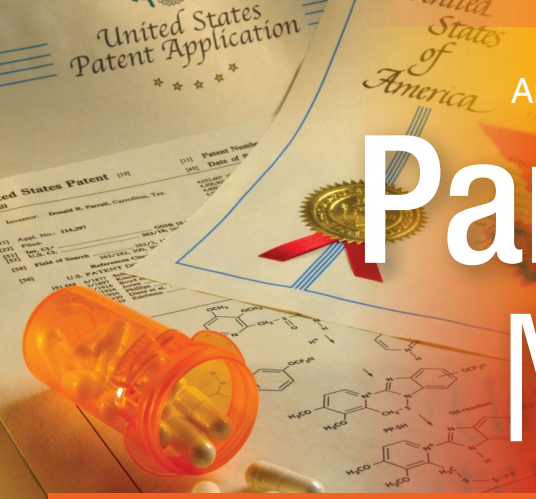

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- Paragraph IV Due Diligence Strategies Analyses
- Pending Patent Reform Legislation and Its Potential Impact on Hatch-Waxman Litigation
- Personal and General Jurisdiction Challenges Under *Daimler* and *Mylan*
- IPR, CBM, and PGR Utilization in ANDA Litigation
- FRCP 16 and 26 Dilemmas Relative to ANDA Litigation
- *Myriad* 101 Rejections and *Nautilus* 112 Indefiniteness Findings
- *Barraclude* and New Obviousness Considerations
- The Merits of Bringing A Declaratory Judgment Action in a Paragraph IV Case
- At-Risk Launches and Damages
- Markman Analysis post – *Teva v. Sandoz*
- Willfulness and Recklessness Considerations in Relation to ANDA Filings

Insights from the Judiciary and Government:

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Chief Judge
United States District Court, Northern District of Illinois

Honorable Sidney I. Schenkier, U.S.M.J.
United States District Court
Northern District of Illinois

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Master the Necessary Skills to Rise to the Newfound Challenges of the Pharmaceutical Patent Endgame

Dear Colleague:

For the last three years, leading Hatch-Waxman litigators representing brand name and generic pharmaceutical companies have come to Chicago to exchange ideas and engage in in-depth discussions addressing the challenges and conundrums of ANDA litigation at **American Conference Institute's (ACI's)** industry-acclaimed **Paragraph IV Disputes Master Symposium.**

This symposium – a companion to **ACI**'s flagship **Paragraph IV Disputes** conference which takes place in New York each spring – is an advanced forum which delves into the complexities of today's Hatch-Waxman litigation. This event picks-up on where our New York conference left off to bring you the latest information and developmental analysis of the next phase and interpretation of case law, legislation and proactive and reactive industry trends.

We welcome you to join our exceptional faculty and your peers as we examine the consequences of the 2015 patent cliff escarpments which will result in some $32 billion dollars in patent losses for drugs such as Lantus, Abilify, Copaxone, Neulasta, and Androgel. Within this context, we will explore the impact of *Teva* on Markman hearings, questions of personal and general jurisdiction, the probable impact of proposed patent reform legislation on ANDA litigation, due diligence assessments prior to District Court or PTAB filings, the propriety of declaratory judgment actions relative to ANDA litigation, the effect of cases such as *Myriad* and *Nautilus*, new obvious considerations in light of *Baraclude*, the increased utilization of PTO proceedings, the continuing controversy in settling these matters in a post-*Actavis* era, damages assessment, as well as the importance of legal ethics. This year's event will also feature a keynote by the FTC and two Judicial Roundtables — one with District Court Judges and the other with PTAB Judges.

Finally, in response to your requests, we are pleased to offer two post-conference workshops: the first on the Anatomy of a PTO PTAB Patent Trial in the Hatch-Waxman Arena; and the second on the essentials of Biosimilars and BPCIA litigation.

Clearly, there is not a minute to lose. This is the time to acquire and master the necessary skills to rise to the challenges of this costly and ruthless endgame.

