

 **AUGUST 20, 2020 EDT** •  **VIRTUAL CONFERENCE**



Paragraph IV on Virtual Trial COVID-19 Edition

Advanced Town Hall on COVID-19 Disruption and Critical Virtual Litigation Strategies

Discovery | 30-Month Stay | Motion Practice and Trial

The global pandemic has ushered in extraordinary roadblocks for the Hatch-Waxman community. Practitioners and litigants are battling with unforeseen hurdles as they navigate FDA approval schedules, filing deadlines, the 30-month stay, launch dates, and practicing law in the virtual courtroom.

In response, we are excited to introduce **ACI's Paragraph IV on Virtual Trial: COVID-19 Edition on August 20th.**

This new virtual conference will guide you through the many procedural dilemmas that ANDA litigators are experiencing as a result of the novel coronavirus **and provide solutions to coronavirus-related disruptions to Hatch-Waxman litigation.**

AGENDA



8:45

Co-Chair's Opening Remarks



Guy Donatiello
*Senior Vice President,
Intellectual Property*
Endo Pharmaceuticals



Josephine Liu
*Vice President of IP,
North America*
Sandoz

9:00

Fireside Chat with The Federal Circuit: Quarantine Edition



Hon. Kathleen M. O'Malley
United States Circuit Judge

INTERVIEWED BY:



Hon. Mary Pat Thyng
Chief Magistrate Judge
United States Federal District Court, District of Delaware

10:00

Finding Solutions to COVID-Related Pharmaceutical Patent Litigation Delays: Addressing Brand and Generic Concerns in the District Courts and at the PTAB



Chad A. Landmon
Partner
**Axinn, Veltrop &
Harkrider LLP**



**Mira Atanassova
Mulvaney**
Partner
Kirkland & Ellis LLP

- Examining how COVID-19 is causing havoc on ANDA litigation timetables established under Hatch-Waxman
- Exploring brand name and generic concerns about the probability and consequences of potentially tolling the 30-month stay in light of COVID court delays
- Assessing whether measures taken by the District of New Jersey and Delaware have been successful in mitigating COVID-19-related interruptions to ANDA litigation
- Looking at measures taken by the PTO relative to the extension of PTAB filings and proceedings under the CARES Act
 - » How this has impacted IPR proceedings as they relate to parallel proceedings and related stays

- Analyzing whether the use of virtual media, such as teleconferencing or web-related activity has been useful in mitigating litigation disruption
- Understanding the economic and business impact of COVID-related ANDA and other patent litigation delays on:
 - » Patent rights
 - » Generic entry/180-day exclusivity

10:45 Morning Break

11:15

Spotlight on the USPTO: Gauging the Impact of the Global Pandemic on the Patent Office and PTAB



Hon. Jacqueline D. Wright Bonilla
Deputy Chief Administrative Patent Judge
Patent Trial and Appeal Board, U.S. Patent and Trademark Office



Honorable Teresa Rea
Partner
Crowell & Moring LLP
Former Acting Under Secretary of Commerce for Intellectual Property and Former Acting Director of the United States Patent and Trademark Office

11:45

CASE STUDY on *Mitsubishi Tanabe Pharma Corp. v. Zydus*

Collaboration and COVID-19: Extending the Hatch-Waxman Automatic Stay



Bruce M. Wexler
Partner
Paul Hastings LLP



Donna Meuth
Associate General Counsel, IP
Eisai

1:00 Lunch Break

Welcome to the Virtual Courtroom: Navigating Paragraph IV Litigating from Home

While courts were already exploring virtual media for procedures such as conference calls, scheduling meetings, etc., the coronavirus forced traditional litigation into the virtual forum. Further, there is every indication given the efficiency as well as cost saving aspects of virtual litigation, that this trend may continue well after the time of a COVID cure. In this three-part series, leaders from industry will help you navigate this brave new world as it applies to ANDA litigation.

2:00

PART I: Virtual Discovery



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



Guy Donatiello
Senior Vice President,
Intellectual Property
Endo Pharmaceuticals



Gregory A. Morris
Partner
Honigman LLP

3:00

PART II: The Impact to Motion Practice



Stephanie L. Donahue
Principal Counsel,
Patent Litigation
Sanofi



Eric I Abraham
Partner
Hill Wallack LLP



William C. Baton
Partner
Saul Ewing Arnstein & Lehr

4:00

PART III: Virtual Trial and Adjudication



Christopher H. Strate
Director
Gibbons P.C.

5:00 Conference Concludes

SPECIAL DISCOUNT

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For more information on ACI's CLE process for virtual events visit: www.americanconference.com/accreditation-instructions-for-virtual-attendance/

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