4 Legislative Proposals Reflect Growing Scrutiny Of Pharma IP

By **Olga Berson** (May 7, 2025)

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Bipartisan legislative momentum in Congress is signaling a renewed effort to address perceived abuses of pharmaceutical patents and pricing mechanisms. A recent package of bills advanced by the U.S. Senate Judiciary Committee reflects growing interest in curbing exclusivity strategies that delay generic and biosimilar competition.

While these measures target bad faith conduct, they also introduce meaningful strategic, compliance and litigation risks for branded companies, as well as biosimilar and generic drug companies. As these proposals move forward, industry stakeholders should begin reviewing how core business practices — particularly those around lifecycle management and portfolio strategy — may need to evolve.

This article outlines several key bills under consideration and highlights practical implications for companies and investors with interests in pharmaceutical innovation, biosimilar market entry and long-term IP value.

Key Legislative Proposals and Their Implications

The Drug Competition Enhancement Act

The Drug Competition Enhancement Act targets product hopping, a tactic in which branded manufacturers reformulate existing drugs — such as switching from a capsule to an extended-release tablet, substituting a racemic mixture with a single enantiomer, or combining previously marketed drugs — to delay or avoid generic entry.

While the legislation aims to eliminate abuse, it may also deter clinically meaningful reformulations, creating uncertainty around the viability of follow-on products. Legal and commercial teams should therefore reexamine reformulation strategies and ensure that justifications for product transitions are well-documented and capable of withstanding scrutiny under this evolving regulatory framework.

The Affordable Prescriptions for Patients Act

The Affordable Prescriptions for Patients Act seeks to limit the use of so-called patent thickets by capping the number of patents a reference product sponsor can assert in Biologics Price Competition and Innovation Act litigation.

However, its practical scope remains unclear. The proposed 20-patent limit applies only to litigation, not to the information exchange process known as the patent dance.

Additionally, method-of-use patents — those covering specific indications, dosing regimens, or routes of administration in therapeutic, diagnostic or prophylactic contexts — are expressly excluded.

The bill also does not address other commonly asserted claim types, such as device, kit, packaging or design claims. There is ambiguity around how multiclaim patents will be treated if only some claims fall within the cap or are asserted in litigation.

Moreover, since courts already tend to narrow BPCIA cases to fewer than 20 patents, the bill's actual impact may be limited unless clarified through rulemaking or litigation.

For reference sponsors, this bill may reduce flexibility in asserting broader portfolios and introduce ambiguity in how multiclaim patents will be treated. For biosimilar applicants, uncertainty around the scope and exceptions to the 20-patent cap may complicate litigation planning and delay clarity on the extent of disputes.

Branded companies should proactively review and, where appropriate, restructure their patent portfolios to maximize protection both within and beyond the proposed litigation cap.

Special attention should be given to device-related and method-of-use claims that may fall outside the 20-patent threshold. Strategic, layered and litigation-ready portfolio planning will be critical for maintaining market exclusivity.

Biosimilar developers should carefully identify potential exceptions and loopholes in the cap, and prepare for assertion strategies that may exceed its intended boundaries. Early-stage diligence and thorough landscape analysis will be essential to shaping litigation strategy, managing risk and informing settlement posture.

The Interagency Patent Coordination and Improvement Act

The Interagency Patent Coordination and Improvement Act proposes the formation of a formal task force to improve coordination between the U.S. Patent and Trademark Office and U.S. Food and Drug Administration in pharmaceutical patent matters.

While the objective is to enhance consistency and efficiency, increased coordination could lead to procedural delays or affect the timing of exclusivity determinations.

Furthermore, even minor discrepancies between regulatory and patent filings may receive heightened scrutiny, increasing the risk of delay or rejection. To mitigate these risks, regulatory and IP teams should closely align their submissions and disclosures to avoid inconsistencies that could raise flags during interagency review.

The Preserve Access to Affordable Generics and Biosimilars Act

The Preserve Access to Affordable Generics and Biosimilars Act targets pay-for-delay settlements in Hatch-Waxman Act litigation, seeking to restrict agreements that would delay the launch of lower-cost drugs.

If enacted, the bill could significantly constrain settlement flexibility and increase the cost, risk, and unpredictability of litigation. Companies should therefore reassess their current and future settlement approaches through an antitrust lens, ensuring that resolution structures are supported by documented, legitimate business justifications.

Strategic Compliance Priorities

Branded pharmaceutical companies should reevaluate their patent and lifecycle strategies to ensure they are defensible under the new legislative and antitrust scrutiny. Particular focus should be placed on product reformulation, follow-on indications and device claims.

Enhancing alignment between regulatory and IP disclosures will be key to reducing risk,

particularly under increased USPTO-FDA coordination. Companies should also be proactive in documenting the scientific and clinical rationale for all patent filings and citizen petitions to minimize exposure under potential new rules discouraging perceived abuse.

In the litigation context, companies will need to prepare for frameworks that may limit the number or type of patents that can be asserted. Developing fallback strategies — such as relying on broader claim types or method-of-use protections — will help preserve exclusivity if more restrictive limits are implemented.

For biosimilar and generic manufacturers, a more robust early-stage patent landscape analysis will be crucial to anticipating and navigating portfolios that may be narrowed but still strategically designed to maintain exclusivity.

These companies should also begin formulating litigation strategies that account for exceptions to the proposed 20-patent cap in APPA, including the uncertainty surrounding how multiclaim patents and excluded claim types will be treated. Close coordination between legal and regulatory teams will be essential to ensure timely and effective challenges to weak or nonessential patents during the patent dance and litigation phases.

Additionally, tracking Federal Trade Commission and FDA enforcement developments will allow companies to leverage new legislative tools to challenge anticompetitive behaviors, such as product hopping, pay-for-delay agreements and sham petitions.

The current legislative landscape signals a growing shift toward increased regulatory and policy scrutiny of life sciences IP strategies. For companies and investors alike, understanding how these proposals impact exclusivity timing and durability is critical — not only for compliance but also for long-term value creation, competitive strategy and innovation planning.

Whether you're advancing a biologics pipeline, preparing for biosimilar launch or conducting diligence on a new asset, now is the time to reassess your IP risk exposure and refine your strategic approach.

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