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Very truly yours,

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

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7:00 Registration and Continental Breakfast

8:00 Co-Chairs' Opening Remarks

Mark Bowditch
Vice President –
Intellectual Property and Litigation
Coherus BioSciences (Redwood City, CA)

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

8:15 Paragraph IV Due Diligence Analysis: Economic Impact of Pharmaceutical Patent Wins and Losses at District Courts and PTAB

Stephen R. Auten
Partner
Chair of Pharmaceutical & Life Sciences Litigation
Taft Stettinius & Hollister LLP (Chicago, IL)
(Former Vice President, IP, Sandoz, Inc.)

Paul Simboli
Vice President
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Depomed, Inc (Newark, CA)

PTO Proceedings such as Inter Partes Review (IPR) have been a game changer in the world of pharmaceutical patent challenges. Patent challengers have used these proceedings to bypass District Court litigation and in some instances received an alternative result. The addition of these administrative proceedings have not only altered the schematic of ANDA litigation, but have also changed economic considerations. This panel will examine patent wins and losses at the District Court and PTAB, their economic consequences and overall impact on due diligence strategies.

- Survey and analysis of pharmaceutical patent challenges outcomes at District Court and PTAB
  - evaluating the type of patent in question and track record for invalidity findings
    - District Courts and PTO
- Weighing the costs of PTO litigation, District Court litigation and parallel proceedings
  - what are the odds of success in the District Courts and PTO?
- Evaluating the economic sense of patent wins and losses on pharmaceutical patent litigation and prosecution strategies as well as R&D

9:00 Patents, Politics and Paragraph IV Litigation: An Update on How Proposed Patent Reform Legislation May Impact the Patent End Game

John L. Abramic
Partner
Steptoe & Johnson LLP (Chicago, IL)

Graham L. Day
Shareholder
Polsinelli PC (St. Louis, MO)

This spring, three new bills aimed at promoting further patent reform measures were introduced to Congress, i.e., the STRONG Patents Act (S. 632), the PATENT Act (S. 1137), the TROL Act (H.R. 2045). In addition, the Innovation Act, H.R. 9, was reintroduced. These bills, if passed, may have a profound impact on both District Court litigation and PTAB practice. This panel will discuss the potential impact of these measures on Paragraph IV litigation and related PTO proceedings as well as their ultimate impact on the Hatch-Waxman pharmaceutical patent endgame. Points of discussion will include:

- Status of bill in both houses
- Review of antitroll measures and potential impact on pharmaceutical patents
- Understanding how the provisions in these bills may affect pharmaceutical patent challenges at the District Court and PTAB

9:45 Morning Coffee Break

10:00 Establishing Personal and General Jurisdiction in A Paragraph IV Case in the Aftermath of *Daimler* and *Mylan*

Ali I. Ahmed
Chief Intellectual Property Counsel,
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Partner
Ropes & Gray LLP (New York, NY)

The Supreme Court's decision regarding personal and general jurisdiction in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014) is permeating the Hatch-Waxman arena. In the last year, several motions challenging jurisdiction have been filed in Paragraph IV stronghold venues. The District of Delaware issued the first decision in these matters in *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*, C.A. No. 14-696-GMS (D. Del. Nov. 5, 2014) ("*Mylan*"). In this Hatch-Waxman case, the Delaware court found grounds for specific jurisdiction consistent with *Daimler*. *Mylan* is currently on appeal before the Federal Circuit. At time of press, there are several other Paragraph IV cases pending (including several others brought by *Mylan*) in which jurisdiction is also being challenged. This panel will examine *Mylan* and other related jurisdiction cases within the context of *Daimler*. Points of discussion will address:

- Analyzing the Supreme Court's ruling in *Daimler* and its holding on personal and general jurisdiction and how it altered prior jurisprudence on this subject
- Examining Judge Sleet's opinion in *Mylan* and the court's logic in determining how service of the Paragraph IV Notice Letter satisfies the *Daimler* requirements for personal jurisdiction

