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Senate Patent Bill To Boost Biosimilars Needs Work, Attys Say

By **Ryan Davis**

Law360 (March 8, 2019, 10:05 PM EST) -- A new Senate bill to create a patent framework for biosimilars akin to the Hatch-Waxman system for generic drugs could clarify the biosimilar approval process, but attorneys say it may conflict with current rules and likely won't curb the patent tactics its sponsors decry.

The Biologic Patent Transparency Act, S.659, was introduced Wednesday by Sen. Susan Collins, R-Maine, and a bipartisan group of five other senators. They said in a statement that the measure would "encourage competition in the prescription drug marketplace and put an end to the harmful patent strategies that block new drugs from coming to market."

The bill, pitched as a way to reduce drug costs, contains two main provisions. One would require makers of biologic drugs to list their patents with the U.S. Food and Drug Administration — similar to how patents must be listed for small-molecule pharmaceuticals under the Hatch-Waxman Act — and the other would put some restrictions on infringement litigation over those patents.

The sponsors say the legislation is aimed at curbing "patent thickets" of dozens or hundreds of patents that biologic-drug makers can use to deter competition from lower-priced biosimilars. However, the text of the measure does not "fulfill all the promises they're making with this proposed legislation," said Kevin Nelson of Schiff Hardin LLP.

"I think there's a good chance this goes forward, but I hope they make the necessary changes in order to shore up the intent that they do have for this legislation," he said.

Jeff Francer, general counsel for the generic-drug industry trade group the Association for Accessible Medicines, said the group "applauds" the bill and called it "a first step in addressing abuses of the patent system that unnecessarily delay generic and biosimilar competition and that keep drug prices unsustainably high."

A representative of Pharmaceutical Research and Manufacturers of America, the trade group for the branded drug industry, said the group is still reviewing the bill.

Traditional drugs, which are governed by the Hatch-Waxman Act, are manufactured in labs with small chemical molecules. Under Hatch-Waxman, makers of those small-molecule branded drugs are required to list the patents covering their products in an FDA publication called the Orange Book, which lets potential makers of generic versions of the drugs know which patents may be at issue when there is infringement litigation over their product.

The FDA's Purple Book lists information about large-molecule biologic drugs, which are medications that are made of large-protein molecules through complicated biotechnology processes. The Purple Book currently does not require patents covering the drugs to be listed, but the Senate bill would require that. Attorneys said the basic concept of transparency about patents would be a welcome change, though the bill's approach may need to be tweaked.

"The problem with the biosimilar pathway as compared to the Hatch-Waxman Act is that a company looking to go into it isn't sure of the patent barriers it's going to face," Nelson said, adding that a requirement for all patents to be publicly listed would be "a good first step because it attempts to recreate one of the good parts of Hatch-Waxman."

A central listing of patents on biologic drugs would give biosimilar makers more information about the patents they are up against. It could also allow them "to challenge weak or invalid patents earlier in the product development process," according to the senators' summary of the bill, possibly in inter partes reviews.

However, the bill's requirement to list patents up front seems to be in tension with the Biologics Price Competition and Innovation Act, the 2009 law that created an abbreviated pathway for biosimilar drugs, which requires the biologics maker and the biosimiliar maker to engage in a complex exchange of patent information known as the "patent dance."

Co-sponsor Sen. Mike Braun, R-Ind., said in a statement that the bill would "turn off the music on the so-called patent dance." But attorneys say that by requiring biologics makers to list their patents, the bill doesn't actually stop the dance, but rather adds or moves the steps.

"It is somewhat inconsistent with the patent dance that was contemplated when the BPCIA was adopted," said Paul Ainsworth of Sterne Kessler Goldstein & Fox PLLC.

Biosimilar makers will welcome more information about patents, he said, but biologic makers "might be a little annoyed that after a carefully negotiated BPCIA, they're changing the structure of the dance" and creating a new burden to identify patents in advance.

Rather than adding new requirements to the existing system, a better approach might have been to simplify the exchange of patent information, Nelson said. For instance, the biologics maker could allege certain of its patents are infringed and the biosimilar maker could respond, he said, noting that "it could be a much, much easier and more streamlined process."

The bill, therefore, may not simplify the biosimilar approval process the way sponsors suggest. It also could put biologics makers in a difficult position, since its disclosure requirements are broader than those in Hatch-Waxman, and the penalties for not complying could be severe.

The bill requires disclosure of all patents the holder believes could be asserted against the biosimilar. That includes patents on things like manufacturing processes, rather that just things like compounds and dosages under Hatch-Waxman. It also states that if a patent should have been on the list, but was not, the biologic maker cannot bring an infringement suit under the BPCIA on that patent.

Those proposed requirements will face opposition from biologics makers, said Ha Kung Wong of Venable LLP. While the basic concept of listing patents doesn't present any major issues, he said, the bill's approach "appears overly broad on the front end on what has to be listed and overly harsh on the back end as to what the downside is if you don't list it."

In the Hatch-Waxman Act, branded-drug makers who list their patents secure a 30-month stay of approval of generic competitors. The new bill doesn't include any similar incentive for biologics makers, Wong said, noting that "there's a little bit of give-and-take in Hatch-Waxman. There's no clear give-and-take here."

The actual text of the bill appears to fall short of the sponsors' promise that it would curb patent thickets and so-called "evergreening," where drugmakers obtain new patents on relatively minor changes like dosages in order to extend protection after the initial patents expire.

The senators' summary of the bill states that it "targets competition-stymieing patent thickets ... by restricting enforcement of patents that are issued after a biosimilar application has been submitted to the FDA." However, the text does not appear to do that, attorneys say.

The only reference to a restriction on infringement claims comes in the section that limits suits when patents are not listed with the FDA, and doesn't say anything about a biosimilar application being filed, Nelson said.

"While the intent might be that lawsuits can't be filed, it's unclear that they've actually put in the proper wording and legal structure to prohibit those lawsuits," he said.

The bill also states that the list of disclosed patents can be updated within 30 days of the date new patents are issued, which suggests that the bill would not do anything to stop biologics makers from obtaining additional patents.

Even if the bill were to explicitly prohibit suits on patents issued after a biosimilar application was filed, it's not clear that Congress has the authority to effectively render patents unenforceable based on such a quirk of timing, rather than anything to do with the patent itself.

"Everyone talks about evergreening, but at the end of the day the question is, is it a valid patent,

regardless of the commercial goals of that patent," Ainsworth said. He added that "there would be real concerns if they tried to declare a certain class of validly issued patents to be unenforceable."

More generally, while requiring patents on biologics to be listed with the FDA could bring more clarity to the process, it likely wouldn't really address the senators' core concern about dozens or hundreds of patents on the same drug making it difficult for biosimilars to enter the market.

"I disagree with the notion that this would somehow eliminate the problem of the patent thicket," Ainsworth said. "Just look in the Orange Book: There are lots of products out there that have dozens of Orange Book-listed patents."

Telling biologics owners they have to list all their patents or they can't sue over them doesn't solve that issue, Wong said: "It puts the problem on paper but hasn't made the problem any better."

With several bipartisan sponsors for the bill and widespread concern in Congress about high drug prices and patent strategies that limit generics or biosimilars, lawmakers will likely keep working on legislation on the issue, but it may ultimately look different from the bill that's been introduced.

"There's a little more work to do, so hopefully they'll work it out in committee," Nelson said.

--Editing by Kelly Duncan and Alanna Weissman.