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ACI's Hatch-Waxman SERIES

14th Annual

PARAGRAPH IV DISPUTES

Expert Strategies for Brand Names and Generics

October 6–7, 2020 • Virtual Conference
Workshops: October 8, 2020

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Plus leading in-house patent counsel from a dozen brand and generic drug companies

Enter ACI's Virtual Conference Room to Meet And Network With Key Stakeholders Shaping The Law, Policy, and Proceedings of Paragraph IV Litigation.

Dear Colleague:

As the co-chairs of **American Conference Institute's 14th Annual Paragraph IV Disputes** conference, we invite you to join us for **invaluable professional development opportunities, meaningful networking, and vital "*take aways*"** for legal strategies and cost-analysis for every aspect of this complex form of litigation.

The **Hatch-Waxman Act** created a pathway for generic drugs to enter the market, while also establishing rules of engagement for brands to enforce patents. **ACI's flagship Paragraph IV Disputes conference created a collegial environment for the most active brand and generic companies in the industry to exchange ideas and find camaraderie — even now — in the age of COVID-19.**

Each year since 2006, when the inaugural conference was launched, pharmaceutical patent practitioners from throughout the country and across the globe attend the conference to get caught up on legal developments, learn how their peers (***and opponents***) are navigating the ever-changing Hatch-Waxman landscape, and **often times, settle their disputes.**

This unique dynamic epitomizes not only the importance of the academic content and legal theory presented, **but the contending business acuities as well**.

After considering attendee feedback from 2019, studying key developments impacting both brands and generics, and being mindful of the effects of the global pandemic, the 2020 agenda -- now in a virtual format -- incorporates new and innovative approaches to become more agile, ask burning questions, benchmark and grow your network.

With reports of reform of the generic drug framework in the offing, **ACI's highly anticipated Paragraph IV Disputes** will provide stakeholders with updates and insights on the **section 101 situation**, the shifting regulatory landscape and the Trump Administration's efforts to **drive down drug prices, multiple bills impacting Paragraph IV practice, and analyses of the most important decisions rendered during the past year** that reflect the ever-evolving law on topics including **venue, standing to appeal decisions from the PTAB, reasonable expectation of success, and induced infringement**.

As such, and as the industry prepares to address the fallout of global pharmaceutical patent losses of billions of dollars and the impact of evolving law, regulation and policy impacting the Hatch-Waxman landscape, the time for this conference has never been more relevant.

We hope that you and your colleagues will join us virtually for yet another productive conference!

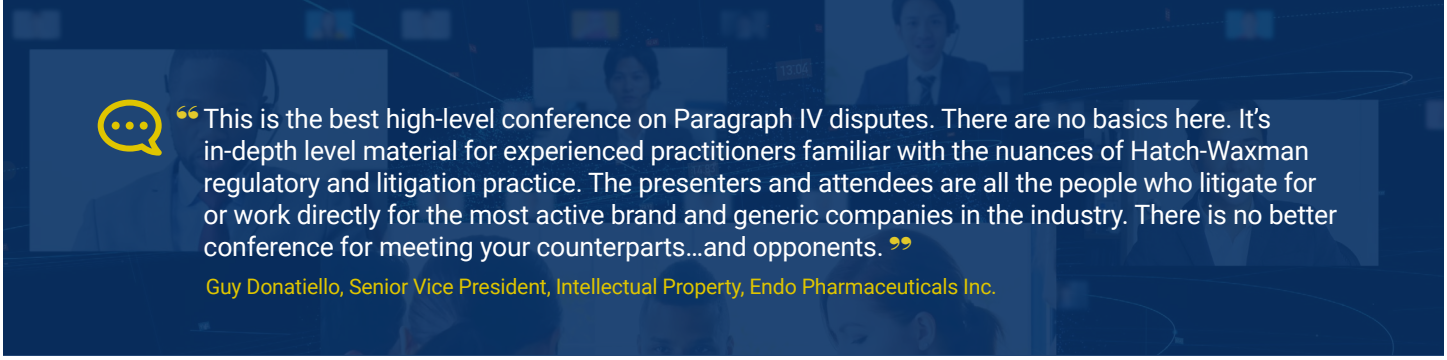
Sincerely,

Stephanie Donahue
Principal Counsel, Patent Litigation
Sanofi

Pearl T. L. Siew
Senior Vice President and
Head, Intellectual Property
Eagle Pharmaceuticals, Inc.

