Roger Kuan in Law360: 'Biosimilars Caught in Crosshairs of Supreme Court ACA Fight'

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PRACTICES Intellectual Property, Precision Medicine and Digital Health, Biosimilars

Haynes Boone Partner Roger Kuan was quoted in a *Law360* article about a case at the U.S. Supreme Court that challenges the Affordable Care Act (ACA), as well as a critical provision governing biosimilars.

Below is an excerpt:

The Biologics Price Competition and Innovation Act (BPCIA), which was passed as Title VII of the ACA, provides a regulatory pathway for similar or copycat versions of patent-protected biologics to get to market, comparable to the Hatch-Waxman Act for small-molecule drugs. If the entire act is found to be unconstitutional, then biosimilar makers will face increased hurdles to get approval.

Attorneys say there are several ways the case could go that keep them hopeful, and action from Congress is near guaranteed if the Supreme Court exercises the nuclear option. Their clients aren't making business decisions out of fear quite yet, but they are watching the case closely.

If the law does get struck down and the BPCIA isn't severed, attorneys seem positive Congress will pick it back up. The companies that make biosimilars are huge players in the pharmaceutical market and aren't likely to drop the issue.

Beyond changing the exclusivity period, biosimilar makers may push Congress to change the hurdles involved in getting their products approved, Haynes Boone Partner Roger Kuan told *Law360*.

All 28 biosimilars currently approved by the U.S. Food and Drug Administration have been cleared in a way that lets them be marketed alongside their corresponding biologic, but none of them has met the higher threshold to be considered interchangeable. As a result, pharmacists are unable to replace the original biologic with the theoretically cheaper biosimilar, as is possible with generic drugs.

"There isn't that same incentive now for the branded manufacturers to lower prices on their branded version," Kuan said. "Having BPCIA revoked and opening the possibility that there could be a recasting of the framework, and hopefully substitute legislation, may solve some of those issues."

Meanwhile, Kuan said he's seen a bit more urgency from clients.

"It makes these barriers to getting these biosimilars into the marketplace much higher and creates a lot of uncertainty," he said. "Any time you have those two pieces involved, biopharma companies are definitely concerned."

To read the full article, click here.