clients know that we will bring an efficiently staffed and experienced team to bear on their behalf.

Working in support of the litigators who develop strategies in pursuit of your rights are numerous professionals in our practice with PhDs in fields valuable to the pharmaceutical industry, including Biochemistry, Chemistry, Chemical Biology, Molecular and Cellular Pharmacology, and Organic Chemistry.

O'Melveny is home to some of the nation's preeminent practitioners in Hatch-Waxman and biologics litigation. Offering the technical depth of an intellectual property boutique, coupled with the resources of an elite global litigation powerhouse, our team provides unparalleled service to innovator companies. As scientists, and litigators, we know the pharmaceutical industry. We know chemistry. We know biotechnology. We know formulation technology. We know the law. And we know the regulatory environment. Our team has handled dozens of significant cases for drug manufacturers whose patents were threatened by generic challengers, and protected billions in sales revenue.

Patterson Belknap is a 200-lawyer firm based in New York City. More than half of our attorneys are litigators, many with a focus on patent disputes. We litigate "bet-the-company" matters on behalf of major corporations in industries including pharmaceuticals, manufacturing and software. Many of our attorneys have scientific and technical backgrounds and varied industry experience, including in chemistry, biochemistry, biology, biotechnology, statistics, mathematics, electro-mechanical computer technology, metallurgical engineering, electrical engineering, semiconductor manufacturing, electro-optical circuits and associated software. Our patent and biotechnology attorneys author NYPatentDecisionsBlog.com, a source for the latest patent decisions from the U.S. District Courts for the Southern and Eastern Districts of New York, and BiologicsBlog.com, which tracks and analyzes developments in intellectual property law related to biotechnology and biologic medical products.

Polsinelli's Hatch-Waxman team has extensive experience leading Abbreviated New Drug Application (ANDA) cases. We represent some of the world's largest and most influential generic, brand, and specialty pharmaceutical companies, in both first-to-file and later filer cases. We understand well that each case, and each client, requires its own approach, so we partner with our clients early on to develop a strategy to achieve desired results in a cost-effective manner. We bring to bear a formidable team, including not only first-chair trial lawyers and experienced litigators, but team members with scientific backgrounds in a variety of relevant disciplines such as organic chemistry, biochemistry, biology, pharmacy, medicine, molecular biology, microbiology, neuroscience, pharmacology, genetics, immunology, and molecular biophysics, among others.

We are experienced handling cases involving compositions and APIs, formulations (oral dosage forms, controlled release, ODTs, transdermal, topical, ophthalmic, transmucosal, parenteral, etc.), methods of use, polymorphs, enantiomers, drug delivery devices, and methods of manufacture. We are prepared to assist clients every step of the way — from strategically evaluating potential drug products, to pre-litigation counseling and advice, to preparing and filing an ANDA or 505(b)(2) application, to trial, appeal, and/or settlement.

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