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Senate Judiciary Committee Passes Bill Limiting the Number of Patents for BPCIA Litigation

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At a hearing on June 27, 2019, the Senate Judiciary Committee passed four separate bills aimed at pharmaceutical competition and pricing issues. One of those bills, the "Affordable Prescriptions for Patients Act of 2019" (S.1416), limits the number of patents that can be raised in litigation under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").[1] Senator John Cornyn, a co-sponsor of the bill, stated that, with this legislation, biosimilar "competitors would be able to resolve patent issues faster and focus on those patents that really matter the most," thereby resulting in "better competition and prices for patients."[2]

In this article, we outline the patent provisions of S.1416 and offer insight on its practical impact. The proposed legislation, which will now proceed to the full Senate for a vote, also codifies the Federal Trade Commission's powers to investigate alleged product-hopping schemes, which we will address in a future article.

BPCIA Patent Resolution Overview

A brief overview of the BPCIA's patent resolution process is useful to understand the import of the Judiciary Committee's bill. The BPCIA provides an abbreviated pathway to obtain FDA approval of a drug that is biosimilar to an approved large molecule biologic product.[3] Informed by the Hatch-Waxman Act governing the small molecule market, the start of patent litigation is accelerated under the BPCIA by making the submission of a biosimilar application an artificial act of infringement under Section 271(e) of the Patent Act.[4]

Central to the BPCIA is a two-phase litigation scheme for preparing to adjudicate, and then adjudicating, patent disputes between the maker of the biologic, i.e., the "reference product sponsor" ("RPS"), and the biosimilar applicant. After an application is filed with the FDA, the biosimilar provides the RPS its application and "other information" describing its manufacturing process to start what is colloquially referred to as the "patent dance."[5] Once triggered, the parties exchange patent lists and detailed contentions to identify a subset of patents for immediate litigation in the first phase.[6] The initial patent list, i.e., the "3A list," is provided by the RPS to the biosimilar and includes those patents for which it believes a claim of patent infringement could reasonably be asserted.[7] There is no limit on the types of patents an RPS can include on its 3A list. The second phase concerns patents not litigated in the first phase and is triggered when the biosimilar applicant gives the RPS notice at least 180 days before commercially marketing the biosimilar.[8]

In *Sandoz v. Amgen*, the Supreme Court ruled that the patent dance is optional.[9] A biosimilar applicant thus has a strategic option: trigger the patent dance and two-phase litigation scheme by providing its application and manufacturing information to the RPS, or decline to do so, thereby forcing the RPS to bring a declaratory judgement action for patent infringement. According to the Court, this framework to resolve patent disputes grants biosimilar applicants "substantial control" over the process.[10]

Key Provisions of Senate Bill 1416

The Affordable Prescriptions for Patients Act of 2019 (S.1416), as passed by the Committee, limits the number of certain patents that can be asserted in BPCIA litigation by amending Section 271(e) of the Patent Act.[11] More specifically, the proposed law states that, if the patent dance has been completed, an RPS "may assert in the action a total of not more than 20 patents of the type described in subparagraph (B), not more than 10 of which shall have issued after" the date the RPS provides its initial 3A list to the biosimilar applicant.[12] The type of patents in subparagraph (B), in turn, must meet each of the following requirements:[13]

- "Patents that claim the biological product that is the subject of a [biosimilar application] (or use of that product) or a method or product used in the manufacture of such biological product."
- "Patents that are included on the [RPS's 3A patent list, including supplemental listings of newly issued or licensed patents]."
- "Patents that—(I) have an actual filing date of more than 4 years after the date on which the reference product is approved; or (II) include a claim to a method in a manufacturing process that is not used by the [RPS]."

Despite this limitation, the legislation grants the court discretion to increase the number of such patents upon a showing of good cause or "if the interest of justice so requires."[14] As to the good cause provision, it "shall be established" if the biosimilar applicant fails to provide the RPS the required FDA application and manufacturing information that would enable the RPS to reasonably form an infringement analysis for its 3A list. Further, good cause to increase "may be established" if (1) there has been a "material change" to the biosimilar, (2) a later-issued or licensed patent would have issued in time for 3A listing but for Patent Office failures, or (3) another reason as deemed appropriate.

In an important carve out, any patent that claims "a method of using [a biological product] in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use," is exempt from the proposed legislation.[15] As such, the amendments to Section 271(e) appear to impact composition, formulation, and manufacturing patents.

