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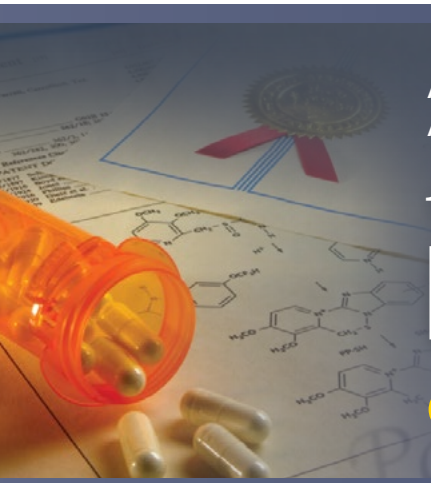

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In 2016, pharmaceutical patent losses equated $127 Billion.*

Master your defensive moves and offensive plays for the Hatch-Waxman endgame. Meet and network with the key influencers shaping the law, policy and proceedings of Paragraph IV litigation.

Dear Colleagues:

It is an evolving and transformative time in the world of Paragraph IV Disputes. With 2016 witnessing patent losses in excess of $125 billion, the stakes for brand name and generic pharmaceutical companies have never been higher.

As we enter this new decade together, ACI's 11th annual **Paragraph IV Disputes Conference** will continue to bring you up-to-the minute information on the latest developments impacting every facet of this complex type of litigation from pre-suit considerations, case filings, final adjudication and every step in between.

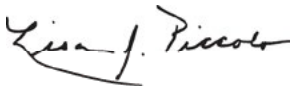
This year, we are excited to bring you a conference program that will feature:

- A faculty of 90+: the "who's who" of Hatch-Waxman litigators, industry decision makers and stakeholders, including:
  - Esteemed Judges — from the District Court and PTAB
  - Key representatives from the FDA, PTO and FTC
  - In-house counsel from 15 top pharmaceutical companies
  - Leading attorneys from A-list law firms for both brand name and generic companies
- An Advisory Board comprised of present and former high-level in-house counsel who helped shape the conference program topics and discussion
- More than 300 attendees to network with and learn best practices from
- Over 30 sponsors and exhibitors who will be available to meet with you face-to-face to showcase their capabilities and solutions
- Networking opportunities throughout the conference
- Post-conference workshops designed to provide in-depth information on IPRs, parallel proceedings and biosimilars

Do not miss this opportunity to be a part of the leading conference that continues to provide top level guidance for this type of complex litigation.

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

Very truly yours,



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

** https://www.drugs.com/article/patent-expirations.html*

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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MONDAY, APRIL 24, 2017
Main Conference, Day One

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

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

Guy Donatiello
Senior Vice President
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Endo Pharmaceuticals (Malvern, PA)

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

8:15 **The Politics and Policy of Pharmaceutical Patents in the New Administration: Town Hall**

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

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

Shashank Upadhye
Partner
Amin Talati & Upadhye
(Chicago, IL)

Mark E. Waddell
Partner
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Moderator:
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)

Pharmaceutical patents, especially small molecule, Orange-Book listed patents are unique entities. Under the Hatch-Waxman-Act and its subsequent amendments, these patents fall under the jurisdiction of three government agencies, the USPTO, the FDA and the FTC. At time of press, it is expected that the leadership as well as the objectives of each of these agencies will change during the Trump presidency. This begs the question of how these changes may affect these patents and Hatch-Waxman strategies. There are also questions as to how the status of pending legislation in the New Congress, the appointment of Judges in various courts including the Supreme Court may all impact these patents as well. This panel, in town hall fashion, will take questions as it explores such matters as:

- How new PTO leadership may impact pharmaceutical patents
- Exploring the future of Patent Reform II and possible statutory IPR carve-out for Hatch-Waxman patents
- Understanding what changes at FDA and its parent agency HHS may mean for Orange Book patents
  - › calls for drug pricing reform and consequences for drug patents
- Predicting how changes at FTC may impact the future of "pay for delay" enforcement and investigations

