ACI
American Conference Institute

New Features for 2020:
- Exclusive Keynotes
- In-Depth Focused Sessions
- Extended Networking Opportunities

ACI's Hatch-Waxman SERIES

14th Annual

PARAGRAPH IV DISPUTES

Expert Strategies for Brand Names and Generics

August 20–21, 2020
Sheraton New York Times Square Hotel, NY
Attend Virtually via Livestreaming Available

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Co-Chairs

Brian Anderson
Formerly Vice President & Assistant General Counsel, IP Litigation
Allergan

"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."

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

"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."

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Grail Sipes
Deputy Center Director for Regulatory Policy, CDER
U.S. Food & Drug Administration

Maryll Toufanian (invited)
Drug Policy, CDER
U.S. Food & Drug Administration

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.**

Each spring 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 and studying key developments impacting both brands and generics, the 2020 agenda 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 for yet another productive conference!

Sincerely,

Brian Anderson
Formerly Vice President & Assistant General Counsel, IP Litigation
Allergan

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

Can't Join Us in-Person?

If you are unable to attend this important conference in-person, register to the Livestream option which will allow you attend virtually from anywhere.

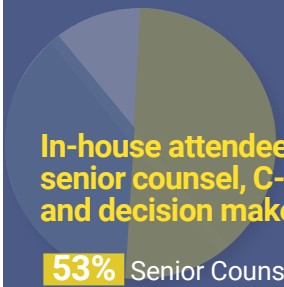
For more information, visit: AmericanConference.com/PIVDisputes/Livestream

Attend the Only Forum which Shapes the Law, Policy, and Proceedings of Paragraph IV Litigation

Network with Pharmaceutical IP Decision Makers

Numerous representatives from the TOP 50 brand name and generic drug companies* have attended ACI's conference on Paragraph IV Disputes since its inception in 2006.

* Source: pharmexec.com – *PharmExec's Top 50 Companies 2019*



In-house attendees comprised of senior counsel, C-suite executives, and decision makers:

53% Senior Counsel titles including: General Counsel, Corporate Counsel, IP Litigation Counsel

37% C-Suite Executives, Directors, VPs

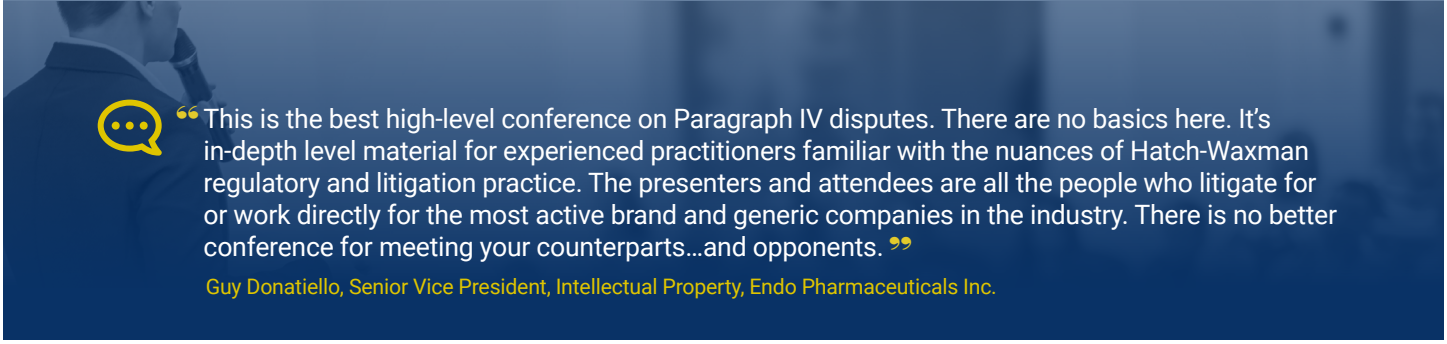
10% Senior Managers, Others

Benchmark with Your Peers in the Global Markets

3500+ attendees from the United States, in addition to the following countries since 2006:

- Canada
- China
- India
- Israel
- Japan
- South Korea
- United Kingdom

and many more.