Key Takeaways and Practical Considerations

If passed into law, S.1416 will impact strategic considerations for biologic and biosimilar companies alike. As an initial matter, the proposed legislation will play a significant role in a biosimilar applicant's decision about whether or not to engage in the patent dance, particularly in situations where an RPS maintains a portfolio of numerous patents falling within the scope of the limitation provision. If the patent portfolio is small in number or heavily focused on methods of use patents carved out of the bill, however, then biosimilars may be more likely to skip the patent dance and proceed straight to a declaratory judgment proceeding. In either scenario, the act further incentivizes companies to consider monitoring the issuance of patents to the RPS.

Under the current BPCIA framework, an in-depth understanding of the large molecule and its manufacture from a legal perspective before the patent dance is important. The proposed legislation would make that even more critical. Take, for example, the limitation provision applying to patents that "include a claim to a method in a manufacturing process that is not used by the [RPS]." Given the number of steps required to make a biologic product, as well as the reality that processes can change over a product's lifecycle, an RPS will need to have a full understanding of its patent portfolio and applicability to its own processes before providing a 3A list to a biosimilar applicant. In our experience, organization and advance preparation is essential.

Patent prosecution strategies for an RPS may also be impacted by S.1416. For instance, one can imagine a process patent that includes various dependent claims with different numerical limitations. Given the express language of the bill limiting patents that "include a claim" not practiced by the RPS, parties may argue that, if just one of the dependent claims include an unpracticed claim element, then the entire patent meets the limitation provision. Therefore, companies may benefit from increased collaboration between prosecution and litigation teams to balance the need for full patent protection while also considering how the claims would play in eventual BPCIA litigation.

Companies should also be cognizant of potential mechanisms to resolve disputes concerning the patent limitation provision. While the legislation aims to narrow the number of patents for litigation, the bill does not expressly articulate when, or how, a biosimilar applicant could challenge whether the RPS has included patents in a BPCIA case beyond the allowable scope (including patents that were not listed during the patent dance). And the practical reality of the likely need for discovery to allow the court to evaluate the issue could create problems for an early resolution of the dispute. It will be important for parties on both sides to strategize around this issue as part of their overall analysis of the patent dance and enforcement.

Yet another strategic point involves the amount of manufacturing information a biosimilar provides the RPS when it triggers the patent dance process. As noted above, an RPS may seek the court's discretion to increase the numbers of patents upon a showing of good cause, which "shall be established" if the biosimilar applicant fails to provide information required under the BPCIA that would enable the RPS to make a reasonable infringement assessment for its 3A list. The relevant provision, in turn, states that biosimilar applicants shall provide to the RPS the application and "such other information" that describes the biosimilars manufacturing process. These provisions may lead to more disputation about whether a biosimilar applicant has disclosed sufficient information to initiate the patent dance, including under S.1416's good cause provision.

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As we saw with the Hatch-Waxman Act, after its enactment, Congress continued to make modifications as issues were brought to light through litigation. Similarly, passage of the Affordable Prescriptions for Patients Act of 2019 reflects ongoing efforts by Congress to address the process for resolving biosimilar patent disputes. The next step for the bill is a vote by the full Senate followed by consideration in the House.✧ ✧ ✧

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If you have any questions concerning these developing issues, please do not hesitate to contact either of the following Paul Hastings New York lawyers:

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[1] Affordable Prescriptions for Patients Act of 2019, S.1416, 116th Cong. (as reported by S. Comm. on the Judiciary, June 27, 2019 with Cornyn Amendment) (hereinafter "S.1416"), *available at* https://www.judiciary.senate.gov/imo/media/doc/EHF19581.pdf.

[2] *Executive Business Meeting Before the Comm. on the Judiciary*, 116th Cong. (June 27, 2019) (statements of Sen. John Cornyn), *available at* https://www.judiciary.senate.gov/meetings/06/27/2019/executive-business-meeting.

[3] *See* 42 U.S.C. § 262(k).

[4] 35 U.S.C. § 271(e)(2)(C).

[5] 42 U.S.C. § 262(l)(2)(A).

[6] *Id.* at §§ 262(l)(3)-(7).

[7] *Id.* at § 262(l)(3)(A).

[8] *Id.* at § 262(l)(8).

[9] *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664 (2017).

[10] *Id.* at 1671.

[11] S.1416.

[12] *Id.* at pp. 14-18.

[13] *Id.* at pp. 15-16.

[14] *Id.* at pp. 16-17.

[15] *Id.* at 18.