Vital Briefing

Senate passes legislation addressing "patent thickets" that impede marketing of new biosimilars

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Legislation intended to speed the market entry of lower-cost biosimilar alternatives to branded biologic drugs passed the Senate by unanimous consent on July 21, 2026. The measure, titled "Affordable Prescriptions for Patients Act" (S. 1041), would place a limit on the number of patents a branded drug manufacturer can assert in the so-called "patent dance" against a competitor seeking to market biosimilars. According to the measure's sponsors, this limitation will help deter manufacturers from abusing the system established by the Biologics Price Competition and Innovation Act (BPCIA), while preserving incentives to encourage innovation. Importantly for branded drug makers, the limit would not apply to patents claiming certain methods for using the biologic drug.

Key Takeaways

If enacted, the Affordable Prescriptions for Patients Act (S. 1041) would:

- Amend BPCIA "patent dance" to limit patents asserted in biosimilar litigation.
- Allow courts to increase the patent limit when justified.
- Expand scope of biologics infringement to manufacturing methods/products.
- Preserve certain treatment-use patent claims.

Biosimilars. Biosimilars, unlike generics, are not exact copies of the original drug ("reference product"), but instead are highly similar, with any differences being clinically insignificant. They are designed to be as safe and effective as the original medication. A biosimilar is analogous to a generic drug for a small-molecule medication, but for a complex, biological drug. Biological drugs are more complex than small-molecule drugs, with a more intricate manufacturing procedure and a more rigorous and extensive approval process.

Statutory pathway for biosimilars. Congress amended the Public Health Service Act in 2010 via passage of the BPCIA, codified at 42 U.S.C. § 262, which created an abbreviated Food and Drug Administration approval pathway for biosimilar versions of complex biological drugs. This pathway was meant to provide for the quick resolution of patent litigation over the prospective introduction of biosimilars, in a similar fashion to the generic drug pathway provided under the Hatch-Waxman Act.

Under this process, the biologics connected to the applied-for biosimilars are referred to as "reference products," and their manufacturers are "sponsors." An application for FDA licensure of a biosimilar must include information showing that the biological product is similar to the reference product. Information submitted with the application must show that both the reference and biological products share the same mechanism of action, prescribed use conditions, and administration, dosage, and strength of the drugs. The Food and Drug Administration then evaluates the biological product and determines if it should be licensed.

The "patent dance." The BPCIA created a dispute resolution process commonly referred to as the "patent dance." Within 20 days after the FDA accepts the biosimilar application for review, an applicant must provide the reference product sponsor with the application and manufacturing-process information. The reference product sponsor then has 60 days to identify patents that it believes could reasonably be asserted and to identify patents it would be prepared to license. The applicant may also provide its own patent list. It must provide, for each listed patent, either a detailed claim-by-claim statement of invalidity, unenforceability, or noninfringement, or a statement that it will not commercially market before patent expiration. The reference product sponsor then submits its own detailed claim-by-claim infringement, validity, and enforceability positions. The parties are then to negotiate which patents will be the subject of an infringement action. If they fail to reach an agreement, the parties exchange litigation lists, with the statute limiting how many patents the sponsor may place on its list. The sponsor then is required to sue over the listed patents within a certain time period.

Patent thickets. The term "patent thicket" in the pharmaceutical industry refers to a large

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portfolio of overlapping patents held by a company to protect a branded drug against the market entry of generic or biosimilar versions. Use of patent thickets—which are primarily composed of continuation patents covering a single product or minor variations on a single product, such as tweaks to delivery mechanisms, dosages, and formulations—can effectively extend the market exclusivity of a drug beyond the original patent's expiration, thus increasing prescription drug costs and limiting patients' access to more affordable options.

Limit on patents asserted. To address the patent thicket problem, S. 1041 would amend Section 271(e) of the Patent Act, 35 U.S.C. § 271(e), to provide that a sponsor of an approved biologic that sues a biosimilar applicant for patent infringement generally may assert no more than 20 patents total and no more than 10 patents issued after the statutory patent-list exchange date in the "patent dance."

The limitation applies only to patents that:

- Claim the biological product itself;
- Claim a use of the biological product;
- Claim a manufacturing method or manufacturing product related to the biologic; and
- Are included on the patent lists exchanged during the "patent dance."

To be covered by the limitation, patents also must (1) have been filed more than four years after the reference biologic was approved or (2) claim manufacturing methods not actually used by the reference product sponsor.

Court discretion. S. 1041 would provide that a court may allow a sponsor to exceed the limit if the request is made without undue delay, and the interests of justice require it. Alternately, the court may increase the number if good cause is shown. Examples of good cause include:

- The biosimilar applicant fails to provide information that would enable the reference product sponsor to form a reasonable belief as to whether a claim of infringement could reasonably be asserted.
- There is a material change to the biosimilar or a process with respect to it.
- Patent Office delays caused a patent to issue later than it otherwise would have.

The court also may decide to increase the number of patents for other reasons that it considers good cause.

Further restrictions on the cap. The 20-patent limit applies only if the biosimilar applicant takes all the required notification and information-exchange actions specified in the "patent dance." Additionally, the limit does not apply to patents claiming a method for using the biological product in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use. As a result, some medical-use patents can still be litigated beyond the 20-patent limit.

Infringing acts. The bill also amends Section 271(e) to expand the scope of patent infringement triggered by a biosimilar application submission. A biosimilar filing would be deemed an act of infringement, if the bill becomes law, not only for patents claiming the biologic itself or its uses, but also for patents claiming (1) methods of using the biological product and (2) methods or products used to manufacture the biological product.

Practical impacts. If enacted, the measure would limit the ability of biologic drug makers to assert large numbers of patents in a single infringement case against a biosimilar applicant. At the same time, it would preserve their ability to assert important product, manufacturing, and treatment-use patents.

For biosimilar manufacturers, the legislation would reduce exposure to extensive patent-thicket litigation, potentially lowering litigation costs while accelerating market entry of biosimilars. As a practical note, it is critical that makers of biosimilars comply with information-sharing requirements to receive this protection.

Next steps. The bill is now before the House of Representatives. The measure's sponsors in the Senate have touted its virtues. "For too long, pharmaceutical companies have been allowed to abuse the patent system, stifling innovation and driving up costs for consumers," said bill sponsor Sen. Blumenthal (D-Conn.). "This legislation cracks down on drug companies' manipulative and exploitative practices, promoting competition and lowering prescription drug costs for patients."

The bill has bipartisan support, with sponsors on both sides of the aisle, and is likely to appeal to both parties in the House. Primary sponsor Sen. John Cornyn (R-Tex.) said, "By putting an end to the anti-competitive practice of patent thicketing, this legislation would encourage innovation, ensure generics can enter the market, and prevent prescription costs from increasing, and I urge the House to swiftly send it to President Trump's desk to become law."

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