"The ACI PIV conference is the "must attend" conference for any Hatch-Waxman practitioner. No other conference provides the opportunity to hear from and network with the top in-house representatives and leading law firms representing companies on both sides of the "v." This conference annually delivers lively discussion and debate with thought leaders on up-to-the-minute trends and hot-button issues in this specialized practice area."

"I'm very excited about ACI PIV 2020. This conference brings together many of the top contributors in Paragraph IV litigation, from in-house and outside counsel to Patent Office, District Court, and Federal Circuit Judges. It's an excellent opportunity to exchange ideas and shape strategies in larger groups and smaller break-out sessions."



> "This is the best high-level conference on Paragraph IV disputes. There are no basics here. It's in-depth level material for experienced practitioners familiar with the nuances of Hatch-Waxman regulatory and litigation practice. The presenters and attendees are all the people who litigate for or work directly for the most active brand and generic companies in the industry. There is no better conference for meeting your counterparts…and opponents."
>
> Guy Donatiello, Senior Vice President, Intellectual Property, Endo Pharmaceuticals Inc.

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MAIN CONFERENCE DAY ONE

Tuesday, October 6, 2020 (EDT)

8:00

Co-Chairs' Opening Remarks

8:15 **PARAGRAPH IV STATE OF THE UNION**

Developing a New Game Plan for the New Normal: Assessing Legal, Regulatory, and Jurisprudential Developments in the Era of COVID-19

- Assessing Paragraph IV filing trends and district court decisions impacting the business and practice of ANDA litigation
- Understanding the effect of the global pandemic on the business and practice of Hatch-Waxman litigation
  - » Understanding the potential long-term impact the coronavirus could have on supply chain disruption
  - » Evaluating the impact of the conservation of resources on future investment in research and development
  - » Reconciling court docket delays and Hatch-Waxman Act 30-month stays
  - » Assessing the threat of compulsory licensing and march-in rights
- Examining how recent Paragraph IV filings and litigation results have influenced business judgments including mergers and acquisitions, research and development initiatives, and licensing decisions
- Analyzing the nexus between PIV legislative proposals and the evolving drug pricing debate
- Assessing the current state of proposed Hatch-Waxman reform measures

9:00

The Continuing §101 Saga: Examining the Latest Patent Eligibility Developments in the Courts and at the PTO and How They are Influencing R&D, Claims Drafting, and Litigation Strategies

- Exploring the latest 101 jurisprudence relative to Hatch-Waxman
- Understanding how the Supreme Court's denial of cert. in Vanda has impacted Hatch-Waxman and Paragraph IV
- Examining Federal Circuit's ruling in Vanda relative to secondary patents
  - » *Mallinckrodt v. Praxair* (Fed. Cir. 2019)
- Analyzing the PTO's Revised Patent Subject Matter Eligibility Guidance and how it applies to Hatch-Waxman patents
- Assessing faults in claim construction relative to a 101 denial
  - » How does a claim need to be written in order to satisfy 101?
  - » Evaluating proof and proffers which can uphold or defeat 101 assertions
- Predicting R&D trends in pharmaceuticals relative to the 101 conundrum

10:00 **Extended Morning Break**

10:25

And Now a Word from the District of Delaware: A Conversation with Chief Judge Stark and Chief Magistrate Judge Thynge

11:10

The Doctrine of Equivalents: Analyzing the Effects of Recent Federal Circuit Decisions on ANDA Litigation Strategies

