

insights

TYPES NOT MAPPED YET April 24, 2025 | TTR not mapped yet | Olga Berson, Ph.D.

Olga Berson Discusses Legislative Impact on Pharma Innovation and Risk

In a recent Life Sciences IP Review article, Thompson Coburn intellectual property partner [Olga Berson](#) shared insights on how bipartisan legislative efforts could impact drug development, amid concerns about reduced patent protections and greater litigation risks.

Proposals for innovation in pharma have already created hurdles by disadvantaging new products that are seen as “not innovative enough.” The measures, Olga said, introduce “new compliance and litigation risks for both branded and generic/biosimilar pharmaceutical companies.”

The Drug Competition Enhancement Act discourages pharmaceutical innovation by hindering the development of “follow-on” products, which include reformulations like new dosage forms, single enantiomers, and drug combinations. Olga said the risk is that “overreach could discourage legitimate reformulation efforts tied to clinical benefit.” In response, she said, legal and commercial teams should vet reformulation strategies for defensibility under the new framework.

Regarding the APPA bill targeting “patent thickets,” Olga said the bill may reduce the flexibility of branded or reference sponsors in claiming broad portfolios, while also creating uncertainty around how multi-claim patents will be treated. For biosimilar applicants, the same uncertainty may complicate early litigation strategy and delay clarity on the scope of disputes.

“Branded companies should re-examine how patent claims are structured—particularly claims related to delivery systems, method-of-use, and device components—to optimize protection under and beyond the 20-patent limit,” Olga said.

She added that portfolio planning “must be strategic, layered, and litigation-ready,” and biosimilar developers should work with IP counsel to identify potential gaps in the proposed cap and prepare for “broader-than-expected assertion strategies,” she said.

[Click here](#) to read the full article (subscription required).

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Olga Berson, Ph.D.