9:00 **USPTO Keynote: Patent Rights and Generic Entry - An International Perspective**

Mary Critharis
Senior Patent Counsel
Office of Policy and International Affairs
U.S. Patent & Trademark Office
(Alexandria, VA)

- Review of leading international standards regarding the relationship between patent rights and generic entry
- Overview of the TRIPS Agreement
- US Free Trade Agreements: from Australia to Central America to the Andean Region to Korea
- Discussion of Hatch-Waxman provisions of the TPP—lessons learned
- Future agreements

9:45 *Morning Coffee Break Hosted by* HONIGMAN

10:00 **The Dollars, Cents and Due Diligence of Pharmaceutical Patent Life Cycle Management and Litigation Planning**

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

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Moderator:

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

- Appreciating new IP and economic due diligence strategies for brand name and generic manufacturers in view of current legal considerations and market trends
- Understanding how the current stage of the patent cliff, the alternative litigation route at the PTAB and new federal court jurisprudence have reshaped Hatch-Waxman strategies
- Examining how brand names and generics are utilizing this new legal and economic paradigm in determining which patents are ripe for challenge in the PTAB and District Courts
- Comparing patent strength assessments in clinical testing phases I and II to predicted ROI in phases III and IV to determine drug value and probability of suit
- Understanding why less lucrative branded drugs are becoming more attractive targets
- Assessing probable win or loss at District Court and PTAB on patent type and recent decisions
- Exploring cost saving options for ANDA District Court litigation and PTAB filing
- Examining alternative billing, contingencies
- Evaluating use of outside funding
- Knowing when to aim, fire, fight, fold or license
- Understanding when settlement is your best option sometimes even before suit is commenced

Focus on the Final MMA Rule

11:00 Q&A with the FDA on the Final MMA Rule: Understanding the Impact for Hatch-Waxman Practice

Maryll W. Toufanian, J.D.
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On December 5, 2016, new regulations to implement portions of the 2003 Medicare Modernization Act went into effect. According to FDA, the new regulations are intended to "reduce unnecessary litigation, reduce delays in approval of 505(b)(2) applications and ANDAs that are otherwise ready to be approved, and provide business certainty to both brand name and generic manufacturers." The highly technical and far-reaching regulations significantly affect how NDA and ANDA applicants will interact with one another and with FDA both during and after approval of a marketing application.

Among other things, the new regulations deal with the submission of patent information by NDA holders and patent certifications from ANDA applicants, patent use codes, 30-month patent litigation stays, application amendments and supplements, and, to some extent, 180-day exclusivity. This session, formatted in a Q&A fashion, will provide analysis of the new regulations as well as strategies for incorporation into daily practice.

12:00 Revisiting Use Codes and Carve-Out Cases in Light of the Final MMA Rule

Vincent L. Capuano, Ph.D.
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Moderator:

William L. Mentlik
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Use code manipulation, carve-outs and skinny labeling have been a proverbial tempest in the Orange Book teapot. The Supreme Court blessed the carve-out concept in 2012 with *Caraco*, but the utilization of carve-outs has still led to many a dog-fight. The final MMA Rule seeks to put an end to this. However, questions remain as to how use code dilemmas will be handled in the aftermath of the Rule.