- Examining the significance of recent series of ANDA cases before the Federal Circuit finding infringement through the Doctrine of Equivalents
  - » *Eli Lilly & Co. v. Hospira, Inc.* (Fed. Cir. 2019)
  - » *Galderma Laboratories, L.P. v. Amneal Pharmaceuticals LLC* (Fed. Cir. 2020)
- Analyzing the role of the DOE's sister doctrine, prosecution history estoppel relative to this line of cases
  - » Tangential relationship test
- Exploring how this new line of DOE and PHE cases will influence findings of infringement in future ANDA cases
- Anticipating whether the Supreme Court will grant cert. in *Lilly* and what could this mean for the Hatch-Waxman landscape

12:25 **Lunch Break**

1:25

Examining How New and Narrow Interpretations of the Scope of Patent Term Extension Will Affect Patent Rights and Generic Entry

- Understanding how the Federal Circuit's decision in *Biogen Int'l GmbH v. Banner Life Scis. LLC* (Fe. Cir. 2020) may influence the future application of patent term extension
- Exploring the Federal Circuit's as well as the District of Delaware's reasoning as the scope and limitation of PTE rights as being specific to "the active ingredient of… a new drug… including any salt or ester of the active ingredient."
- Examining the Biogen decision as part of developing PTE jurisprudence
- Assessing how this case may impact the Hatch-Waxman realm

2:25 **Afternoon Break**

DAY ONE AFTERNOON TRACKS

	TRACK A The Solution Room with ACI's Hatch-Waxman Series Advisory Board Members	TRACK B Litigation War Room: The Practice of Paragraph IV with The Magistrate Judges
2:40	**Monitoring Legal Spend and Balancing the Paragraph IV Litigation Budget** • Implementing practices to minimize surprises and increase predictability • Forecasting the budget by phase and quarter » Knowing when to reevaluate use of task codes • Deciding what components go into the budget » Vendors » Experts » Appeals » Costs vs. fees • Understanding the source of error when surprises and overages occur • Evaluating the appropriateness of alternative fee arrangements • Considering license deals as a means to save litigation spend and remain within budget	**Understanding and Harnessing the Nuances of Local Rules** • Evaluating the "go to" jurisdictions for patent litigation by comparing adopted local patents rules meant to expedite and streamline patent litigation • Comparing jurisdictions that have specified processes for limiting contention amendments and claim construction hearings • Understandings the considerations to make when deciding on the best venue for your case • Identifying which jurisdictions require the alleged infringer to produce contentions, document and claims charts first
3:30	**Effectively Managing Global Pharmaceutical Patent Litigation** • Understanding the importance of aligning legal and business functions • Assessing common international business scenarios encountered by both brand name and generic manufacturers which may lead to patent and/or exclusivity loss • Identifying potential safe-harbor violation liabilities related to foreign manufacturers and finishers • Building a winning global litigation team » Selecting the right foreign counsel » Coordinating multi-jurisdictional proceedings • Assessing the impact and dangers of applicable international treaties on the PIV landscape	**Evaluating the Effectiveness of Summary Judgment in Different Venues** • Reviewing novel strategies for utilizing venue in Hatch-Waxman litigation » Appreciating the increased importance of venue in view of the varying practice considerations for different jurisdictions • Analyzing which courts have added additional hurdles for litigants to file for summary judgment • Highlighting summary judgment practice in Delaware and New Jersey • Key takeaways and strategic concerns under §101 • Assessing venue implications and success rates of dispositive motions
4:10	**Practical Strategies and Tactics for Effective Settlement Negotiation** • Developing timelines for business and legal milestones relative to the terms of the settlement • Understanding the application of antitrust law's "rule of reason" on pharmaceutical patent settlement practice • Examining recent decisions concerning pharmaceutical patent settlements in the PIV context • Analyzing practical strategies and tactics for effective settlement negotiation	**Appreciating the Magistrate Judge's Role in Settlement Discussions** • Investigating recent judicial efforts to promote settlements • Understanding the limits of judicial settlement authority • Evaluating the dissemination of settlement-oriented innovations » Adjusting to the magistrate's role in the settlement process • Viewing the magistrate's role in promoting settlement as a tool to manage your own dispute and avoid the uncertainties and limitations of fully litigates cases

