ACI American Conference Institute

ACI's Hatch-Waxman SERIES

Join us virtually as we celebrate our *15th anniversary*!

AmericanConference.com/PIVDisputes

15th Anniversary

PARAGRAPH IV DISPUTES

Expert Strategies for Brand Names and Generics

April 26–27, 2021 (ET) | Virtual Conference

EARN CLE/ETHICS/DIVERSITY CREDITS

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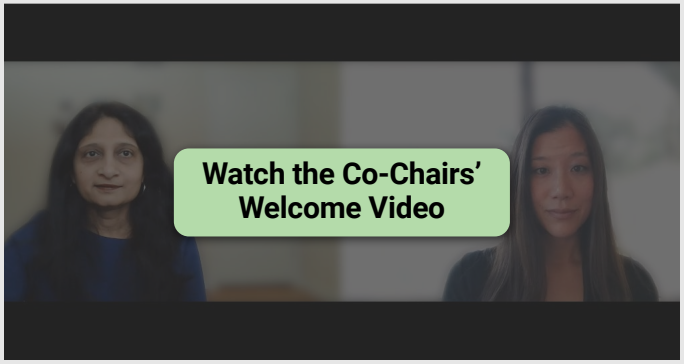
Enter ACI's Virtual Conference Room to Master Your Defensive Moves and Offensive Plays for the Hatch-Waxman Endgame.

2021 marks the 15th anniversary of **American Conference Institute's Flagship Paragraph IV Disputes conference**. From the time of its first launch through to its present iteration, we have witnessed the evolution of Hatch-Waxman pharmaceutical patent litigation. The rules which once seemed straightforward are changing, but some of the original questions remain in play — such as where to file suit and which forum to file in.

ACI's Paragraph IV Disputes events have created a community where even the most active brand and generic companies in the industry can gather, exchange ideas, and find fellowship. Even in times of tremendous uncertainty — and during the era of COVID-19, the Hatch-Waxman bar convened, as they have for 15 years, to confer with one another, assess new and changing jurisprudence, and analyze the related legal and economic effects.

This conference remains the constant. It is the only event which shapes the law, policy, and proceedings of Paragraph IV litigation.

In this 15th anniversary year, we will continue to bring you cutting-edge information on the latest developments impacting Paragraph IV disputes and offer insights into how these developments impact every facet of this complex type of litigation. We will examine the leadership objectives of the new administration, as well as the enforcement priorities of the three government agencies that regulate Orange-Book listed patents.



Rekha Hanu
Vice President, Associate General Counsel
Chief IP Counsel
Akorn, Inc.

Andrea Hutchison
Senior Associate General Counsel,
IP Litigation
Gilead Sciences

In sum, this year's Paragraph IV Disputes Conference will help you rewrite your Hatch-Waxman patent playbook for the next five years and provide you with a comprehensive and engaging overview of the inventive and strategic approaches that are critical to success.

Register today to benchmark, network, and connect with your peers *(and opponents)*, get caught up on the latest legal developments, and the shifting legislative and regulatory landscape through a virtual platform that makes through a virtual platform that makes distance irrelevant.

Register Now

ACI's Hatch-Waxman Series Advisory Board

American Conference Institute's Hatch-Waxman Series Advisory board was created as a part of ACI's ongoing effort to provide industry leading content and a world renowned speaker faculty. The board is composed of a selection of all-in-house advisers, including Chief IP and very senior IP/Patent counsel from the leading brand name and generic pharmaceutical companies in the country and in some cases the world. This 'inner circle' counsels ACI on the impact of litigation trends and emerging topics.

