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We Can Dance If We Want To, We Can Put Our Patents Online

By **Dani Kass**

Law360 (July 13, 2021, 9:39 PM EDT) -- Biologics companies must be more strategic than ever about whether to engage in the patent dance — an exchange of patent information before infringement litigation — now that a new law has gone into effect that would put the patent information online for the first time.

Since the Biologics Price Competition and Innovation Act went into effect in 2009, information shared during the patent dance was kept between the reference product sponsor and the biosimilar candidate until patents were asserted in litigation. But as of June 25, the information provided by the former now goes online in the U.S. Food and Drug Administration's Purple Book.

Attorneys say this new requirement will alter the calculations for both sides about whether to swap information, as the reference product maker wants to keep its patent information private and the biosimilar maker is interested in keeping the list away from competitors' eyes.

"I think it adds a layer of strategy and sophistication that you didn't have before, and it's a layer that's going to be important to both the reference product sponsor and biosimilar applicant," said Tim Shea, director of Sterne Kessler Goldstein & Fox PLLC.

With small-molecule drugs, patents have always been listed alongside drug information in the FDA's Orange Book, so generic-drug makers can see which patents cover the branded drug they're copying and what they could be sued over. The Hatch-Waxman Act also entitled the branded drug to an automatic stay of regulatory approval for the generic in certain circumstances — something biologics don't have.

The Purple Book, for biologics, had information like the date of the drug's approval, but not the patent information. The BPCIA, however, said it's up to the parties to engage in this patent dance, where they can elect to exchange information about patents covering the biologic ahead of entering into any litigation.

If the reference product sponsor doesn't engage in the patent dance, then the biosimilar maker is allowed to file declaratory judgment actions. If a patent is left out of the information exchanged, it can't be asserted.

But the Purple Book Continuity Act, passed in December, required patent information to be added starting in late June. The bill's sponsors had aimed to target high drug prices by helping lower-cost biosimilars get on the market, and otherwise increase transparency.

Unlike the Orange Book though, the Purple Book only lists patents once the reference product sponsor gives them to a biosimilar product maker in the patent dance. If the parties choose not to dance, or if the reference product sponsor waives the right to sue over certain patents, then the listing will not be wholly comprehensive.

"It's just such a seismic shift that both sides will first think, 'What does it mean that these patent lists are not kept confidential? What does this mean for us?'" said Caila Heyison of Choate Hall & Stewart LLP.

Heyison noted that this change will have a bigger effect on new biologics than on those that are already facing competition, since those patent lists have become public over time through litigation.

"This doesn't affect the biologics at issue in the first wave of biosimilar litigation — everyone knows what patents are out there," she said. "This is really only biologics that haven't been litigated."

When biosimilar makers are developing drugs, they are able to dig through patent listings and make their best guess about what may cover the product they're referencing, but it's not always simple, Sterne Kessler's Shea said. For example, some patents could be exclusively licensed without that license being publicly recorded, or a patent may be used across multiple products.

"It may be very difficult to know what patents are going to get asserted against you in that regard," Shea said.

Engaging in the patent dance makes the process easy, because now the biosimilar maker will know the full list of patents that could be asserted against it. However, with the patents going online, it means other biosimilar makers will also get access to that list.

"They're probably going to be your direct competitors," Shea said of those later companies.

The desire to keep patent information out of the hands of further competition may encourage parties to settle early, before they get to the patent dance stage, he added.

The reference product company may also choose not to show all its cards at once, Heyison said. For example, if the original biologic maker knows the first biosimilar is being made with a different purifying process than what it has patented, it wouldn't include those patents. That way, follow-on biosimilars wouldn't be able to design around all the known patents.

"If they don't want to broadcast all the patents that could be at issue so early, they may want to think more carefully about what they're going to put on their list," she said. "They wouldn't want to limit themselves, but they'd want to put a little more thought into what patents are going to be listed in the Purple Book."

Shea added that some clients just feel comfortable with the list of patents they've found on their own, and may want to skip the patent dance — which can take 250 days — and go straight to litigation to speed things up.

Foley & Lardner LLP partner Courtenay Brinckerhoff noted that in the end, companies are still going to proceed with developing products just as they did before, despite maybe having to adjust litigation tactics.

"[The Purple Book] might make it a little bit more transparent what patents are out there to be reckoned with, but I don't think it's going to change a biosimilar company's mind over whether they're going to develop a product or not," Brinckerhoff said.

--Editing by Robert Rudinger and Kelly Duncan.
