

## 3 Things To Watch After Sandoz's Biosimilars Win

By **Jeff Overley**

*Law360, New York (March 20, 2015, 6:33 PM ET)* -- Sandoz Inc.'s triumph over Amgen Inc. in the first big court fight over key provisions of the Biologics Price Competition and Innovation Act carries major implications for a coming wave of biosimilars and related litigation, attorneys say. Here are three things to watch in the aftermath.

### Is Court's Decision on Solid Ground?

Thursday's ruling from U.S. District Judge Richard Seeborg is headed to the Federal Circuit, and so it's possible that part or all of the decision could be reversed on appeal. But experts found little to criticize in the California federal judge's decision and suggested that Amgen faces an uphill climb to overturn it.

One hurdle for Amgen is that its argument places immense weight on a few words in the BPCIA, which is problematic because courts tend to take holistic views when it comes to statutory interpretation. For example, Amgen says that the word "shall" in one section of the law creates an absolute obligation to share information. In a separate section, Amgen says the presence of the word "licensed" means that biosimilars must win clearance before required marketing notices can be supplied to brand-name companies.

It's also true that Amgen's interpretation would delay biosimilars, an outcome contrary to the main purpose of the BPCIA and something judges can take into account when deciphering legislative language. With all that in mind, Sandoz appears to have the upper hand as the case moves to the circuit court level.

"Our consensus is that Sandoz's position is very strong and will be very defensible on appeal," said Andrew C. Ryan of Cantor Colburn LLP, an intellectual property boutique where attorneys have followed the case closely.

### How Many Biosimilars Will Follow Sandoz's Path?

Some aspects of Judge Seeborg's decision will help all biosimilars, including his conclusion that manufacturers don't have to wait for licenses before providing a 180-day notice of marketing plans to their brand-name rivals.

What's not clear is how often a central dispute in the case will apply to other products. Sandoz, after failing to reach an agreement with Amgen on confidentiality protections, declined to disclose its

application and manufacturing processes, a refusal that Judge Seeborg called permissible under the BPCIA.

The main benefit of that refusal is bypassing an information-exchange process, or "patent dance," that can take many months, allowing the parties to skip straight to patent infringement litigation that's all but inevitable.

But that only makes sense if the biosimilar is copying an old drug — such as Amgen's Neupogen, which Sandoz copied — with little or no remaining market exclusivity. Otherwise, exclusivity could still block a biosimilar, even if information exchanges were skipped and patent infringement litigation were resolved.

"It's very definitely going to be a case-by-case basis," Axinn Veltrop & Harkrider LLP counsel Stacie Ropka said. "You need to have sort of a perfect situation for this to pay off for the biosimilar maker."

### **Could Sandoz's Win Eventually Help Amgen?**

Just as many brand-name drugmakers have found ways to profit by selling traditional generics — especially so-called branded generics — so too are they expected to fatten their wallets by making biosimilars. Amgen, for one, has publicly announced plans for at least nine biosimilars, including a copy of AbbVie Inc.'s blockbuster Humira, as part of a portfolio that's set to launch in 2017.

With that in mind, Judge Seeborg's decision doesn't look like a total loss for brand-name companies. In the future, when they're the ones copying products, they'll be able to follow Sandoz's lead and quite possibly launch sales sooner than if Amgen had prevailed.

"It is possible that down the road Amgen may benefit from having lost in this particular go-round," Ropka said. "Stranger things have happened."

--Editing by Katherine Rautenberg and Mark Lebetkin.