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Features for 2021:

- Two Regional Strategy Sessions Focusing on Pharmaceutical Patent Reformation in **China** and **Europe**
- Three opportunities to hear from **District Court** and **PTAB Judges**
- Four **Breakout Rooms** Focused on the Business and Practice of Paragraph IV Disputes
- Key Agency Roundtable Featuring Representatives from **USPTO, FDA** and **FTC**
- In-Depth Focused Sessions on **§101, Venue, Skinny Labeling and Assignor Estoppel**
- Dedicated Panels on **Diversity, Inclusion, and Ethics**

Meet and Network with:

Key stakeholders shaping the law, policy, and proceedings of Paragraph IV litigation from:

- Akebia Therapeutics
- Akorn, Inc.
- Apotex Inc.
- Baxter International Inc.
- Eisai
- Eli Lilly and Company
- Endo Pharmaceuticals
- Fosun Pharma USA Inc.
- Fresenius Kabi USA, LLC
- Gilead Sciences
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Partner and Global Co-Chair, Intellectual Property
Paul Hastings LLP

Vanessa Yen
Partner
King & Spalding LLP

"Very good experience. The ability to jump in and out of rooms was nice."

Partner, Axinn, Veltrop & Harkrider LLP

DAY ONE ▸ April 26, 2021 (ET)

8:00 **REGIONAL BREAKFAST BRIEFING**

China Strategy Session: An Inside Look at the Reformations to the Patent Law of the People's Republic of China Relative for the Hatch-Waxman Practitioner

Modifications by China's National People's Congress (NPC) to its country's patent laws which go into effect on June 1st will considerably change its legal structure for pharmaceutical patents. The regulation, endorsed by China's National Medical Products Administration (NMPA), protects pharmaceutical patent rights, and fosters competition by establishing a Hatch-Waxman-style arrangement for both brands and generics. This session will cover the most relevant updates to the law and everything the U.S. Hatch-Waxman practitioner needs to know, including:

- The Chinese patent linkage system
- The 12-month exclusivity period
- Extensions of patent terms
- The good faith requirement
- Enhanced damages, and more

8:50

Opening Remarks from Co-Chairs

Rekha Hanu, *Vice President, Associate General Counsel, Chief IP Counsel,* **Akorn, Inc.**

Andrea Hutchison, *Senior Associate General Counsel, IP Litigation,* **Gilead Sciences**

9:00 **VIRTUAL TOWN HALL**

Patents, Prices, and Politics: Unwritten Lessons from the Election and Geopolitical Developments

Ryan M. Daniel, *Chief Patent Counsel, Region North Americ,* **Fresenius Kabi USA, LLC**

Evan Diamond, *Partner,* **King & Spalding LLP**

Shashank Upadhye, *Partner,* **Upadhye Tang LLP**

The original intent of the "Drug Price Competition and Patent Term Restoration Act of 1984," otherwise known as the Hatch-Waxman Act was provide an abbreviated approval pathway for generic drugs and to maintain patent integrity for innovator products.

In the 36 years since its enactment, prized generics have become more elusive due to the sophistication and complexities of drug development by brand name or innovator manufacturers — thus, bringing into focus the political debate between patents and price which the law by its official title sought to redress. This panel, in town hall fashion, will take questions as it explores such matters as:

- Reviewing the status of pending legislation impacting pharmaceutical patents and pricing in the new Congress
- Analyzing the Impact of the Orange Book Transparency Act
- Anticipating new amendments to the Hatch-Waxman Act
- Considering how these changes may affect pharmaceutical IP rights and Hatch-Waxman litigation strategies
  - » Identifying challenges and opportunities in an evolving landscape to monetize your IP portfolio

10:00 **AUDIENCE POLLING**

GSK v. Teva: What's the Skinny on Carve Outs?

David L. Anstaett, *Partner,* **Perkins Coie LLP**

James P. Leeds, *Assistant General Patent Counsel,* **Eli Lilly and Company**

Donna Meuth, *Associate General Counsel, IP,* **Eisai**

Jeffrey A. Marx, *Partner,* **Rakoczy Molino Mazzochi Siwik LLP**

Bruce M. Wexler, *Partner and Global Co-Chair, Intellectual Property,* **Paul Hastings LLP**

In October of 2020, the Federal Circuit held that Teva induced the infringement of a GSK patent and reinstated a $235 million verdict in favor of GSK. Teva subsequently filed a petition for ***en banc***, reiterating the dissent from the Chief Judge Prost thereby claiming that the majority, in effect, invalidated the relevant section of the Hatch-Waxman Act that permits skinny labeling. Presently, both brand and generic drug manufacturers await an outcome which likely will merit Supreme Court review.