5:00

Focus on the PTAB

PART I

PTAB Stats and Substance: Questions and Controversies Surrounding Filings, Judicial Appointments, Standing, and Expanded Powers

- Surveying the types and numbers of life sciences patent cases brought before the PTAB in the last year
- Comparing and contrasting the number of small vs. large molecule cases in IPRs and PGRs
- Understanding the significance of the Federal Circuit's denial of rehearing in *Arthrex Inc. v. Smith & Nephew* (Fed. Cir. 2020) and what it means for the future of IPRs as well as the PTAB under the Appointments clause
  - » Anticipating Supreme Court and/or Congressional review
- Examining the nexus between injury and standing to appeal an IPR
  - » *Argentum v. Novartis* (Fed. Cir. 2020)
- Analyzing how the Supreme Court in *Thryv, Inc. v. Click-to-Call Technologies, LP, et al.* (Supreme Court 2020) essentially expanded the powers of the PTAB through its ruling that the time bar cannot be appealed

PART II

The APJs Speak on Practice, Policy and Procedure

- Surveying notable pharmaceutical patent wins and losses
- Assessing IPR, PGR and CMB filings involving life science patents
- Considering emerging case law shaping the role of prior art in the PTAB's discretionary denial of IPRs
- Establishing when petitioners may rely on prior art previously considered by the PTAB

6:00 **End of Day One – Conference Adjourns**

MAIN CONFERENCE DAY TWO

Wednesday, October 7, 2020 (EDT)

8:00

Co-Chairs' Opening Remarks

8:15

Morning Roll Call with the District Judges

All rise! Distinguished jurists with some of the liveliest PIV litigation dockets in the country will examine decision-making practices employed by the judicial system and provide sage advice for both patent holders and patent challengers.

9:15 **Morning Break**

DAY TWO MORNING TRACKS

TRACK C

In-House Perspectives on The Future of IP Teams and Working with Outside Counsel

9:30

Powerful Portfolio Management: Product Selection, Identifying Targets for Litigation and Monetizing IP Portfolios

- Appreciating the importance of global portfolio planning
- Developing techniques for an accurate assessment of the current value of your portfolio
  - » Analyzing trends within your portfolio
  - » Evaluating the strength of your patents in your current portfolio and how to monetize them
- Recognizing potential portfolio targets and vulnerabilities
- Identifying "good" targets and how they "complete" portfolio development
- Utilizing business functions to advance product portfolio planning
  - » Identifying team members from operations, business development and life cycle management
- Making adequate preparations for negotiations as well as litigation

10:20

How the IP Team Can Present a Unified Front: Mastering Intradepartmental Communication

- Communicating a cohesive story with consistency across all IP stakeholder groups and levels of engagement
  - » Devising a central message digestible by C-level leadership, corporate communications, finance, legal/compliance, manufacturing, operations, etc.
- Establishing the desired level of commitment amongst teams based on availability and responsiveness
- Succinctly focusing on shared, pragmatic business goals

TRACK D

The Practice of Hatch-Waxman Litigation: Paragraph IV on Trial

Devising Strategies for Proving Infringement and Defending Validity

- Understanding that the battle for validity/invalidity and infringement/non-infringement begins during the prosecution history
- Devising tactics for drafting a high-quality patent that can be enforced and withstand close scrutiny
- Examining patent challenges and defenses in ANDA proceedings under new 112 jurisprudence
  - » *Nalpropion Pharmaceuticals, Inc. v. Actavis Labs. FL, Inc.*, (Fed Cir. 2019)
  - » *Nuvo Pharmaceuticals, Inc. v. Dr. Reddy's Laboratories Inc.*, (Fed. Cir. 2019)
- Developing strategies to follow when the validity opinion is written by in-house counsel, a patent agent or an engineer
- Identifying circumstances constituting willful infringement and thus, treble damages
- Proving that the product or process infringes your patent
- Ensuring acts of infringement are easily detected
- Identifying patent vulnerabilities giving rise to claims of invalidity or non-infringement, thus forming the basis of a Paragraph IV Certification