- Comparing Judge Gilstrap's opinion in *Allergan Inc. v. Actavis Inc. et al.*, case number 2:14-cv-00638 (E. D. Tex.) to Judge Sleet's opinion in *Mylan*
- Anticipating the Federal Circuit's decision in *Mylan*
- Predicting outcomes for future jurisdictional challenges in a Paragraph IV setting

11:00 FRCP 16 and 26: Brand and Generic Viewpoints on Scheduling Orders, Protective Orders and ESIs in a Hatch-Waxman Setting

Daniel P. DiNapoli
Partner
Kaye Scholer LLP (New York, NY)

Elese E. Hanson
Patent Counsel
Sagent Pharmaceuticals, Inc. (Schaumburg, IL)

Mark H Remus
Partner
Katten Muchin Rosenman LLP (Chicago, IL)

Scheduling Orders, Protective Orders and ESIs are some of the most contentious initial components of litigation. They are particularly onerous in the world of ANDA litigation. In this session, brand name and generic counsel will share their insights and perspectives on protocols for the initial steps of a Paragraph IV dispute. Points of discussion will include:

- Establishing best practices for scheduling conferences
  - scheduling orders
- Negotiating protective orders as they relate to:
  - the use of one defendant's Confidential Business Information against another defendant
  - prosecution bars in post-grant (IPR or CBM) proceedings
- Limiting the number of discovery requests and depositions when cases are consolidated for discovery
- Tailoring discovery requests to issues relevant to the patent claims.
- Using interrogatories, requests for admission, and other written discovery early to limit the scope of document discovery
- Considering the use of alternatives to depositions for document authentication

12:00 Networking Luncheon

1:15 Obviousness of the Unexpected: Understanding How a Compound Patent Defeat in *Baraclude* May Raise New Questions for Prior Art

Karen E. Brown, Ph.D., J.D.
Vice President &
Chief Intellectual Property Counsel
Ironwood Pharmaceuticals (Cambridge, MA)

James F. Hurst
Partner
Kirkland & Ellis LLP (Chicago, IL)

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

Steven H. Sklar
Member
Leydig, Voit & Mayer, Ltd. (Chicago, IL)

The *Baraclude* case, *i.e., Bristol-Myers Squibb Company v. Teva Pharmaceuticals USA, Inc.* sent shock waves through the pharmaceutical industry – the undefeatable compound patent had been finally defeated in the District of Delaware on grounds of obviousness. The Federal Circuit affirmed and the Supreme Court denied cert. Some industry observers have viewed *Baraclude* as the doomsday case for compound patents, while others still maintain it is simply a fact specific anomaly. Nevertheless, it is still a pivotal decision in the world of Paragraph IV litigation and on the subject of obviousness. This panel will explore the significance of *Baraclude* and provide insights on:

- Review of obviousness criteria post *KSR* and its unique application to *Baraclude*
- Review of BMS's denied cert. petition and its argument concerning a lower court's consideration of "post-filing evidence showing the actual differences between a patented invention and the prior art"
- Re-examining the District Court's findings and Federal Circuit's subsequent affirmation for structural obviousness rendering the *Baraclude* patent invalid in light of the question presented in the cert. petition
- Analyzing the criteria for lead compound analysis relative to *Baraclude*
- Understanding how *Baraclude* will impact both prosecution and litigation under Hatch-Waxman
  - preparation of patent application for lead compounds
  - trial strategies
  - expert testimony
- Predicting future obviousness rulings in light of the Supreme Court's cert. denial

2:15 PTO Proceedings Update: The Continuing Use of IPR, PGR and CBM Review in the Hatch-Waxman Arena

Richard Berman
Partner
Arent Fox LLP (Washington, DC)

Stephen B. Maebius
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Foley & Lardner LLP (Washington, DC)

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Moderator:

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

Petitions for Inter Partes Review (IPR) relative to pharmaceutical patents are being filed in increasing numbers and are becoming an ancillary although integral part of Hatch-Waxman litigation. Post Grant Review (PGR), and Covered Business Method Patent Review (CBM) petitions have also been filed in conjunction with Paragraph IV litigation. Other PTO proceedings such as re-issue applications and supplemental re-exam are also being incorporated into the Hatch-Waxman schematic. This panel will explore the use and utility of these proceedings. Points of Discussion will include:

IPR

- Assessing strategic benefits that can be derived from IPR proceedings as opposed to District Court litigation in a Hatch-Waxman scenario
- Understanding how brands are rethinking Paragraph IV litigation strategies in light of this new proceeding and its use by generics
  - *Amneal Pharmaceuticals LLC v. Supernus Pharmaceuticals Inc.*, case numbers IPR2013-00372, IPR2013-00368 and IPR2013-00371
- Analyzing the first IPR decisions in the Hatch-Waxman sphere – what can we glean about the PTAB's thought processes through these initial decisions?
- Survey of the types of Hatch-Waxman patents and success rates for IPR petitions brought so far
  - compound
  - composition
  - method of treatment
- Exploring how IPR may be used to bypass findings of non-obviousness in the federal courts
- Deciphering Federal Circuit's decisions regarding PTO obvious determinations
- Evaluating questions of IPR abuse and extortion claims, e.g., Celegene and Allergan petitions
- Examining uses of IPR for second, third and other subsequent ANDA fliers
  - forfeiture triggers
  - query: if an Orange Book-listed patent is found invalid in an IPR proceeding – does it need to be delisted?
- Taking a closer look at discovery in IPR proceedings
- Evaluating requests for joinder and or ex partes re-examination in an IPR proceeding in the Hatch-Waxman space
- Settlements, final dispositions and appeals

PGR

- *Accord Healthcare, Inc. v. Helsinn Healthcare S.A.*, et al., IPR2014-00010

CBM

- *Amneal Pharmaceuticals, LLC, Par Pharmaceutical, Inc., and Roxane Laboratories, Inc.* (REMS relative to Orange Book listed patent)

Ex–Partes Re–Exam

- Exploring the use of this proceeding in a Hatch-Waxman scenario

Reissue Applications

- Examining how and when a pharmaceutical patent holder can file a reissue application at the PTO after a finding of invalidity in the District Court or PTAB
  - prior art
  - section 112
- Patent portfolio audits is there an opportunity to use reissue to 'correct' patents that may be most vulnerable
- Understanding when reissue is estopped through the doctrine of res adjudicata/claim preclusion
  - *Senju v. Apotex* (Fed. Cir. 2014)

3:30 Afternoon Refreshment Break

3:45 A Hatch-Waxman Practitioner's Guide to The Patent Trial and Appeals Board: The PTAB Live

Honorable Jacquelin Wright Bonilla
Lead Administrative Patent Judge
Patent Trial and Appeal Board
United States Patent and Trademark Office
(Alexandria, VA)

Honorable Rama G. Elluru
Administrative Patent Judge
Patent Trial and Appeal Board
United States Patent and Trademark Office
(Alexandria, VA)

The Patent Trial and Appeal Board is one of the most watched administrative courts since the creation of the ITC. Given the popularity of proceedings such as IPR in the Hatch-Waxman arena, it is absolutely essential that Paragraph IV litigators have a strong working knowledge of this administrative forum.

Unlike Article III Courts, the Patent Trial and Appeal Board is an administrative body formed through a statute. While, the PTAB is more informal in some respects, it is more intense in others due to the speed by which matters are heard. The PTAB has its own rules of engagement and its own protocols – in addition to substantive and procedural standards that differ greatly from those of the District Courts. In this session, Judges from the PTAB will discuss protocols and the art of appearance before this administrative body.

4:45 A View From the Bench: The Judges Speak

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

Honorable Sidney I. Schenkier, U.S.M.J.
United States District Court
Northern District of Illinois (Chicago, IL)

Moderator:

Meredith Martin Addy
Partner
Katten Muchin Rosenman LLP (Chicago, IL)

Renowned jurists with some of the most active Paragraph IV litigation dockets in the country will share their thoughts and insights on some of the most complex challenges facing both patent holders and patent challengers. Come prepared with your most pressing questions.