- Review of recent Paragraph IV carve-out and skinny labeling challenges
- Examining FDA determinations relative to use code listings
- Understanding the uniqueness and significance of the Depomed NUCYNTA ER (tapentadol) citizen's petition
- FDA's authority to unilaterally change use code
- Exploring how final Rule may remedy the current use code landscape

12:45 *Networking Luncheon Sponsored by* Knobbe Martens

1:45 The Ongoing Jurisdiction Debate: From *Mylan* to *TC Heartland*

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Steven M. Coyle
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- Analyzing the Federal Circuit's finding of jurisdiction in in *Acorda -Therapeutics Inc. v. Mylan Pharms. Inc. and AstraZeneca AB v. Mylan Pharms. Inc.,*
- Reviewing the District of Delaware's decisions in these matters
- Comprehending how Judges' Sleet and Stark each found jurisdiction and how this compared to the Federal Circuit's findings
- Examining the significance of the Federal Circuit's dissent
- Understanding the significance of the Supreme Court's denial of cert. in *Mylan* in view of the Court's grant of cert. in *TC Heartland LLC v. Kraft Food Brands Group LLC*
- Exploring possibility of amendment to Hatch-Waxman to remedy jurisdictional uncertainty

2:30 On Sale Bar – Round II: Understanding The Impact of *Helsinn* on Pharmaceutical Patents in a Post-AIA Setting

Steven A Nash
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Richard T. Ruzich
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At the time of our last meeting, we explored the question of patent invalidity through an on sale bar in a pre-AIA setting in the *Medicines Company's* Angiomax case. Now, we revisit the same question, but this time on a patent issued post-AIA.

- Analyzing the on- sale bar provision of the Patent Act as amended by the AIA
  - › comparison to pre-AIA statute
- Examining the facts of *Helsinn Healthcare S.A. et al. v. Teva Pharmaceuticals USA, Inc. et al.* (Nos. 2016-1284, -1787) and understanding how the language of the amended statute led to the District Court's (DNJ) finding that a so-called non-public, secret sale did not trigger the on-sale bar provision to invalidate the patent
- Anticipating the Federal Circuit's decision in *Helsinn*
  - › assessing repercussions which would ensue should the Federal Circuit reverse the lower court's finding
  - › what can we glean from the Federal Circuit's ruling in *The Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. July 11, 2016)?
- Exploring the consequences of either scenario in future Hatch-Waxman settings

3:00 *Networking Refreshment Break Hosted by* HONIGMAN

3:15 Understanding the Continuing Impact of 101 on Orange Book Listed-Method Claims

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

Paul B. Sudentas
Attorney
Locke Lord LLP (New York, NY)

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

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

Jason A. Wietjes
Shareholder
Polsinelli PC (Dallas, TX)

Moderator:
Martin B. Pavane
Vice Chair
Intellectual Property Department
Co-Chair, ANDA and Biologics
Cozen O'Connor (New York, NY)

- Understanding the implications of the Federal Circuit's decision in *Rapid Litigation Management Ltd., et al. v. CellzDirect, Inc., et al., No. 2015-1570* (Fed. Cir. Jul. 5, 2016) on subject matter eligibility of method claims in the life sciences sector
- Determining subject matter patentability of method patents based on this latest case and prior 101 jurisprudence post-*Myriad*
- Exploring the Federal Circuit's adherence or non-adherence in 101 matters under PTO's *Alice* Rules
  - › *MacroPoint LLC v. FourKites Inc.*, case number 16-1286, Federal Circuit 2016.
- Comparing the Federal Circuit's findings in *CellzDirect* to two Delaware Court decisions in the last year involving 101 challenges to Orange Book listed method claims, *i.e., Endo v. Actavis (2015) vs. Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc.*, C.A. Nos. 13-1973, 14-757-GMS (D. Del. Aug. 25, 2016)
- Understanding how Judges Andrews and Sleet arrived at different 101 decisions with respect to the patents in question
- What can we glean from this jurisprudence with respect to drafting subject matter eligible method claims and bringing 101 motions?