Advanced Pleadings Drafting: Choosing Claims and Defenses Wisely

- Drafting well-constructed claims with diverse scope
  - » Ensuring that all counts are plead with specificity
  - » Avoiding Rule 11 sanctions
  - » Devising strategies for situations with multiple ANDA filers
- Understanding when to reduce claims and defenses to a manageable level
- Analyzing how to masterfully manage protective order disputes
- Choosing your defenses with prudence
  - » Understanding the advantages of not pleading every defense
  - » Knowing which patents to ask to delist
    - ■ Assessing allegations of improper Orange Book listing

DAY TWO MORNING TRACKS

TRACK C

In-House Perspectives on The Future of IP Teams and Working with Outside Counsel

11:05

Diversity and Inclusion, Incorporation and Implementation: A Guide for Creating a Successful IP Team

- Understanding what specific evidence of diversity pharmaceutical companies, and IP departments in particular, are seeking from their law firm counterparts
- Implementing policies and practices that will effect change and promote a diverse workplace
- 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

11:55 **FTC KEYNOTE**

Antitrust Developments Impacting Brands and Generics

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

12:15 **Lunch Break**

1:15

FDA Think Tank on the Latest Regulatory Developments Impacting Hatch-Waxman

- Identifying brand and generic perspectives on the latest FDA initiatives impacting pharmaceutical patents
- Reviewing emerging projects influencing drug access and litigation trends
  - » Understanding the efforts to improve transparency and predictability for generic drug applicants
- Examining questions and consequences of improper device listings in Orange book in *In re Lantus Direct Purchaser Antitrust Litig.*, 18-2086, 2020 WL 728628 (1st Cir. Feb. 13, 2020)
- Understanding the Drug Competition Action Plan
  - » Learning how the efforts aim to increase access to lower cost generic drugs
- Evaluating Competitive Generic Therapy (CGT)
  - » Establishing what may be designated as CGT
  - » Reviewing designation eligibility, mechanics, exclusivity
  - » Interpreting the interplay between Hatch-Waxman and CGT
- Analyzing the Off-Patent and Off-Exclusivity List
  - » Overview of the intentions of the list, what is included and how often it is updated
- Assessing the PIV Patent Certifications List
  - » Analyzing the June 2019 revised PIV Patent Certifications List

2:15 **Extended Afternoon Break**

2:45

New Studies in Obviousness: Thoughts on Inherency, Structure, Prior Art, and Secondary Considerations

Is it so Obvious to be Inherent? New Developments in the Inherency Defense and its Implications for ANDA Litigation

- Assessing whether inherency exists in obviousness
- Evaluating offensive and defensive strategies
- Determining whether inherency demonstrates obviousness
- Understanding the importance of *Hospira v. Fresenius* (Fed. Cir. 2020) relative to future findings of obviousness in inherency
- Under this decision when can the inherency defense be raised
- Determining the necessity of prior art disclosures

Structural Obviousness Implications for Secondary Patents

- Understanding the significance of findings of structural obviousness and lead compound analysis obviousness as illustrated in:
  - » *Valeant Pharmaceuticals Int'l, Inc. v. Mylan Pharmaceuticals Inc.*, No. 2018-2097 (Fed. Cir. April 8, 2020)
  - » *Sanofi-Aventis U.S., LLC v. Fresenius Kabi USA, LLC* (Fed. Cir. 2019)
- Assessing the impact of these cases on formulation and method patents in the Hatch-Waxman arena

Obviousness-Type Double Patenting Review

- Analyzing the latest Federal Circuit and District Court trends related to OTDP
- Examining District Court decisions and subsequent Federal Circuit activity on OTDP as it applies to PTA
- Evaluating circumstances in which a terminal disclaimer must be made

New Considerations in Secondary Considerations

- Understanding the implications of *Fox Factory, Inc. v. SRAM, LLC* (Fed. Cir. 2019) for findings of non-obviousness due to secondary considerations
- Re-examining requirements to meet the nexus presumption
- Assessing applicability of Fox Factory to secondary considerations raised in ANDA obviousness challenges

