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3 Takeaways As Fed. Circ. Limits Biosimilar Lawsuits

By **Jeff Overley**

Law360, New York (December 14, 2017, 9:21 PM EST) -- The Federal Circuit on Thursday averted potential chaos by not letting drugmakers use a wide variety of state laws to extract biosimilar manufacturing information from rivals, and its ruling will turn attention to what sort of information rivals must provide under federal law.

Here are three takeaways from the eagerly awaited decision.

Ruling Removes 'Shadow' of State Law Liability

Thursday's ruling marked the latest interpretation of the Biologics Price Competition and Innovation Act, which governs biosimilar litigation and approvals. It found that Amgen Inc. can't wield state laws to punish Sandoz Inc. for not disclosing its biosimilar approval application and manufacturing information.

That question emerged after the U.S. Supreme Court in June said that the BPCIA can't be used to compel disclosure, but also left open the door to forced disclosure via state laws. Many observers urged the Federal Circuit to slam that door shut, with the U.S. Department of Justice warning that "allowing 50 states to provide additional remedies ... would undermine the uniformity of the federal scheme, subjecting [drugmakers] to different and potentially inconsistent state law remedies."

In Thursday's ruling, the Federal Circuit acknowledged that concern, writing that "compliance with the BPCIA's detailed regulatory regime in the shadow of 50 states' [various laws] could dramatically increase the burdens on biosimilar applicants."

Kevin Nelson, a partner at Schiff Hardin LLP, called the outcome "not all that surprising" in light of the federal government's traditional oversight of patent issues.

"The federal government has kind of occupied that area, and state laws, to the extent they're going to clash with it, they're going to go by the wayside," Nelson said.

Amgen had asserted that Sandoz waived its right to argue that state law remedies are preempted by the BPCIA because it didn't make that argument in district court. Notably, the Federal Circuit didn't push back too strongly against Amgen's assertion. Instead, it exercised its discretion to decide the preemption issue anyway, concluding that the matter was a "significant question of general impact or of great public concern."

Richard McCormick, a partner at Mayer Brown LLP, called the court's reasoning "pretty solid" on the waiver issue, given the far-reaching implications.

"The Federal Circuit didn't want to pass on an opportunity to rule on this, even though I guess it was arguable whether or not Sandoz had actually waived it," McCormick said.

'Next Battlefield' Is Information Disclosure

The BPCIA calls for biosimilar makers to disclose applications as part of the law's "patent dance" — a tightly regimented exchange of intellectual property information meant to encourage orderly patent litigation. After Thursday's ruling, drugmakers are likely to focus increasingly on what information must actually be exchanged.

The issue is unsettled because the BPCIA says that biosimilar makers should hand over their applications and "such other information that describes" their manufacturing processes. It's unclear what circumstances would require an application to be supplemented with additional information.

"There is an open question about whether 'such other information' is kind of folded into the [application], or whether it's something in addition," McCormick said.

That's important because the structure of litigation depends on whether the patent dance is fulfilled. If the dance is satisfied, a biosimilar maker has substantial control over which patents are litigated first. If the dance isn’t satisfied, an innovator can sue immediately for patent infringement on its own terms.

"I think that is kind of our next battlefield," Nelson said. "What sort of information needs to be exchanged in order for there to be good-faith compliance?"

In August, the Federal Circuit blocked an attempt by Amgen to get more information about a Pfizer Inc. biosimilar, saying that Amgen had avenues for doing so without court-ordered discovery. But it didn't resolve what the patent dance requires.

The question has been teed up in a pending battle involving Amgen's biosimilar of Genentech Inc.'s Avastin. In that case, Genentech has said that Amgen “refused to provide Genentech with anything except [its application]” and that Amgen therefore “is barred by statute” from proceeding with a declaratory judgment action that it filed in October.

'Moving Parts' Complicate Patent Dance Decisions

Thursday’s ruling means that biosimilar makers face a new calculus when deciding whether to participate in the patent dance. By removing the threat of state law remedies, including damages or an injunction, the Federal Circuit removed an incentive to participate.

But the calculus is still complicated. For one thing, despite various confidentiality provisions in the BPCIA, drugmakers sometimes remain wary of sharing proprietary information with rivals.

"There's always a concern when that information is released, even in the context of a protective order, that it can be misused or accidentally disclosed," Nelson said.

At the same time, if a biosimilar maker wants to take advantage of the patent dance, concerns about disclosure are probably unlikely, by themselves, to dissuade it from participating.

"If your only reason ... is we don't want to give up our manufacturing information, to me it doesn't seem to make sense that that would be what drives your decision to opt out of the dance," McCormick said.

Ultimately, attorneys say, a whole host of other factors come into play. They include a biosimilar's potential profitability, how soon the biosimilar can be launched, the number of patents that must be challenged, the strength of those patents, and whether a biosimilar maker is willing to do an at-risk launch without fully litigating unexpired patents.

"There's so many moving parts here," McCormick said. "It's kind of hard to get inside the minds of any particular biosimilar applicants."

U.S. Circuit Judges Alan D. Lourie, Pauline Newman and Raymond T. Chen sat on the panel for the Federal Circuit.

Sandoz is represented by Deanne E. Maynard, Joseph R. Palmore, Marc A. Hearron and Erik J. Olson of Morrison & Foerster LLP.

Amgen is represented by Nicholas Groombridge, Eric Alan Stone, Jennifer H. Wu, Jennifer Gordon, Peter Sandel and Arielle K. Linsey of Paul Weiss Rifkind Wharton & Garrison LLP, Vernon M. Winters of Sidley Austin LLP, and in-house counsel Wendy A. Whiteford, Lois M. Kwasigroch and Kimberlin L. Morley.

The cases are Amgen Inc. et al. v. Sandoz Inc., case number 15-1499, in the U.S. Court of Appeals for the Federal Circuit, and Amgen Inc. et al. v. Sandoz Inc. et al., case number 3:14-cv-04741, in the U.S. District Court for the Northern District of California.

--Editing by Mark Lebetkin and Katherine Rautenberg.