- Understanding the profound implications of the Federal Circuit striking down label carve outs
- Examining the Federal Circuit's rationale regarding a skinny label launch
  - » Analyzing Chief Judge Prost's dissent
- Reconciling whether launching with a skinny label that carves out infringing methods violates a patented method of use
  - » Making sense of the inconsistencies in the language from FDA approved indication, the patent language in the claim, and the language in the use code
- Mitigating inducement charges via internal training
- Balancing competing interests in promoting innovation v. permitting generic drugs market entry
  - » Understanding second medical use patents and carve out strategies
    - Clarifying the patentability of further medical use inventions
- Assessing the legal and regulatory implications of second use patents
  - » Market access implications?
- Determining whether post-filing evidence is admissible to show insufficient disclosure of further medical use

11:15 | Morning Break

11:35

Spotlight on Delaware: Fireside Chat with Chief Judge Stark and Judge Noreika

Honorable Leonard P. Stark, *Chief Judge,* **United States District Court, District of Delaware**

Honorable Maryellen Noreika, *District Court Judge,* **United States District Court, District of Delaware**

MODERATOR:

Meg Fasulo, *Partner,* **Bartlit Beck LLP**

12:35

1:1 Networking

12:45 | Lunch Break

1:15

Diversity, Inclusion, Incorporation: How to Manage and Maintain a Diverse Pharmaceutical IP Team

Steven M. Coyle, *Partner, Pharmaceutical Patent Practice Co-Chair, Litigation Co-Chair,* **Cantor Colburn LLP**

Huong T. Nguyen, *General Counsel,* **Fosun Pharma USA Inc.**

Elizabeth S. Weiswasser, *Partner,* **Weil, Gotshal & Manges LLP**

Vanessa Yen, *Partner,* **King & Spalding LLP**

- Increasing awareness among pharmaceutical IP practitioners about underrepresented racial and ethnic groups in the patent bar
  - » Championing their representation in the pharmaceutical IP work force
  - » Advocating for diverse and young attorneys appearing in the court room
  - » Supporting STEM initiatives
- Reviewing data showing the benefits of a diverse workforce
- Accelerating the advancement of a more diverse pharmaceutical IP community via mentoring and networking
- Understanding what specific evidence of diversity pharmaceutical companies and IP departments, are seeking from their law firm counterparts
- Implementing organizational changes that promote diversity
  - » How clients can seek out partnerships with firms that promote:
    - Utilizing NAMWOLF lists
    - Abiding by the Mansfield Declaration
    - Using a DuPont Legal Model
- Identifying best practices for evaluating your outside firm's efforts in promoting diversity
  - » Reviewing firm statistics on women, minorities, sexual orientation, etc.
- Sharing data-driven strategies to address current diversity challenges in STEM

2:15 **AUDIENCE POLLING**

You Can't Go Home Again...Or Can You? Establishing Venue in PIV Litigation Post-*Valeant v. Mylan*

Aziz Burgy, *Partner,* **Axinn, Veltrop & Harkrider LLP**

Derek Johnson, *Associate General Counsel, IP,* **Baxter International Inc.**

Irena Royzman, *Partner,* **Kramer Levin Naftalis & Frankel LLP**

Jeanna Wacker, *Partner,* **Kirkland & Ellis LLP**

MODERATOR:

Gregory A. Morris, Ph.D., *Partner,* **Honigman LLP**

In building on the Supreme Court's decision in *TC Heartland*, the Federal Circuit in *Valeant Pharmaceuticals North America LLC v. Mylan Pharmaceuticals Inc.*, held that "acts of infringement" under 28 U.S.C. § 1400(b) occur "only in districts where actions related to the submission of the ANDA occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated." This panel will help provide clarity as practitioners from both branded and generic drug companies revisit the present and anticipated state of the venue quandary.

