

Speaking Engagements | April 29, 2025 | 10:30 AM - 11:30 AM ET

## ACI 21st Annual Paragraph IV Disputes 2025

**The Altman Building**  
**135 West 18th Street**  
**New York, NY 10011**

### SPEAKERS

[Alan B. Clement](#)

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**Tuesday, April 29 • 10:30 – 11:30 a.m. ET**

Troutman Pepper Locke is proud to sponsor ACI's Paragraph IV Disputes Conference on April 29-30, 2025.

Partner Alan Clement will be speaking on "Charting the Evolving Boundaries of the Safe Harbor 35 USC § 271 in View of Recent Case Law," on April 29 at 10:30 a.m.

The panel will cover:

- Determining what is and is not shielded by the safe harbor following the Federal Circuit decision on *Edwards Lifesciences Corp. v. Meril Life Sciences Pvt. Ltd.*
  - Analyzing the broad interpretation of the term 'solely' for regulatory purposes and the implications for patent enforcement.
  - Exploring Brand and Generic perspectives on the scope of conduct covered by the safe harbor.
- Examining where safe harbor defenses are holding up and where they are being defeated.
  - *Allel Biotechnology & Pharm v. Regeneron Pharm.*
  - Protecting third party manufacturing activities for the purposes of filing an ANDA.
  - Comparing the US safe harbors for drug development with other key jurisdictions.

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