MedicalXpress

# Justices hear dispute over lower-cost biotech drugs sales

April 26 2017, by Sam Hananel

The Supreme Court on Wednesday considered a dispute between rival drug companies that could affect how quickly life-saving generic medicines are available to the public.

The case before the justices involves the cutting-edge field of biologics—drugs made from living cells instead of chemicals. The drugs have led to major advances in treating cancer and other diseases, but often come with a massive price tag.

A 2010 law allows cheaper generic versions known as biosimilars to be produced after a 12-year exclusive run for the original.

At issue is whether companies that make biosimilars must tack on an additional six months after gaining federal approval before they can sell the drugs. The extra time can mean billions of dollars in additional sales of original drugs before biosimilars enter the market.

Several of the justices seemed to side with California-based Amgen, which claims that rival Sandoz did not wait long enough before giving notice of its near-copy of Amgen's cancer drug Neupogen.

"We are being asked to interpret very technical provisions that I find somewhat ambiguous and I'm operating in a field I know nothing about," Justice Stephen Breyer said at one point during the 70-minute argument. "But it's going to have huge implications for the future."

The dispute involves the drug Zarxio, an alternative that Sandoz developed to compete with Neupogen that sells for about 15 percent less than the original product. The drug helps boost red blood cells in cancer patients.

Amgen sued Sandoz for patent infringement, claiming among other things that Sandoz violated the 2010 Biologics Price Competition and Innovation Act. That law requires biosimilar makers to give a six-month notice of sales to rivals.

A federal appeals court ruled in 2015 that the notice can't take place until after biosimilar makers gain approval from the Food and Drug Administration.

Sandoz, a unit of Swiss drug giant Novartis, says that reading of the law is wrong, and unfairly gives an additional six months of exclusive sales to the original drugmaker.

"That ruling will wrongly delay the marketing of every biosimilar," Sandoz's lawyer Deanne Maynard told the justices. She said Congress "would not have extended the 12-year exclusivity period in such a bizarre way."

But Justice Anthony Kennedy said it seems like the time has to start running from the date the biosimilar is licensed. And Chief Justice John Roberts said the original drugmaker would have trouble bringing a patent infringement case without knowing the specifics of the biosimilar.

"We don't even know what this thing is," he said.

The justices had fewer questions for Amgen's attorney, Seth Waxman. He argued that until the FDA determines the type of compound it's approving and what it can be used for "you can't give notice of

anything."

A ruling is expected by the end of June.