6:00 Conference Adjourns to Day Two

7:00 Continental Breakfast

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

8:15 **Myriad and *Nautilus:* Exploring New Paragraph IV Invalidity Challenges Under 101 and 112**

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

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

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

- Examining 101 rejections by the PTO vis-à-vis the Supreme Court's decision in *Association For Molecular Pathology v. Myriad Genetics, Inc.* (Supreme Court Docket Number 12–398) (*Myriad*) and as per the agency's *Myriad* guidance
- Understanding how 101 prosecution rejections under this guidance may translate to 101 invalidity challenges of a small molecule drug in a Paragraph IV setting at the District Court level
- Review of the Supreme Court's new standard for definiteness in *Nautilus, Inc. v. Biosig Instruments, Inc.* (Supreme Court Docket Number 13-0369) under 112
- Evaluating possible impact of *Nautilus's* "reasonable certainty" claim construction interpretation in a Paragraph IV invalidity challenge
- Devising new due diligence strategies for pharmaceutical patent protection and patent challenges in light of this new jurisprudence

9:00 **Re-Evaluating Claim Construction and Markman Strategies in Wake of Teva v. Sandoz**

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

Linda Friedlieb
Senior Counsel, Intellectual Property Litigation
AbbVie (North Chicago, IL)

Paul S. Tully, Ph.D.
Partner
McDonnell Boehnen Hulbert & Berghoff LLP
(Chicago, IL)

On January 20, 2015, the Supreme Court issued its iconoclast decision in *Teva v, Sandoz*, which established a new standard of review for claim construction. In this case which arose from an obscure issue concerning molecular weight in a Paragraph IV scenario, the Court held that a deferential standard of review should be applied to findings of fact in a claim construction matter. The Court also held that the de novo standard still applied to all other components of claim construction that were of a non-factual nature.

In this session our panelists will discuss how this case has impacted claim construction and Markman strategies in Paragraph IV Disputes.

- Analysis of *Teva* and the Court's ruling with respect to de novo review vs. deferential review
- Reassessing claim drafting in view of the *Teva* decision
  - clarity of claims in view of written description and enablement requirements
- Predicting how the Court's decision will impact Markman strategies in Paragraph IV challenges
- Re-evaluating the use of witnesses in a Markman hearing in view of *Teva*

10:00 Morning Coffee Break

10:15 **Evaluating the Merits of Bringing A Declaratory Judgment Action in a Paragraph IV Case: Duplication or Necessity?**

Rekha Hanu, Ph. D
Director, Intellectual Property
Akorn Pharmaceuticals (Lake Forest, IL)

Gary E. Hood
Shareholder, Vice-Chair IP & Technology Litigation Group
Polsinelli PC (Chicago, IL)

Richard T. McCaulley
Partner, Chair IP Litigation Group
Ropes & Gray LLP (Chicago, IL)

The Federal Circuit in *Apotex Inc. v. Daiichi Sankyo Inc.*, Nos. 14-1282 and 14-1291 (Fed. Cir. March 31, 2015) has finally provided some guidance for matters in which allegations of infringement are being brought under the auspices of both the Hatch-Waxman Act and the Declaratory Judgment Act in a Paragraph IV action. The District Courts have long been divided as to when they could exercise jurisdiction under both statutes. This panel will explore brand name and generic strategies and tactics relative to simultaneous filings in view of the Apotex case as well as prior existing jurisprudence in this area. Points of discussion will include:

- Assessing subject matter jurisdiction vulnerability in a pharmaceutical patent infringement action brought under both § 271(e)(2) and § 271(a)-(c) in a Paragraph IV matter
- Identifying circumstances warranting declaratory judgment claims in addition the Hatch-Waxman infringement claims
- Survey of rulings on this matter in different jurisdictions
  - *Takeda Pharmaceutical Co. Ltd. et al. v. Mylan Inc. et al.*, Case No. 5:13-cv-04002 (N.D.CA), the court found that exercising jurisdiction over both declaratory judgment and Hatch-Waxman claims would be duplicative.
- Exploring viability of simultaneous declaratory judgment actions and Hatch-Waxman infringement actions for unlisted and delisted patents

11:00 FTC Keynote: Reverse Payment Settlements and Other Antitrust Concerns Impacting Paragraph IV Litigation in the Wake of *Actavis*

Daniel W. Butrymowicz
Staff Attorney
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 once 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.