- Reviewing the latest precedent regarding venue determination in pharmaceutical patent infringement cases
- Determining where a corporate defendant be sued
  - » Options for foreign defendants
- Outlining the impact of safe harbor provisions on venue determinations
  - » Which activities must be excluded from a venue determination?
    - Whether the analyzing, compiling, and submitting of information in the ANDA or NDA that can be considered?
- Devising strategies for deciding where you should file your case to avoid a motion to transfer
- Developing new approaches for moving to transfer for improper venue in the wake of *Valeant v. Mylan*
- Weighing the chances for success or defeat of a venue transfer motion

3:30 | Breakout Sessions (Choose A or B)

A The Economics and Economy of Drug Patents with ACI's Hatch-Waxman Series Advisory Board Members

Optimizing Product Selection, Identifying Targets for Litigation and Monetizing IP Portfolios

Matt Becker, *Partner,* **Axinn, Veltrop & Harkrider LLP**

Colin Heitzmann, *Senior Corporate Attorney, Senior Director, IP Group Leader,* **Otsuka Pharmaceutical Companies**

Deepro R. Mukerjee, *Partner and Co-Chair, Patent Litigation,* **Katten Muchin Rosenman LLP**

Kevin Zive, *Vice President –Global Intellectual, Property and Legal Affairs,* **Apotex Inc.**

- Considering the critical factors when selecting products for development:
  - » IP constraints and Freedom to Operate
  - » Development costs
  - » Market forces
  - » The potential long-term impact the coronavirus could have on supply chain disruption
- Considering license deals to save litigation spend and remain within budget
- Strengthening your launch strategy
- Examining the value of licensing deals and structures
- Establishing best practices for cost reduction to enhance predictability for cash flow purposes
  - » What kind of case management does a client expect with a low budget when there is no settlement?
- Evaluating the impact of the conservation of resources on future investment in research and development

B The Practice of Hatch-Waxman Litigation: PIV on Trial

Structuring Settlements and Antitrust Considerations for the PIV Litigator

Honorable Tonianne J. Bongiovanni, *Magistrate Judge,* **United States District Court, District of New Jersey**

Jeffrey R. Gargano, *Partner,* **Morgan, Lewis & Bockius LLP**

Henry H. Gu, *Vice President, Chief IP Counsel,* **Akebia Therapeutics**

Adam L. Perlman, *Partner,* **Latham & Watkins LLP**

- Analyzing the implications of the *In re Humira* antitrust decision
  - » Whether patent holders may lawfully obtain and enforce patents against alleged infringers and protects their ability to settle
- Interpreting Judge Newman's dissent in *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms* (Fed. Cir. 2020)
- Examining California "Pay for Delay" Law A824
- Developing timelines for business and legal milestones relatives to terms of the settlement
- Understanding the application of antitrust law's "rule of reason" to pharmaceutical patent settlements
- Investigating recent judicial efforts to promote settlements
- Understanding the limits of judicial settlement authority
- Evaluating the dissemination of settlement-oriented innovation

4:15 | Breakout Sessions (Choose A or B)

A The Economics and Economy of Drug Patents with ACI's Hatch-Waxman Series Advisory Board Members

The Repurposing and Repositioning of Small Molecule Drugs: Strategies for Re-Innovation and Overcoming Related IP Conundrums

Mary J. Morry, *Counsel, IP Litigation, Merck Office of the General Counsel,* **Merck Sharp & Dohme Corp**

Lars Taavola, *VP, Chief Intellectual Property, Counsel,* **Mallinckrodt Pharmaceuticals**

With the COVID-19 pandemic came the international race to identify therapeutic treatments, cures, and vaccines. Under immense pressure to deliver, drug companies across the globe have shown a restored interest in the repurposing of existing drugs, such as remdesivir and dexamethasone that were effective against corona-like viruses.

While the repurposing of existing therapies can be crucial for delivering novel treatments to the population, in turn it raises myriad of pharmaceutical intellectual property questions — this session will address the underlying controversies and challenges posed by these questions.