> "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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AGENDA-AT-A-GLANCE

Main Conference Day One

Thursday, August 20, 2020

7:00 Breakfast & Registration

Closed Door Executive Breakfast with ACI'S Hatch-Waxman Series Advisory Board

(Limited to 25 Attendees – Application Required for Attendance)

8:00 Co-Chairs' Opening Remarks

8:15 PARAGRAPH IV STATE OF THE UNION

Strategic Legal and Economic Guidance in View of Regulatory and Jurisprudential Developments

9:00 The Continuing §101 Saga: Seeking Clarity from the PTO and the Courts on Patent Subject Matter Eligibility

10:00 Extended Networking Coffee Break

10:25 Special Remarks TBA

11:10 Assessing the Limitations and Prospects of Obviousness-Type Double Patenting

12:10 Networking Luncheon

1:10 THE DOCTRINE OF EQUIVALENTS

Analyzing the Effects of Recent Federal Circuit Decisions on Litigation Strategies

2:10 Extended Afternoon Networking Break

DAY ONE AFTERNOON TRACKS

TRACK A The Solution Room with ACI's Hatch-Waxman Series Advisory Board Members

2:40 Monitoring Legal Spend and Balancing the Paragraph IV Litigation Budget

3:30 Effectively Managing Global Pharmaceutical Patent Litigation

4:10 Practical Strategies and Tactics for Effective Settlement Negotiation

TRACK B Litigation War Room: The Practice of Paragraph IV with The Magistrate Judges

2:40 Understanding and Harnessing the Nuances of Local Rules

3:30 Evaluating the Effectiveness of Summary Judgment in Different Venues

4:10 Appreciating the Magistrate Judge's Role in Settlement Discussions

5:00 Focus on the PTAB

PART I A Matter of Constitutionality: The PTAB Appointment Clause and the Increased Responsibility of AIA Trials

PART II The APJs Speak on Practice, Policy and Procedure

6:00 Cocktail Reception Sponsored by: LOEB & LOEB LLP

Main Conference Day Two

Friday, August 21, 2020

7:00 Breakfast & Registration

8:00 Co-Chairs' Opening Remarks

8:15 Morning Roll Call with the District Judges

9:15 Morning Coffee 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

10:20 How the IP Team Can Present a Unified Front: Mastering Intradepartmental Communication

11:05 Diversity and Inclusion, Incorporation and Implementation: A Guide for Creating a Successful IP Team

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

9:30 Devising Strategies for Proving Infringement and Defending Validity

10:20 Advanced Pleadings Drafting: Choosing Claims and Defenses Wisely

11:05 Selecting and Effectively Using Expert Witnesses in Pharmaceutical Patent Litigation

11:55 FTC KEYNOTE

Antitrust Developments Impacting Brands & Generics

12:15 Networking Luncheon

1:15 FDA Think Tank on the Latest Regulatory Developments Impacting Hatch-Waxman

2:15 Extended Networking Break

2:45 ORANGE BOOK V. PURPLE BOOK

Comparing and Contrasting the Similarities and Differences Driving Efficiencies in PIV and BPCIA Litigation

3:45 INTERACTIVE ETHICS DRILLS

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

4:45 Conference Concludes

Pre-Conference Workshops

Wednesday, August 19, 2020

A 8:00–11:30
(Registration opens at 7:30 – Breakfast will be served)

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

B 12:30–4:00 (Registration opens at 12:00)

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

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

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Maryll Toufanian (invited)
Director, FDA Office of Generic Drug Policy, CDER
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PRE-CONFERENCE WORKSHOPS

Wednesday, August 19, 2020

A **8:00 AM – 11:30 AM**
(Registration opens at 7:30 AM – Breakfast will be served)

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
- 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**
(Registration opens at 12:00 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 away 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 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 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

