







AN OVERVIEW OF SECTION 337 INVESTIGATIONS BEFORE THE U.S. INTERNATIONAL TRADE COMMISSION

Join us for an afternoon program introducing Section 337 and discussing developments in and finer points of Section 337 law and procedure. Learn how to use the statute to protect patented goods and other company IP assets from infringement by imported products and to remedy other unfair competition at the border, as well as how to defend fairly traded goods against actions brought under this statute.

Presented at

KLINE INSTITUTE OF TRIAL ADVOCACY, DREXEL UNIVERSITY THOMAS R. KLINE SCHOOL OF LAW

1200 Chestnut Street, Philadelphia 19107

by the

ITC TRIAL LAWYERS ASSOCIATION PHILADELPHIA INTELLECUAL PROPERTY LAW ASSOCIATION NEW JERSEY INTELLECTUAL PROPERTY LAW ASSOCIATION

September 17, 2019

Program 1:00 p.m. – 4:45 p.m. Reception 4:45 p.m. – 6:00 p.m.

REGISTRATION: http://www.itctla.org/upcoming-events/event/40

Cost: ITCTLA, PIPLA and NJIPLA members \$50.00

Non-members \$75.00

Law Students Free (with registration online)

For Information Contact: Tamara Winns at 202-675-8335 or TWinns@thegateam.com

Agenda below







AN OVERVIEW OF SECTION 337 INVESTIGATIONS AT THE U.S. INTERNATIONAL TRADE COMMISION

AGENDA

1:00 pm −1:25 pm Introductory Remarks

Jeffrey M. Telep, President, ITCTLA, King & Spalding LLP Professor Amy L. Landers, Thomas R. Kline School of Law

Sarah E. Hamblin

1:30 pm – 2:10 pm The ITC can provide a viable alternative or supplement to the "patent dance" of the Biologics Price Competition and Innovation Act ("BPCIA")

(a) The panel will discuss a number of reasons why Section 337 investigation can provide a viable alternative or supplement to the patent dance.

(b) While imported licensed biologics and biosimilars are viable candidates for Section 337 jurisdiction, there are further restrictions under which ITC jurisdiction can be obtained with respect to an unapproved biosimilar that is the subject of an Abbreviated New Biologics Application ("ABLA").

Moderator: Tony V. Pezzano, DLA Piper

Panelists: Veronica S. Ascarrunz, Morrison Foerster LLP

Goutam Patnaik, Pepper Hamilton LLP

Adam D. Swain, Alston & Bird

2:15 pm – 2:55 pm Remedy Issues in the High Tech and Bio-Pharma Spaces

(a) Available remedies

(b) Do remedies apply to electronic transmissions? What about components used in electronic transmissions?

The Grant transmissions:

(c) The Commission has not yet decided whether exclusion of a biologic or biosimilar product would be against the public interest. However, a number of public interest issues were outlined by the Commission in Recombinant Factor VIII Products (Inv. No. 337-TA-956) before this investigation settled.

(d) Post remedy considerations.

Moderator: Aarti Shah, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, PC

Panelists: Jeffrey Hsu, Supervisory Attorney, U.S. International Trade Commission

David F. Nickel, Foster, Murphy, Altman & Nickel, PC

Jamie D. Underwood, Latham & Watkins, LLP







3:00 pm - 3:15 pmBreak

3:15 pm - 3:55 pmEstablishing a domestic industry at the ITC

> *Under what circumstances can Research and Development be sufficient?* (a)

(b) What if all your manufacturing is abroad?

Do you have to demonstrate an injury to your domestic industry? (c)

Paul C. Goulet, Winston & Strawn LLP Moderator:

Panelists: Charles E. Bullock, Chief Administrative Law Judge, U.S. International Trade

Commission

Anthony Del Monaco, Finnegan, Henderson, Farabow, Garrett &

Dunner, LLP

Benjamin Levi, Levi & Snotherly, PLLC Matthew J. Rizzolo, Ropes & Gray LLP

4:00 pm - 4:40 pmEnforcement Issues in the High Tech and Bio-Pharma Spaces

> Strategies for Assisting Customs with its Enforcement of Section 337 Exclusion (a) **Orders**

Post-Exclusion Order Strategies/Procedures to Avoid Seizure/Obtain Release *(b)*

(c) ITC Enforcement, Modification, & Advisory Proceedings, including Effective *Use of Cease & Desist Orders and Design-Arounds*

Challenges in Monitoring Shipments in High-Tech and Bio-Pharma, including (d)

Use of Data Services & Update on Tracking Manifest Data

Steven M. Anzalone, Winston & Strawn LLP Moderator:

Panelists: Christopher Bullard, U.S. Customs and Border Protection

> G. Brian Busey, Morrison Foerster LLP Jeffrey M. Telep, King & Spalding LLP

Closing remarks 4:40-4:45 pm

4:45 pm - 6:00 pmReception