4:00 Obviousness Update for PIV Litigation: Latest Developments in the Federal Courts and PTAB

Richard J. Berman
Partner
Arent Fox LLP (Washington, DC)

Mark T. Deming
Patent Attorney
Polsinelli PC (Chicago, IL)

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

Josephine Liu, Ph.D., J.D.
Head, US IP Litigation
Sandoz Inc. (Princeton, NJ)

Lisa B. Pensabene
Partner
O'Melveny & Myers LLP (New York, NY)

Moderator:


Brandon M. White
Partner
Perkins Coie LLP (Washington, DC)

Prior Art

- Understanding how the Federal Circuit's obviousness ruling in *Apple Inc. v. Samsung Electronics Co. Ltd.*, No. 2015-1171, __ F.3d __, 2016 WL 5864573 (Fed. Cir. Oct. 7, 2016) may impact obviousness findings in life sciences patents
- Review of recent obvious decisions involving Paragraph IV litigation at the District Court, PTAB and Federal Circuit
  - › comparison of statistics for obvious invalidity findings at these courts
  - › impact of *Cuozzo*
- Exploring unique obviousness issues in Purdue Oxycodone cases, *i.e., Grunenthal GmbH et al v Teva Pharmaceuticals USA Inc,* U.S. Court of Appeals, Federal Circuit, No. 2014-1311. currently on petition for *cert.* at the Supreme Court
  - › inherency by anticipation
  - › method of solving problem
- Re-visiting secondary considerations

Double Patenting- Type Obviousness

- *Bayer Pharma AG v. Watson Labs., Inc.*, Case No. 12-1726-LPS, 2016 U.S. Dist. LEXIS 96267 (D. Del. July 18, 2016)

4:45 A View from the Bench: The Federal Judges Speak on Paragraph IV Litigation

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

Honorable Jose L. Linares, U.S.D.J.
United States District Court
District of New Jersey (Newark, NJ)

Honorable Robert W. Schroeder III, U.S.D. J. (invited)
United States District Court, Eastern District of Texas (Texarkana, TX)

Moderators:
Barry P. Golob
Co-Chair
Intellectual Property Litigation
Cozen O'Connor (Washington, DC)

Irena Royzman ,Ph.D.
Co-Chair
Biotechnology Practice
Patterson Belknap Webb & Tyler LLP
(New York, NY)

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

6:00 *Conference Adjourns to Day Two*

6:00 Cocktail Reception Sponsored by

LOEB & LOEB LLP

Join the Conversation @ACI_Pharma #ACIPIV ACI's Hatch-Waxman Series

TUESDAY, APRIL 25, 2017
Main Conference, Day Two

7:00 *Continental Breakfast*
Hosted by Taft/

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

8:15 **Illusory Safe Harbors: Exploring Uncertainties in the Boundaries of 271 (e) (1) and the Scope of Divided and Induced Infringement**


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


Jared C. Bunker
Partner
Knobbe, Martens, Olson & Bear, LLP
(Irvine, CA)


Gregory F. Corbett
Shareholder
Wolf, Greenfield & Sacks, P.C.
(Boston, MA)


Uma N. Everett
Director
Sterne, Kessler, Goldstein & Fox P.L.L.C.
(Washington, DC)


Averie K. Hason
Assistant General Patent Counsel, IP Litigation NY/NJ
Eli Lilly and Company (Bridgewater, NJ)

Moderator:


Tracey B. Davies
Partner
Gibson, Dunn & Crutcher LLP
(Dallas, TX)

- Understanding which post-approval activities fall within the scope of the safe harbor per *Amphastar Pharmaceuticals, Inc. v. Momenta Pharmaceuticals, Inc*
- Revisiting the pre-approval v. post approval debate under 271(e)(1)
- Examining the state of the law on divided infringement and its implications for Hatch-Waxman
  - *Akamai* standard
  - *Eli Lilly and Company v. Teva Parenteral Medicines,* No. 10-1376, S.D. Ind, Fed. Cir. Appeal No. 15-2076
- Examining the nexus between these two categories of infringement
- Exploring scenarios in which infringement can be alleged through safe harbor violation and inducement
  - *e.g.*, method of manufacture patent with foreign manufacturers, finishers and US distributors

9:00 **The PTAB Live: Thoughts on Practice, Procedure, IPRs and More in the World of Pharmaceutical Patent Validity Challenges**


Honorable Lora M. Green
Lead Administrative Patent Judge
Patent Trial and Appeal Board, USPTO
(Alexandria, VA)


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


Honorable Rama G. Elluru
Administrative Patent Judge
Patent Trial and Appeal Board, USPTO
(Alexandria, VA)

Moderators:


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


Filko Prugo
Partner
O'Melveny & Myers LLP (New York, NY)

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.