MAIN CONFERENCE DAY ONE

Thursday, August 20, 2020

7:00 **Breakfast & Registration**

Closed Door Executive Breakfast with ACI'S Hatch-Waxman Series Advisory Board

(Limited to 25 Attendees – Application Required for Attendance)

8:00

Co-Chairs' Opening Remarks

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

Strategic Legal and Economic Guidance in View of Regulatory and Jurisprudential Developments

- Assessing Paragraph IV filing trends and district court decisions impacting the business and practice of ANDA litigation
  - » Surveying districts with the most ANDA case filings
  - » Analyzing the decline in new patent, PTAB and Paragraph IV filings in the district court and PTAB
    - ■ Comparing 2016 decline and slight 2018 uptick
  - » Leveraging precedent for a more effective litigation strategy
  - » Reviewing blocking patent developments and §112 advancements
  - » Identifying circumstances when settlement is advantageous during an IPR proceeding
    - ■ Assessing the resulting consequences at the District Court level
- 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
- Interpreting the October 2019 USPTO issued guidance on patent eligibility
  - » Evaluating the *Tillis-Coons* Senate bill on patent eligibility, the features of the current draft and the industry reaction
- Assessing the current state of proposed Hatch-Waxman reform measures affecting
  - » Exclusivities
  - » Citizens petitions
  - » *Inter Partes Reviews*
  - » Competition law
  - » Price controls and importation/reimportation

9:00

The Continuing §101 Saga: Seeking Clarity from the PTO and the Courts on Patent Subject Matter Eligibility

- Understanding the implications of the Supreme Court's denial of *cert.* in *Vanda*, *Berkheimer*, and *Athena*
- Analyzing the recent Federal Circuit decision that sought to provide consistency and predictability under § 101 in *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, No. 18-1763 (Fed. Cir. 2019)
  - » Evaluating the rationale behind striking down a patent owned by *American Axle* based on precedent established by the Supreme Court in *Alice*
  - » Revising the drafting practices of patent applications in the aftermath of the Federal Circuit decision
- Examining the recent USPTO guidance announced in October 2019 that reviews and expounds upon the Revised Patent Subject Matter Eligibility Guidance issued in January of 2019
  - » Understanding why the USPTO will no longer opt for the traditional case-comparison approach when determining whether a claim recited a judicial exception
  - » Identifying when a claim recites a practical application for the judicial exception
  - » Evaluating when appeals to the PTAB are appropriate under the PEG
- Anticipating whether Congress will act in light of the Supreme Court's denial of *cert.* to resolve these manufactured irregularities that hinder predictable outcomes under § 101
  - » Assessing the probability of true clarification of the patent eligibility standard

10:00 **Extended Networking Coffee Break**

10:25

Special Remarks TBA

11:10

Assessing the Limitations and Prospects of Obviousness-Type Double Patenting

- Deciphering the judicially created doctrine of OTDP and the policy rationale behind its creation
  - » Identifying potential limitations and advantages of OTDP
- Understanding how Federal Circuit OTDP decisions influence life sciences patent portfolio management
  - » *Ezra v. Novartis* and the relationship between OTDP and patent term extension
  - » *Novartis v. Breckenridge* and the relationship between OTDP and the order of patent expirations
- Analyzing the expansion of the OTDP doctrine after the *Sun Pharma* and *Gilead* line of cases
- Reviewing strategic direction for defeating OTDP rejections
- Evaluating how Hatch-Waxman practitioners can avoid terminal disclaimers

12:10 **Networking Luncheon**

1:10 **THE DOCTRINE OF EQUIVALENTS**

Analyzing the Effects of Recent Federal Circuit Decisions on Litigation Strategies

- Reviewing the efficacy of ensnarement when filing for summary judgment in view of the *Janssen* and *Jang* decisions
- Understanding when prosecution history estoppel bars a claim for infringement under the DoE after the *Pharma Tech* decision
- Applying effective advice for constructing a winning case for infringement
- Learning how to successfully defend against it claims of infringement
- Employing strategic guidance for narrowing claims at the USPTO
- Appreciating when the "disclosure-dedication" rule trumps infringement claims under the DoE

