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Biosimilar Rules Likely To Survive ACA Battle, Lawyers Say

By **Bill Wichert**

Law360, Newark (March 2, 2017, 10:34 PM EST) -- Amid the ongoing uncertainty over the future of the Affordable Care Act, its provisions for licensing biosimilar products will likely remain in place in light of concerns over escalating drug prices and the hard-fought battle leading to the regulations, lawyers said Thursday at a New Jersey symposium.

Given those pricing concerns — when a big payor is the federal government itself — there appears to be firm support for maintaining a pathway for lower-cost biosimilar drugs to get to market and compete with their more expensive counterparts, according to Brian Walsh, assistant general counsel of intellectual property at Bristol-Meyers Squibb Co.

"I would be shocked if it would be at risk of going away any time soon," said Walsh, referring to the biologic regulations, during a panel discussion at Thursday's "Hot Topics in Life Sciences Law" symposium at Seton Hall University School of Law in Newark.

The symposium was presented by Mayer Brown LLP and the university's Center for Health & Pharmaceutical Law & Policy.

The biologic-related provisions in the ACA — known as the Biologics Price Competition and Innovation Act of 2009 — created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" to or "interchangeable" with a biological product approved by the U.S. Food and Drug Administration.

The regulations also provide biologic innovators with 12 years of exclusivity from the approval date of the product.

As the moderator during Thursday's panel discussion, Mayer Brown LLP partner Lisa M. Ferri noted that biologic products – which treat cancer and various other diseases — represent "the highest growth rate within our pharmaceutical sector" and that the global market this year is estimated to be $255 billion.

"This is a very lucrative market for biologics producers and as well for biosimilar manufacturers," Ferri said.

Despite whatever happens with the ACA, the biologic provisions will likely emerge relatively unscathed, according to panelist and Mayer Brown partner Christopher M. Mikson.

Mikson recalled how when he was involved in efforts to craft earlier versions of the regulations, members of Congress were fighting over the exclusivity period, and different sides commissioned economic studies to justify their positions on the issue.

If lawmakers start tweaking the statute, “instead of moving forward with trying to implement it and trying to figure out what it means and trying to get biosimilars out on the market," Mikson said, "we might be buried again in that same process.”

“I don't think anyone wants to see that happen,” he added. “My sense is the administration certainly doesn't want to see that happen.”

Walsh later noted that companies still had chances to influence how the regulations are implemented, such as through citizen petitions.

“This is a new law,” Walsh said. “It's an opportunity to shape it moving forward.”

Thursday's panel also addressed the showdown before the U.S. Supreme Court between Sandoz and Amgen over a contentious Federal Circuit ruling on biologic regulations.

In addition to whether biosimilar makers must secure licensing approval before supplying 180-day notice of sales to rivals, as the Federal Circuit held, the Supreme Court is examining whether an information-exchange process, known as the patent dance, is mandatory. The Federal Circuit determined that it is optional.

Walsh said Thursday that a mandatory patent dance was needed to have “an organized, efficient process to...resolve patent disputes.”

--Additional reporting by Jeff Overley. Editing by Joe Phalon.