10:00 *Morning Coffee Break*
Hosted by HONIGMAN

Alternate Forums for Pharmaceutical Patent Challenges

10:15 **PTAB Pharmaceutical Patent Invalidity Round-Up: Update on Wins, Losses and Appeals**


Joshua P. Davis
Partner
Reed Smith LLP (Huston, TX)


Laura A. Lydigsen
Shareholder
Brinks Gilson & Lione (Chicago, IL)


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


Pearl T.L. Siew
Senior Vice President and Head Intellectual Property
Eagle Pharmaceuticals, Inc.
(Woodcliff Lake, NJ)


Moderator:
Stephen C. Stout, Ph.D.
Partner
Vinson & Elkins LLP (Austin, TX)

- Survey of notable wins and losses at the PTAB
  - IPR vs. PGR vs. CBM
  - *Altaire Pharmaceuticals, Inc. v. Paragon BioTeck Inc.,*
- Examining statistics for types of challenges bought and types of patents challenged
- Developing parallel proceedings protocols
- Analyzing Federal Circuit decisions relative to pharmaceutical patent challenges brought at the PTAB
  - understanding the impact of *Cuozzo* affirming broadest reasonable interpretation
- Exploring impact of PTAB rules package and status of pending cases impacting new rules
  - *In re Aqua*; motion to amend
- Update on activity of reverse patent trolls
- Status of pending patent reform legislation

11:00 **Examining the ITC as an Alternate Forum in an ANDA Challenge**

Brian Anderson
V.P. & Assist. General Counsel – IP Litigation
Allergan (Parsippany, NJ)


Wanda French-Brown
Counsel
Baker & Hostetler LLP (New York, NY)


Sheila N. Swaroop
Partner
Knobbe, Martens, Olson & Bear, LLP
(Irvine, CA)

- Analyzing the pro and cons of using the ITC in a Hatch-Waxman related pharmaceutical patent challenge
- Examples of such proceedings and other life-sciences related proceedings where the ITC has been utilized
- Determining if ITC 337 petitions are a viable means of protecting the patent life of pharmaceutical products in a Hatch-Waxman scenario

11:30 **A Magistrate Judge's Insights on ANDA Practice**


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


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


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

Moderators


James M. (Jim) Lennon
Partner
Young Conaway Stargatt & Taylor, LLP
(Wilmington, DE)


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

Magistrate Judges have a unique role in ANDA cases. They hear key motions and resolve the disputes which the parties encounter throughout the course of litigation.

Magistrate Judges also work closely with District Judges on these matters. This panel of esteemed Magistrate Judges will offer their insights on these matters and the art of Paragraph IV practice.

12:30 Networking Luncheon

Focus on Antitrust

1:30 FTC Keynote: Update on Reverse Payment Settlements and Other Antitrust Developments Concerning Brand Name and Generic Interests

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

It now been almost four years since the Supreme Court issued its seminal decision in *Federal Trade Commission v. Actavis.* which made it clear that pharmaceutical patent settlement agreements can violate the antitrust laws. Since the *Actavis* decision, there have been more than twenty government and private plaintiffs' actions working their way through the courts, including the Federal Courts of Appeal and the California State Supreme Court.

This session will reflect on the lessons from the last four years. What are the key issues in analyzing settlement agreements post-*Actavis*? Which, if any, of these issues has been resolved? What issues remain in dispute? What are the arguments on each side of the issues? In sum, what's the current state of play on "pay for delay"?