3:45 **ETHICS DRILLS**

Ethics and New Developments Impacting Professional Responsibility in the Hatch-Waxman Arena

- Reviewing the sufficiency of your notice letter
- Establishing standards for determining when attorneys and/or firms should be disqualified for conflicts
- Determining who is a client based on actual representation
- Considering joint defense arrangements in the Hatch-Waxman setting and possible ethical predicaments

4:45 **Conference Concludes**

TRACK D

The Practice of Hatch-Waxman Litigation: Paragraph IV on Trial

Selecting and Effectively Using Expert Witnesses in Pharmaceutical Patent Litigation

- Finding, vetting, retaining, and disclosing expert witnesses in PTAB and District Court proceedings
- Understanding the limitations and exclusion of testimony as evidenced by cases where judges enter Daubert orders

POST-CONFERENCE WORKSHOPS

Thursday, October 8, 2020 (EDT)

A **8:00 AM – 11:30 AM**

Think Tank on State and Federal Pharmaceutical IP Antitrust Initiatives: Patent Settlements, Reverse Payments, and Emerging Legislation

Effective January 1, 2020, a new California law was enacted to curb reverse payment settlements by making these agreements more difficult to defend. To complicate matters further, competition authorities at both the state and federal level are engaging in extensive investigations of patent settlements between brand and generic companies, as well as other potentially anticompetitive behaviors.

In response, leading antitrust practitioners will discuss the finer points of federal and state pharmaceutical IP antitrust initiatives in the aftermath of the Supreme Court's seminal decision in *FTC v. Actavis*.

This think tank will focus on the considerable consequences that pharmaceutical companies entering into these types of settlement agreements may now incur on the state and federal level. You cannot afford to miss this. Topics of discussion include:

- Examining California's Reverse Payment Legislation and understanding how this first state law on this matter may influence other states
- Understanding how this law law dovetails with the multi-state coalition of state Attorneys General's price fixing lawsuit against various generic pharmaceutical companies
- Analyzing plaintiffs and state AG direct and indirect purchaser cases relative to reverse payment settlements
- Reviewing the proper standards of antitrust review and the rising call for a new legislative response
  - » Studying the current legislative and regulatory frameworks
  - » Analyzing the call from lawmakers for greater scrutiny of pharmaceutical mergers over antitrust concerns
  - » Understanding the implications of patent litigation settlement agreements being deemed presumptively anticompetitive
  - » Reviewing abuse of dominance court proceedings in relation to parallel trade of pharmaceuticals
  - » Evaluating product introduction strategies to better maintain life cycle management
  - » Examining government enforcement trends to better understand pricing strategies
- Avoiding costly litigation and associated penalties by effectively complying with the law
- Evaluating the recent FTC reporting findings that detail fewer anticompetitive deals in PIV settlements
- Examining questions of antitrust violation through improper device listings in Orange book in *In re Lantus Direct Purchaser Antitrust Litig.*, 18-2086, 2020 WL 728628 (1st Cir. Feb. 13, 2020)
- Reviewing biosimilars in the antitrust context
  - » Understanding settlement strategies between innovator biologic companies and biosimilar applicants
  - » Whether biologic manufacturers should expect antitrust scrutiny

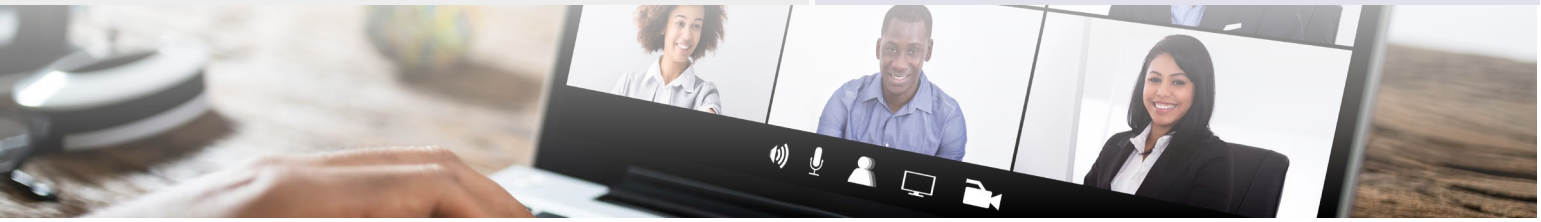
B **12:30 PM – 4:00 PM**

Working Group on IPR Strategies and Parallel Proceedings: Devising Winning Strategies for IPR Best Practices and Navigating Dual Forums in Hatch-Waxman Litigation