11:45 Developing Practical Strategies for Settling A Paragraph IV Case Post-Actavis: A Litigator's Perspective

Jeffrey R. Gargano
Partner
McDermott Will & Emery LLP (Chicago, IL)

Adam L. Perlman
Partner
Williams & Connolly LLP (Washington, DC)

Moderator:

Pearl T. L. Siew
Vice President & Head, IP US
Sandoz Inc. (Princeton, NJ)

- Understanding the application of antitrust law's "Rule of Reason" to pharmaceutical patent settlements
- Examining decisions concerning pharmaceutical patent settlements in the District Courts since *Actavis*
  - *In re Nexium (Esomerprazole) Antitrust Litigation (D. Mass. 2014)*
    - large and unjustified payment – but agreement found to not be anticompetitive
  - *In re Lipitor Antitrust Litigation* (D.N.J. 2014)
  - *In re Effexor XR Antitrust Litigation* (D.N.J. 2014)
    - "reliable cash value of the non-monetary payment"
- Analyzing allegations in pending notable litigation in this area
  - *Federal Trade Commission v. AbbVie et al, 2:14-cv-05151 (E.D. PA 2014)*
    - sham litigation
- Drafting and structuring an agreement in accord with new jurisprudence and pending actions in this area and that will also pass FTC review
- Identifying and avoiding red flags that could trigger FTC scrutiny
- Incorporating elements that emphasize the procompetitive nature of the agreement
- Assessing the role of commitments as to authorized generics and licensing in view of the FTC's views on these topic
- Understanding concepts such as valuation, pricing, government contracting and managed markets, royalties and lost profits as they apply to these agreements
- Developing timelines for business and legal milestones relative to the terms of the settlement
- Devising strategies to employ pending completion of the FTC's review

12:45 Networking Luncheon

2:00 FDA Update: Survey of Agency Activity Impacting Paragraph IV Litigation

David B. Abramowitz
Partner
Locke Lord LLP (Chicago, IL)

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

James C. Shehan
Of Counsel
Hyman, Phelps & McNamara, P.C.
(Washington, DC)

New Developments Impacting Brand Name and Generic Exclusivities

- Assessing the impact of pending MMA guidance impacting forfeiture and other MMA-amendments to Hatch-Waxman Act
- Exploring exclusivity losses in *Hospira, Inc. v. Sylvia Mathews Burwell*, et al (District of Md. 2014)

Related Legislation

- The 21st Century Cures Act Update –implications of the removal of the exclusivity provisions provision
- H.R.1353 - PATIENT Act of 2015

Brands

- Examining new NCE criteria by FDA
- Analyzing FDA NCE exclusivity guidance for certain fixed combination drugs
- Revisiting the concept of additional exclusivity for antibiotic development

Generics

- Reviewing recent FDA decisions revoking 180-day exclusivity
  - Ranbaxy
  - cGMP violations

Other Significant Regulatory Developments Affecting Hatch–Waxman

- Exploring the impact of new RTR guidance by FDA and its impact on first generic filers
  - new data stability requirements
- Determining 'first generic' status under GDUFA
  - priority treatment
- Deciphering Revised ANDA Bioequivalence Guidance and its effect on TE ratings
  - Mallinckrodt downgrade for generic version of Concerta and subsequent lawsuit against FDA

- Review of FDA's REMs guidance relative to ANDA litigation
- Examining FDA's guidance on premature notice filing

2:45 Afternoon Refreshment Break

3:00 Assessing the True Measure of Damages in At- Risk Launch Scenario

Aaron A. Barlow
Partner
Jenner & Block (Chicago, IL)