We will hear the perspectives of the FTC staff on these questions and more.

2:15 Reverse Payment Settlements: The Industry Response

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

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

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

In this interactive session, leading antitrust attorneys for brand name and generic drug manufacturers will respond to the FTC and explore industry challenges in light of recent court decisions and the Commission's stance with respect to designing settlement agreements which will withstand FTC scrutiny, benefit the parties and receive a judicial blessing.

3:00 Networking Coffee Break

3:15 The REMS Conundrum: Exploring Challenges for Both Brands and Generics

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

Katharine R. Rice
Corporate Counsel
Gilead Sciences (Foster City, CA)

Tedd W. Van Buskirk
Partner
Lerner David Littenberg Krumholz & Mentlik, LLP (Westfield, NJ)

- Overview of the REMS process and analysis of obstacles it poses to both brand name and generic manufacturers in a Hatch-Waxman scenario
- Examining scenarios in which patent infringement can be alleged not only on the drug which is the subject of a REMS but on the REMS process itself
- Exploring scenarios of FDA intervention in brand and generic discord in REMS design
- Understanding antitrust implications
- Status of pending legislative fix

4:00 Case Studies in New Ethical Developments Impacting Paragraph IV Practice

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

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

James Kellerman
Vice President
Intellectual Property
Astellas (Northbrook, IL)

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

Moderator:

Benjamin C. Hsing
Partner
Baker & Hostetler LLP
(New York, NY)

- Exploring the status and significance of the USPTO's proposed Rule to adopt the duty of disclosure under *Therasense* as an amendment to Rule 56
  - › understanding the impact of this proposed Rule on Paragraph IV practice
- Examining the new willfulness standard under *Halo* and understanding its application in a Hatch-Waxman scenario

5:00 Conference Ends

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

POST CONFERENCE WORKSHOP A

IPR Strategies and Parallel Proceedings Master Class: Devising Strategies for IPR Best Practices and Navigating Dual Forums in Hatch –Waxman Litigation

Vishal C. Gupta
Partner
Steptoe & Johnson LLP (New York, NY)

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

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

Alyson L. Wooten PharmD
Attorney
Kilpatrick Townsend & Stockton LLP (Atlanta, GA)

Parallel litigation in the District Court and PTAB in a Hatch-Waxman setting is becoming more and more commonplace and adds to the "no-holds barred" 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 navigating these dual forums, even the most seasoned of District Court litigators is only now learning the art of appearing before the PTAB. They are developing best practices and also becoming aware of certain things to avoid in these procedures. In this very interactive session, we will illustrate the "ins and outs" of IPR practice and appearing in dual proceedings in both the District Court and PTAB.

- Devising strategies relative to the filing of an IPR or similar proceeding during the pendency of District Court litigation
- Formulating strategies based on type of pharmaceutical patent
- Establishing jurisdiction at the PTAB
  - special considerations for ex-U.S. parties
- Ensuring all RPIs are properly named
- Assessing split petition strategies
- Understanding when requests for joinder can be made and when they should be made
- Analyzing secondary considerations
- Developing sound discovery strategies relative to dual proceedings
- Evaluating chances of getting a stay granted in the District Court
  - stay pros and cons
- Understanding claim construction dichotomy in both forums and devising tactics to address both simultaneously
- Managing experts and use of experts in both forums
- Best practices for simultaneous trials
- Appealing decisions in both forums
- Addressing settlement in both forums
  - 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)

POST- CONFERENCE -WORKSHOP B

Biosimilars 2.0 for the Paragraph IV Litigator

Corey M. Casey
Shareholder
Polsinelli PC
(Kansas City, MO)

Erin Ator Thomson
Counsel
Vinson & Elkins LLP
(Austin, TX)

Despite the fact that BPCIA litigation has been filed and that a few decisions have been rendered notably in one case, *Amgen v. Sandoz,* we are still only at the beginning of beginning.

