

Sandoz Seeks High Court Take On Biosimilar Law

By **Jeff Overley**

Law360, New York (February 17, 2016, 9:22 AM ET) -- Sandoz is seeking U.S. Supreme Court review of a milestone Federal Circuit ruling that found biosimilar makers must wait until their products receive U.S. Food and Drug Administration approval before providing 180-day advance notice of sales, the company said Wednesday.

The drugmaker petitioned the high court on Tuesday's deadline. The petition involves a legal fight with Amgen and applies to a ruling in which the Federal Circuit interpreted key provisions of the Biologics Price Competition and Innovation Act.

Sandoz argued that the circuit erred by finding that 180-day notice can only be supplied after approval. That finding effectively grants six months of extra exclusivity for no good reason, according to Sandoz.

"The Federal Circuit turned this mere notice provision into a grant of 180 days of additional exclusivity for all biological products beyond the exclusivity period Congress expressly provided — delaying the launch of all future biosimilars by six months," Sandoz's petition said.

According to the petition, the circuit also ignored an explicit BPCIA remedy for failing to provide notice — permission to file a patent suit — and handed down a 180-day injunction.

The Federal Circuit "disregarded the only remedy provided by Congress — the right to initiate patent litigation — and instead created its own extrastatutory injunctive remedy to bar the launch of FDA-approved biosimilars."

Paul Calvo, a director at Sterne Kessler Goldstein & Fox PLLC who is not involved in the case, told Law360 that Sandoz's petition appeared to reprise the company's prior arguments.

"I don't think there is anything particularly notable in Sandoz's petition that they haven't argued already," Calvo said.

But Sandoz did say that high court review is "urgently needed," an apparent effort to discourage justices from waiting for lower courts to flesh out the issues any further.

"The most important part of Sandoz's petition is the 'why now' section," Goodwin Procter LLP partner Willy Jay said. "Sandoz recognizes that the court can be reluctant to take an issue before it percolates, and has gone to great lengths to show the court that the Federal Circuit's ruling will make further percolation impossible and hold up every biosimilar launch."

However, the death of Justice Antonin Scalia may have made the high court wary of accepting major cases unless absolutely necessary, given the potential for ties until a

successor is confirmed.

"The possibility of a 4-4 split decision has increased dramatically, and that is not a good result for anyone," said Timothy J. Shea Jr., a director at Sterne Kessler. "So, I think this issue is another important factor that would make the court reluctant to take this case at this time."

Amgen previously declined to seek review of another part of the ruling that found biosimilar makers need not participate in the BPCIA's so-called patent dance, an exchange of intellectual property information. Sandoz's move, however, gives Amgen an opening to file a "conditional cross-petition" seeking review after all.

In a statement on Wednesday, Amgen said that it believes the Federal Circuit "properly applied the 180-day notice provision of the BPCIA." It didn't respond to a question about whether it now intends to submit a petition to the high court.

The Federal Circuit's ruling consisted of three partially overlapping opinions from three judges. Despite the fractured decision, the full circuit declined to revisit the outcome.

Notably, the Federal Circuit has subsequently moved on and is **hearing a case** between Amgen and Apotex, which are debating the impact of the ruling in Sandoz's case. The circuit has expedited briefing in the case, and it could rule in the next few months.

With that in mind, it's possible that the Supreme Court could ultimately consolidate the Amgen-Sandoz and Amgen-Apotex cases in hopes of resolving multiple issues, said Thomas H. Wintner, a member at Mintz Levin Cohn Ferris Glovsky and Popeo PC.

"A lot depends on timing," Wintner said.

Sandoz is represented by Morrison & Foerster LLP.

Amgen is represented by Sidley Austin LLP, Paul Weiss Rifkind Wharton & Garrison LLP and in-house counsel.

The case is Sandoz Inc. v. Amgen Inc. et al., case number 15A672, in the Supreme Court of the United States.

--Editing by Sarah Golin.