Parallel litigation in the District Court and PTAB in a Hatch-Waxman proceeding has become a way of life for life sciences patent litigators, adding to the "no-holds barred" atmosphere of this high stakes type of litigation. The art of navigating proceedings between 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 are still learning the evolving art of appearing before the PTAB. 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 with a special focus on IPR practice.

- Developing new strategies for parallel proceedings in the District Courts and PTAB in view of a single standard
  - » Weighing the future of parallel proceedings in view of a single standard adoption
- Considering the takeaways from the patent challenger's perspective in addition to the patentee perspective
- 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
- 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



Join the "who's who" of Hatch-Waxman litigators at the event that sets the standard for Paragraph IV practice.

2020 agenda features include:

SPOTLIGHT ON DELAWARE
A Conversation with **Chief Judge Stark** and **Chief Magistrate Judge Thynge**

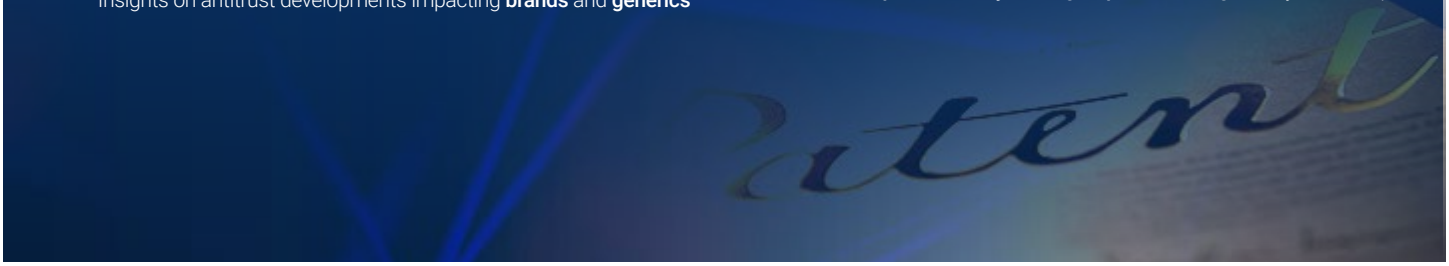
SPECIAL FOCUS SESSIONS ON THE PTAB
APJs Roundtable and advanced discussions on policy, practice, procedure, and the **Appointments Clause**

FTC KEYNOTE ADDRESS
Insights on antitrust developments impacting **brands** and **generics**

FDA THINK TANK
Initiatives impacting **drug access and litigation**

FOUR NEW BREAKOUT TRACKS
Featuring an In-House **Solutions Studio** and Litigators **War Room**

TWO INTERACTIVE WORKING GROUPS
Advanced discussions going beyond textbook theory to provide the **real and practical "at your fingertips" knowledge** that you will require



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As the current global situation continues to unfold, we understand that it may not be possible to attend our events in person.

At the same time, we also understand that collaboration is more vital than ever and for that, you can still rely on ACI to bring the industry together *but* in a different way. We are transforming quickly to ensure you can now connect virtually and continue to gain unparalleled access to market leading intelligence and to the facilitation of a global exchange of expertise. Our new virtual events continue to be guided by our unifying philosophy: we believe that growth and success occurs when the power of people and the power of information come together. We may not be able to gather in person, but nothing stops connection and innovation.

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BIOSIMILARS & INNOVATOR BIOLOGICS
September 23 – 24, 2020

FDA BOOT CAMP
September 23 – 24, 2020

LIFE SCIENCES IP DUE DILIGENCE
November 9 – 10, 2020

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