In this hands-on session, we 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*
- 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.*

THANK YOU TO OUR SUPPORTING SPONSORS

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**

Part of a full-service Life Sciences Group, **BakerHostetler's Biotechnology and Pharmaceutical IP** Litigation team are patent litigators and trial lawyers who have real-world experience in both the pharmaceutical and biotech industries. Focused on the enforcement of patent rights in the life sciences industry, BakerHostetler represents innovators of pharmaceuticals, biologics, vaccines, biotechnology, medical devices, and diagnostics, as well as innovative pharmaceutical clients, in connection with Hatch-Waxman litigation. BakerHostetler's attorneys have represented pharmaceutical companies in Hatch-Waxman litigation involving oncology, anti-viral, antidepressant, inhalation, antihistamine, and cholesterol lowering drug products.

More than 50 BakerHostetler intellectual property attorneys hold advanced degrees across a spectrum of scientific disciplines including organic chemistry, chemical engineering, biophysics and molecular biology, pharmacology, veterinary medicine, and pharmacy. We are able to offer our clients insight into highly technical legal issues. BakerHostetler has many long-standing life sciences clients, and those relationships have given us an understanding of what life science-focused businesses and their leaders need as well as a practical view of the issues and the industry.

Brinks is among the most elite law firms representing generic pharmaceutical companies in Hatch-Waxman patent litigation. Brinks' pharmaceutical litigators have handled ANDA and 505(b)(2) cases involving drugs from A (atomoxetine) to Z (zolpidem) and virtually every type of drug patent, including patents directed to compounds, formulations, polymorphs, and methods of treatment. We leverage our legal experience and strong technical backgrounds to provide useful advice and obtain excellent results for the problems faced in the contemporary pharmaceutical marketplace. We have defeated patents covering blockbuster drugs and we have defended those victories in successful appeals to the Federal Circuit.

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.

Kilpatrick Townsend is a leading international law firm with over 650 attorneys across 18 offices. Our attorneys are fully engaged in the success of the firm's clients. We deliver results-oriented counsel for corporations at all stages of the growth cycle, from the challenging demands of financial transactions and securities to the disciplines of intellectual property (IP) management. A close collaboration between the firm's practice areas ensures that we are well-positioned to serve all of our clients' needs. At Kilpatrick Townsend, we have more than 300 attorneys devoted to the practice of IP law. Our experience in IP has earned us an international reputation for excellence.

Our diverse practice assists clients all over the globe with:

- Patent prosecution, counseling and licensingIP due diligence and transactions
- Patent litigation and proceedings before the PTAB
- Trademark registration, counseling and licensing
- Trademark and trade dress litigation
- Copyright transactions, counseling and litigation

Unique qualifications of our IP practice include:

More than 200 Kilpatrick Townsend attorneys and patent agents are registered to practice before the USPTO.

We have approximately 90 lawyers specializing in distinct areas of trademark and copyright law.

Our lawyers hold scientific and engineering degrees in virtually every technical discipline, ranging from electronics to the life sciences.

More than 50 of our patent attorneys hold PhDs in their fields, and more than 80 of our attorneys and technical and scientific staff have master's degrees.

Our patent group includes former engineers, scientists, patent examiners and federal law clerks.

Consistently ranked among the top intellectual property firms in the nation and worldwide, **Knobbe, Martens, Olson & Bear, LLP** has over 300 lawyers and scientists nationwide and dedicates its practice to all aspects of intellectual property law, including litigation. Knobbe Martens serves a diverse group of clients from multinational corporations to emerging businesses of all stages. The firm is headquartered in Orange County, California, with offices in San Diego, Silicon Valley, Los Angeles, San Francisco, Seattle and Washington, D.C., and enjoys an international reputation for excellence. The firm has been servicing clients in the generic pharmaceutical industry for nearly 20 years. The firm has litigated 150 cases under the Hatch-Waxman Act and has the experience and technical resources necessary to service all facets of the generic drug process. More information about the firm can be found at **www.knobbe.com.**