- Analyzing the types of exclusivities available for repurposed drugs
  - » Outlining whether patent or regulatory based
    - Orphan drug exclusivity
    - Three-year data exclusivity

B The Practice of Hatch-Waxman Litigation: PIV on Trial

I'm here Live – I'm Not a Cat: Gracefully and Effectively Navigating Remote Hearings, Trials, Depositions, and Discovery

Hon. Christopher J. Burke, *Magistrate Judge,* **District of Delaware**

Eric W. Dittmann, *Partner and Global Vice-Chair, Intellectual Property,* **Paul Hastings LLP**

Anne Shea Gaza, *Partner,* **Young Conaway Stargatt & Taylor, LLP**

Ryan Hagglund, *Partner,* **Loeb & Loeb**

To stop the spread of the coronavirus, courts around the country pivoted to video conferences or telephonic proceedings. Like the Hatch-Waxman Act itself, practicing virtually comes with a unique set of obstacles. Attend this breakout session and replenish your toolkit in view of these unprecedented circumstances, with a special focus on:

- Hearings and trial practice
- Depositions
- Discovery planning and scheduling
- Privilege and confidentiality considerations
- Motions to compel
- Document requests

5:15

Faculty-Attendee Roundtables

New for this year — through a feature on our virtual platform, take advantage of the opportunity to meet our speakers in smaller group settings, ask targeted questions, receive real time answers, and share your own thoughts on pressure points and challenges.

5:30 | Conference Adjourns to Day Two

Interactive Virtual Conference Experience

This program is designed to bring the dynamic, in-person conference experience to you virtually with multiple ways to engage with speakers, stay connected with industry peers and expand your professional network through 1-on-1 conversations.

Virtual Networking Opportunities

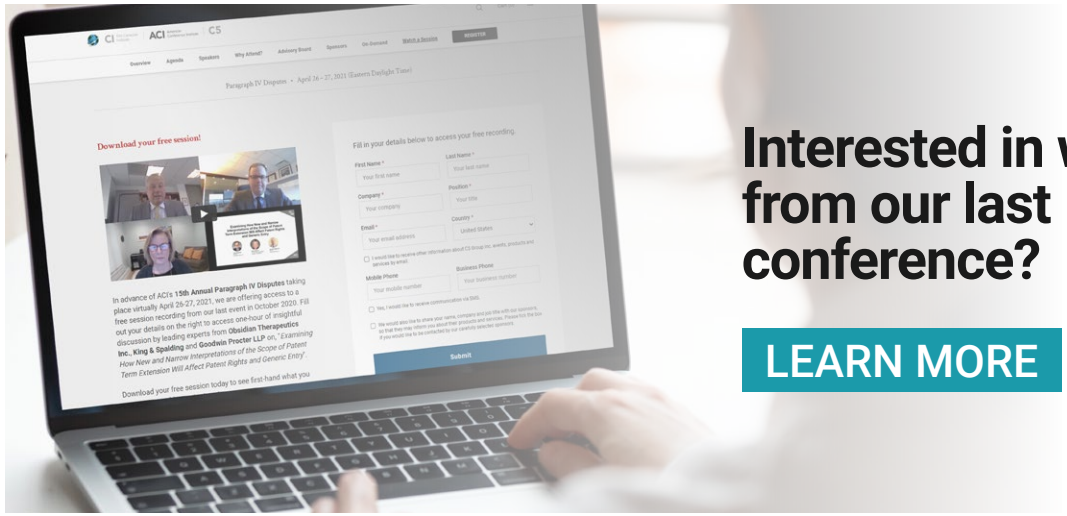
Take advantage of 1:1 speed networking, exhibit hall meetups and direct video chats with fellow conference participants. Your next legal team, business partner or client could be right in one of our virtual networking rooms — it is up to you to find them!

Polling

Weigh in and seize the opportunity to benchmark with peers in real-time on leading issues such as sensitive, complex hypothetical scenarios.

Virtual Breakout Sessions

Engage in small-group, interactive think-tanks with some of our key speakers. Take advantage of the opportunity to meet our speakers face-to-face, ask targeted questions, receive real time answers and share your own thoughts on pressure points and challenges.



Interested in watching a session from our last Paragraph IV Disputes conference?

