



The Current State of the Skinny Label Regime: Press Release Language, Marketing Materials, and the Liability for Insurance Companies

Location

Hyatt Regency Boston
 One Avenue de Lafayette
 Boston, MA 02111

Date & Time

Start Date: 06/28/2022
 Start Time: 11:45 a.m. ET
 End Time: 12:45 p.m. ET

Blake Coblentz will be speaking at the American Conference Institute's Biosimilars & Innovator Biologics conference. Subsequent to the Federal Circuit's skinny label ruling in *GSK v. Teva*, the District of Delaware in *Amarin v. Hikma* (D. Del. 2022) embraced a narrower approach in dismissing an induced infringement claim based on an allegedly inadequate skinny label carve out. The Delaware court also examined the novel question of whether a health insurer's formulary placement of the drug in question induced infringement of method-of-use patents. Further, confirming that without any bright line rules, and absent a decision from the U.S. Supreme Court or legislation, the fate of the skinny label remains in the balance.

- Considering whether the language of press releases, web pages and other marketing materials require more scrutiny
- Analyzing potential liability faced by insurers for placement of skinny label on formularies
 - Does liability exist for induced infringement by listing a skinny label on a formulary
 - Taking stock of the potential impact to patients
- Understanding when information can put you at risk for infringement claims regardless of labeling revisions have been approved by FDA as part of a skinny label

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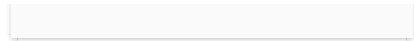


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