"When we need someone to really dig in and fight a good fight, we typically turn to **Lerner David**." This comment, by the counsel for a Fortune 100 client, reflects our firm's attention to substance and detail, and our aim to achieve, in as efficient a manner as possible, the business goals of our clients that gave rise to any litigation in which they may find themselves. When the stakes are high – as they always are in ANDA litigation – you can count on Lerner David to understand your business, legal, and regulatory goals.Lerner David thrives on what has become unique in the legal world: an IP specialty firm dealing with all aspects of intellectual property. Since 1969, our firm has devoted itself exclusively to IP. Whether we are assisting a client in procuring an IP asset, protecting an asset in litigation, or conducting due diligence in a technology deal, the sophistication we bring to the table is based on our nearly 50 years of counseling successful businesses on IP issues. Our philosophy of "clients for life" is not a slogan, but rather a demonstrable achievement of which we are most proud.Our Life Sciences Pharma team of patent attorneys includes skilled courtroom advocates and crafty IP strategists, and we bring to bear our backgrounds and advanced degrees in chemistry, organic chemistry, biochemistry, biology, biotechnology, chemical engineering, materials science, genetics, and bacteriology. We have been involved in the blockbuster cases of the past three decades representing some of the world's most recognized generic, brand, and specialty pharma companies. And in doing so, we always partner with our clients to develop a strategy to achieve favorable results in a cost-effective manner that aligns with their individual business goals.

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.

THANK YOU TO OUR SUPPORTING SPONSORS

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 BiologicsBlog.com, which tracks and analyzes developments in intellectual property law related to biotechnology and biologic medical products, and NYPatentDecisionsBlog.com, a source for the latest patent decisions from the U.S. District Courts for the Southern and Eastern Districts of New York.

Polsinelli's Hatch-Waxman team has extensive experience leading pharmaceutical patent cases. We represent some of the world's largest and most influential generic, brand, and specialty pharmaceutical companies. Our attorneys have litigated a broad variety of drug products, many in first-to-file cases as well as in subsequent filer cases, and we understand that each case and each client requires its own approach. We partner with our clients to develop a strategy to achieve favorable results in a cost-effective manner that aligns with our client's individual business goals. Our attorneys have first-chair experience litigating Hatch-Waxman cases in key venues, including Delaware, New Jersey, and the Eastern District of Texas. We are skilled courtroom advocates, and we employ a multidisciplinary team that includes trial attorneys, FDA and antitrust counsel, patent attorneys, and agents, to bring to bear not only our courtroom experience, but scientific backgrounds in chemistry, organic chemistry, biochemistry, biology, pharmacy, medicine, molecular biology, microbiology, neuroscience, pharmacology, genetics, immunology, and molecular biophysics, among others. Our knowledge of the pharmaceutical sciences includes 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 assist clients every step of the way — from preparing and filing an ANDA or 505(b)(2) application through trial, appeal, and/or settlement.

Reed Smith is a global relationship law firm with more than 1,700 lawyers in 26 offices throughout the United States, Europe, Asia and the Middle East. Founded in 1877, the firm represents leading international businesses, from Fortune 100 corporations to mid-market and emerging enterprises. Its lawyers provide litigation and other dispute-resolution services in multi-jurisdictional and high-stakes matters, deliver regulatory counsel, and execute the full range of strategic domestic and cross-border transactions. Reed Smith is a preeminent advisor to industries including life sciences, health care, financial services, advertising, entertainment and media, shipping and transport, energy and natural resources, real estate, manufacturing and technology, and education. Reed Smith's Intellectual Property Group comprises nearly 100 attorneys worldwide and handles a range of IP matters for clients, including those involving patents, copyrights, trademarks, unfair competition and trade secrets, transactions, and domain name disputes.

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