LEARN MORE

DAY TWO ▸ April 27, 2021 (ET)

9:00 **REGIONAL BREAKFAST BRIEFING**

Pharmaceutical Patent Litigation in the EU: A New Look at *Bolar* Exemptions and Recent Critical Developments Impacting Pharmaceutical Patent Litigation

Dominic Adair, *Partner,* **Bristows LLP**

Bert Oosting, *Partner,* **Hogan Lovells**

This regional assembly will bring you up-to-speed on the most significant developments from the last 12 months — including important, practical takeaways that will help prepare you to successfully manage European pharmaceutical IP litigations. Topics of discussion will include:

- Named for the United States Supreme Court case, *Roche v. Bolar*, the *Bolar* Exemption is a research safe harbor allowing for the exemption of necessary data related to the regulatory approval process. This exemption was adopted into the Hatch-Waxman Act in the United States and later implemented in several EU countries
  - » Understanding which medical products are available for *Bolar* exemptions
  - » Determining whether a company is free to market and sell generic versions of patented pharmaceuticals under the *Bolar* exemption
- Examining life cycle strategies and filing divisionals
- Developing best practices for managing and winning global patent litigation disputes
- Coordinating strategies and assessing the role of early decisions in key countries
  - » Detailing the role of experts, claim construction standards, rationalizing potentially inconsistent positions that may need to be taken in different countries
- Determining whether anti-trust issues still have a role on the European stage
- Leveraging the substantive and procedural nuances between the U.S. and Europe When and where to bring infringement suits in various global jurisdictions

9:50

Main Conference Resumes | Opening Remarks from Co-Chairs and Recap of Day One

Rekha Hanu, *Vice President, Associate General Counsel, Chief IP Counsel,* **Akorn, Inc.**

Andrea Hutchison, *Senior Associate General Counsel, IP Litigation,* **Gilead Sciences**

10:00 **KEY AGENCY BRIEFING FOR THE HATCH-WAXMAN PRACTITIONER**

Challenges and Opportunities in an Evolving Landscape Featuring USPTO, FDA and FTC

Markus H. Meier, *Acting Director, Bureau of Competition,* **United States Federal Trade Commission**

Maryll W. Toufanian, *Director, Office of Generic Drug Policy,* **United States Food and Drug Administration**

MODERATOR:

David B. Abramowitz, *Partner,* **Locke Lord LLP**

Please join us for this highly anticipated briefing with representation from the three key agencies governing Hatch-Waxman Litigation — USPTO, FDA and FTC, and they contemplate legal, regulatory and policy changes under the Biden Administration.

11:00 **AUDIENCE POLLING**

Definitely, Maybe: Determining Patentable Subject Matter and the Future of Section 101

Karen E. Brown, *SVP, IP and Legal Affairs,* **Obsidian Therapeutics, Inc.**

Guy Donatiello, *SVP Intellectual Property,* **Endo Pharmaceuticals**

Dr. D.J. Jonathan Loeb, Ph.D., *Partner,* **Dechert LLP**

MODERATOR:

Matthew A. Pearson, *Partner,* **Akin Gump Strauss Hauer & Feld LLP**

In recent years, competing interests have kept the reformation of patentable subject matter eligibility under 35 U.S.C. 101 from getting before the Congress. A frustrated federal judiciary went so far to invoke Supreme Court intervention. In *Am. Axle & Manufacturing, Inc. v. Neapco Holdings LLC* (Fed. Cir. 2020), Judge Moore in dissent, reiterated the Federal Circuit's request for guidance in 101 jurisprudence and emphasized the need for the Supreme Court to grant certiorari in a 101 case to resolve the "bitter divide" in the application of §101. This session will review the most impactful cases from the last 12 months, including:

- Reviewing recent District Court cases tackling 101 at the motion to dismiss and summary judgment stages
- Taking stock of the recent 101 cases applying the Supreme Court's Alice/Mayo tests before the Federal Circuit
  - » *Boehringer Ingelheim Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc. (Fed. Cir. 2020)*
  - » *Illumina, Inc. v. Ariosa Diagnostics, Inc. (Fed. Cir. 2020)*

- Deciding whether a new application of an abstract idea is abstract
- Analyzing when courts will conclude that any claim at issue is deemed invalid as claiming ineligible subject matter
  - » Whether there was direction to a natural phenomenon

