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How pharma should prep for the six-bill avalanche from Congress

The bipartisan legislative push could create big hurdles for drug development, with concerns mounting over limited patent protections and increased litigation risks, hears Marisa Woutersen.

The US pharmaceutical industry may soon face major regulatory changes as six bipartisan bills designed to rein in tactics that keep drug prices high and delay generic competition close in.

The Senate Judiciary Committee unanimously voted to advance all six of the bills at the beginning of this month, in an attempt to target long-criticised practices by branded drugmakers.

Led by committee chairman and Iowa Senator Chuck Grassley, the bills aim to end pay-for-delay deals, curb alleged abusive patent tactics like product hopping and patent thickets, and improve coordination between agencies like the US Patent and Trademark Office (USPTO) and the Food and Drug Administration (FDA).

They also target "sham" citizen petitions that delay generics and ensure the Federal Trade Commission (FTC) completes its review of pharmacy benefit management's impact on competition.

"Americans facing skyrocketing prescription drug costs are eager for Congress to act. It's why reducing prescription drug costs is one of my highest priorities," Grassley said following the vote.

"These bills will help shine a light on prescription drug pricing and clamp down on the abusive practices that continue to unfairly drive up drug costs for Iowans."

Regulatory changes ramp up pressure

The six bills are the Prescription Pricing for the People Act, Drug Competition Enhancement Act, Affordable Prescriptions for Patients Act (APPA), Interagency Patent Coordination and Improvement Act, Stop STALLING Act, and Preserve Access to Affordable Generics and Biosimilars Act.

President Donald Trump also signed an executive order, April 15, that outlined a revamp to pharma pricing policies and reverse what the administration called “setbacks” under the previous administration.

The order took aim at the Biden administration's Inflation Reduction Act, adding more pressure to the industry.

For pharmaceutical patent practitioners and life sciences execs, these proposed reforms and executive order could bring big changes to drug development, market exclusivity, drug pricing, and competition.

Concerns for patent system integrity

Chris Schott, partner at Latham & Watkins, highlights that the patent and licensing framework established by the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA) has long been the foundation for pharma innovation in the US.

However, his concern is that 30 years later, “the very patents that allow innovators to benefit from their inventions seem to be increasingly viewed as suspect. Many of the provisions in these bills appear to be motivated by that sentiment.”

Schott warns the proposals for innovation in pharma, noting that recent statutory provisions—often implemented through what he described as “overreaching guidance from the Centers for Medicare & Medicaid Services (CMS)”—have already created hurdles for innovation by looking to disadvantage new products that are seen as ‘not innovative enough’.

“One example is the so-called line extension concept, and another is how CMS has implemented the Inflation Reduction Act’s negotiation provisions (a euphemism for price capping and price controls),” he explains.

The measures, according to Olga Berson, partner at Thompson Coburn, introduce “new compliance and litigation risks for both branded and generic/biosimilar pharmaceutical companies”.

New bill ‘could stifle innovation’

Schott points specifically to the Drug Competition Enhancement Act as continuing the trend of making it harder to innovate, by discouraging the development of so-called “follow-on” products.

This bill aims to spur generic and biosimilar competition by banning brand-name drugmakers from using product hopping—a tactic where companies shift patients to a slightly changed version of a drug to avoid competition from generics when their exclusivity is ending.

This includes reformulations such as dosage forms, single enantiomers, and combinations of previously marketed drugs.

The risk, according to Berson, is that "overreach could discourage legitimate reformulation efforts tied to clinical benefit."

In response, she advises legal and commercial teams vet reformulation strategies for defensibility under the new framework.

Schott argues that protecting the patient access afforded by generics and biosimilars should "not come at the cost of limiting pharmaceutical innovation".

Instead, Congress should focus on "fixing the Inflation Reduction Act provisions that, in practice, have turned out to be true barriers to generics and biosimilars," he says.

Targeting patent thickets

Another of the bills, APPA, looks at preventing drugmakers from using "patent thickets"—layers of overlapping patents—to block competition.

It aims to clear a path for biosimilars to compete with branded drugs and lower prices for consumers.

Cole Schotz member Kumar Vinnakota notes that the bill looks to streamline the biosimilar "patent dance" that originator and biosimilar companies face in BPCIA litigations.

If enacted, the APPA would cap the number of reference product sponsor patents a brand-name drugmaker can use in BPCIA litigation at 20.

The exceptions in the proposed APPA bill may decrease the cost of BPCIA litigations, explains Vinnakota.

According to Berson, 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 optimise protection under and beyond the 20-patent limit," she advises.

Berson adds that portfolio planning "must be strategic, layered, and litigation-ready".

And biosimilar developers should work closely with IP counsel to identify potential gaps in the proposed cap and prepare for "broader-than-expected assertion strategies," she says.

Early diligence and a thorough patent landscape analysis, according to Berson, will be key to shaping litigation and settlement options.

Pharma should 'consider product classifications'

Schott advises pharma companies to closely consider whether upcoming products may be seen as line extension or follow-on products, and evaluate how this could impact patent protections, market entry, and compliance with federal programmes such as Medicaid, Medicare, and 340B.

Berson agrees, adding branded pharma companies should also better align their regulatory and IP disclosures to reduce risks under the increased USPTO-FDA coordination through the Interagency Patent Coordination and Improvement Act.

She also suggests documenting the scientific and clinical basis for all patent filings and citizen petitions to avoid ending up on the wrong side of new rules aimed at discouraging perceived abuse.

Additionally, companies should prepare for litigation frameworks that may limit patent assertions and develop backup strategies to maintain exclusivity, such as using broader claims or method-of-use protections.

Berson recommends that biosimilar and generic companies develop litigation strategies that anticipate exceptions to the proposed 20-patent limit under the APPA, including any potential ambiguity in how multi-claim patents and excluded claim types (eg, method-of-use, device, or packaging claims) will be treated.

Biosimilars and generics should also coordinate regulatory and legal teams to effectively challenge weak or non-essential patents during the patent dance and litigation phases.

News Americas Marisa Woutersen