2:10 **Extended Afternoon Networking Break**

DAY ONE AFTERNOON TRACKS

	TRACK A	TRACK B
	The Solution Room with ACI's Hatch-Waxman Series Advisory Board Members	**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 v. 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

A Matter of Constitutionality: The PTAB Appointment Clause and the Increased Responsibility of AIA Trials

- Examining agency proceedings that consider the patentability of issued patent claims
- Analyzing the Federal Circuit opinion in *Arthrex* which held that the appointment of APJs violates the Appointments Clause of the Constitution
- Identifying the potential effect of the *Arthrex* decision on other IPR proceedings and APJ determinations
  - » Categorizing which cases must be vacated and remanded in view of the *Arthrex* decision

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

Cocktail Reception Sponsored by LOEB & LOEB LLP

MAIN CONFERENCE DAY TWO

Friday, August 21, 2020

7:00 **Breakfast & Registration**

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 Coffee 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
- 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 vulnerbabilties 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

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

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 **Networking Luncheon**

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
- 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 Networking Break**

2:45 **ORANGE BOOK V. PURPLE BOOK**

Comparing and Contrasting the Similarities and Differences Driving Efficiencies in Hatch-Waxman and BPCIA Litigation

- Weighing the patent provisions and procedures in the Hatch-Waxman Act and the BPCIA
  - » Reviewing the processes for resolving patent disputes
- Comparing the filing rated for AIA petitions challenging Orange Book patents v. Purple Book patents
- Analyzing the outcomes to instituted Orange Book-listed or biologic patents
- Contrasting FDA regulation of large molecule drugs and biological products

3:45 **INTERACTIVE 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**

C5 GROUP'S VIRTUAL EVENTS

Meeting Your Needs in Challenging Times

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.

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The livestream conference is designed for those who are not able to be in the room but wish to participate remotely by virtual format. With just a click, you can be part of the live conference without ever having to leave your home or office.

UPCOMING EVENTS:

BIOSIMILARS & INNOVATOR BIOLOGICS
September 23 – 24, 2020 • Boston, MA

FDA BOOT CAMP BOSTON EDITION
September 23 – 24, 2020 • Boston, MA

PARAGRAPH IV DISPUTES MASTER SYMPOSIUM
October 5 – 6, 2020 • Chicago, IL

LIFE SCIENCES IP DUE DILIGENCE
November 9 – 10, 2020 • Boston, MA

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Attend the conference that the "who's who" of Hatch-Waxman litigators have designated as the forum which sets the standards for Paragraph IV practice. The 2020 agenda features:

DISTRICT COURT INSIGHTS
Interactive discussions with District Court Judges and Magistrate Judges from **D.N.J.**; **D. Del.**; **E.D. Pa.**; **E.D. Tex.**

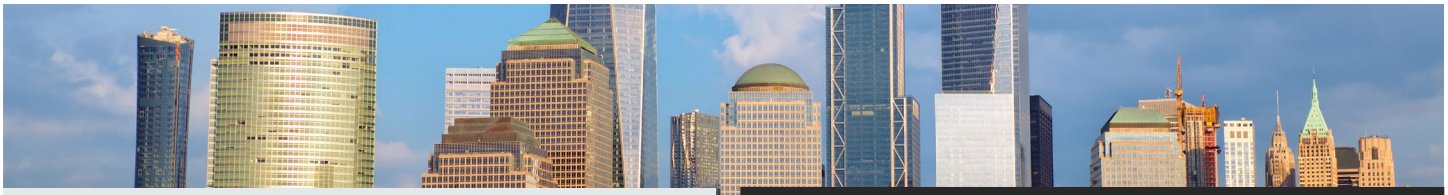
SPECIAL FOCUS SESSIONS ON THE PTAB
APJs Roundtable and advanced discussions on policy, practice, procedure, and the **Appointments Clause**

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**

EXTENDED NETWORKING BREAKS
Connect and **reconnect** with industry colleagues and establish new relationships



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