12:00 **VIEW FROM THE BENCH**

All Rise! District Court Judges Address Brand and Generic Concerns

The Honorable Alan D. Albright, *District Judge,* **United States District Court, Western District of Texas**

CO-MODERATORS:

Gerald J. Flatmann, Jr., *Partner,* **King & Spalding LLP**

Paul J. Molino, *Managing Partner,* **Rakoczy Molino Mazzochi Siwik LLP**

1:00

1:1 Networking

1:10 | Lunch Break

1:45

A Study in Stats, Status, Standing, and Sustainability: The PTAB Year in Review

Hon. Jacqueline Wright Bonilla, *Deputy Chief, Administrative Patent Judge,* **USPTO Patent Trial and Appeal Board**

Michael P. Kahn, *Partner,* **Akin Gump Strauss Hauer & Feld LLP**

Liane M. Peterson, *Partner,* **Foley & Lardner LLP**

- Assessing the latest developments on the PTAB's expanded use of discretionary denials of petitions
- Analyzing how the Supreme Court in *Thryv, Inc. v. Click-to-Call Technologies, LP, et al.* (Supreme Court 2020) expanded the powers of the PTAB through its ruling that the time bar cannot be appealed
- Anticipating the impact of the Supreme Court's review of the Federal Circuit's denial of rehearing in *Arthrex Inc. v. Smith & Nephew* (Fed. Cir. 2020) and predicting what the decision will mean for the PTAB under the Appointments clause as well as the status of invalidated patents under past proceedings
  - » Determining whether APJs are "principal officers" or "inferior officers"
- Reviewing the Federal Circuit's decision in *Network-1 Technologies, Inc. v. Hewlett-Packard Co.*, (Fed. Cir. Sept. 24, 2020) that limited the scope of IPR estoppel and vacated claim construction based on expert testimony
- Interpreting the new claim amendment process
- Taking stock of the number of small vs. large molecule cases in IPRs and PGRs
- Examining the nexus between injury and standing to appeal an IPR
  - » *Argentum v. Novartis* (Fed. Cir. 2020)

2:45 **MOCK ARGUMENT | AUDIENCE POLLING**

Debating the Applicability of the Doctrine of Assignor Estoppel: What Every Hatch-Waxman Practitioner Needs to Know About the Anticipated SCOTUS Decision in *Hologic v. Minerva*

Alan Clement, *Partner,* **Locke Lord LLP**

Noah Leibowitz, *Partner,* **Dechert LLP**

William D. Marsillo, *Partner,* **Boies Schiller Flexner LLP**

Last year, in *Hologic, Inc. v. Minerva Surgical, Inc.* the Federal Circuit held that the doctrine of assignor estoppel does not prevent an assignor from lodging a validity challenge of an assigned patent in an IPR proceeding. The doctrine precludes inventors from assigning a patent to someone and then challenging the validity of the patent. In reviewing the Federal Court's decision, The Supreme Court will decide whether a defendant in a patent infringement action who assigned a patent or is in privity with an assignor of the patent, may have a defense of invalidity heard on the merits. Join us for an intriguing debate where panelists will make both arguments to understand the salient repercussions of this anticipated decision on Hatch-Waxman practice.

- Argument I: The doctrine should be abolished
- Argument II: The doctrine's scope should be expanded to cover proceedings before the PTAB
  - » At time of press, the doctrine is only relevant in litigations before the Federal Courts

4:00 **ETHICS LAB | AUDIENCE POLLING**

The Ethical Practice of Paragraph IV Litigation: New Developments Impacting Professional Responsibility in the Hatch-Waxman Arena

Mark Waddell, *Partner,* **Loeb & Loeb**

This session will identify common ethical dilemmas in Hatch-Waxman litigation and help you incorporate practices to avoid them. Points of discussion will include:

- Drafting conflicts of interest waivers, whether actual or potential
- Identifying hidden dangers in joint defense arrangements
  - » What happens if the clients do not agree or a dispute between them arises?
    - Do all parties have to seek new counsel?
- Analyzing the requirements for pleadings, whether in the complaint, the answer, or the counterclaim
  - » Interpreting Rule 11 and other standards

5:00 | Conference Concludes

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