Michal A. Malkiewicz
Director
Epsilon Economics (Chicago, IL)

Keith D. Parr
Partner
Locke Lord LLP (Chicago, IL)

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

- Survey of recent at-risk launches, status and outcomes
- 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 determination in Hatch-Waxman matters
  - examining inconsistencies in these determination given discord between District Courts, Federal Circuit and Supreme Court in these matters
- Asserting damages in an at-risk scenario
  - *Ferring v. Actavis* (D.NV. 2014)
- Exploring recent damages award in an at-risk launch scenario, post- Protonix
- Determining the quantification of damages in an at risk-launch
- Lost profits
  - assessment of profit as a true measure of damages
    - questions of profitability and sales
  - when is it the only thing that you can seek?
  - circumstances under which lost profits can be denied
  - *analysis of lost profits determination in Sanofi-Aventis v. Glenmark,* No. 2012-1489 (Fed. Cir. Apr. 21, 2014)
  - exploring novel lost profit determinations
    - does launch of an authorized generic defeat request for lost profits?
    - if holder of patent to whom damages is awarded is an off-shore entity – should lost profits assessment be based on transfer pricing?
- Reasonable royalties:
  - establishing the basis for royalty
  - looking at market share
  - the point where infringement began
- Mitigating factors impacting damage award

4:15 The Ethics of Paragraph IV Practice: New Developments Impacting Professional Responsibility in the Hatch-Waxman Arena

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

Steven Nash
Senior Patent Counsel
Xellia Pharmaceuticals, Inc. (Grayslake, IL)

- Review of recent inequitable conduct cases impacting Hatch-Waxman litigation post- *Therasense*
  - *Apotex Inc. v. UCB, Inc.* (Fed. Cir. 2014)
  - *American Calcar v. American Honda* (Fed. Cir. 2014)
    - "but-for materiality" and withholding of information
- Willfulness and recklessness considerations in relation to ANDA filings
- Understanding the ethics implications for *Octane Fitness v. Icon Health & Fitness* (Supreme Court Docket Number 12-1184)
  - how the Court's lowering of the standard from clear and convincing to preponderance theory for exceptional case may impact ethics considerations in a Paragraph IV setting
  - *Classen Immunotherapies Inc. v. Biogen Idec* (D. Md. May 14, 2014)

5:15 Conference Ends

WHO YOU WILL MEET

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

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

Workshop A

8:30 am – 12:00 pm (Registration opens at 8:00 am. Continental Breakfast will be served.)

PTO Practice Master Class: Anatomy of a PTO PTAB Patent Trial in the Hatch-Waxman Arena

Honorable Teresa Stanek 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)

Post- Grant Proceedings, IPRs, in particular, and to lesser but still relevant extent, PGRs and CBMs have become and an ancillary if not integral part of Hatch-Waxman litigation. These petitions may be filed in advance of traditional Paragraph IV litigation or in some instances stay or run parallel to such proceedings. In this interactive workshop, Ms. Rea will guide you – step by step – through the anatomy of a PTAB trial involving a patent for a small molecule drug from inception through final disposition and every step in between. Through a mock fact pattern, she will go through expedited scheduling, petition and response, oral argument, adjudication and appeal. Mock documents will be provided.

Points of discussion will include:

- Strategies for operating in an expedited time line
- Best practices for petition and petition response drafting
- Amending petition/response
- Amending claims during petition process
- Discovery parameters
- Preparing for argument
- Criteria and assessment for requesting a stay
- Strategies for parallel District Court and PTAB proceedings
- PTAB adjudication, settlements and appeal options

Workshop B

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

Biosimilars Boot Camp for the Paragraph IV

Krista Hessler Carver
Partner
Covington & Burling LLP (Washington, DC)

Louis E. Fogel, Ph.D., J.D.
Partner
Jenner & Block LLP (Chicago, IL)

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. 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 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 Attending Both Workshops A and B.

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