

Pharmaceutical & Life Sciences News

Amgen Kidney Drug Ruling May Expand Patent Protection

By Valerie Bauman

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- Federal Circuit vacates lower court ruling of non-infringement by Amneal
 - Court sets precedent on scope of Markush groups
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A Federal Circuit ruling giving Amgen Inc. another shot to prove Amneal Pharmaceuticals LLC infringed its patent for the kidney disease drug Sensipar could make it harder for generic drug makers to escape patent lawsuits.

The appeals court Jan. 7 vacated a ruling by the U.S. District Court for the District of Delaware that Amneal didn't infringe claims in Amgen's patent. The U.S. Court of Appeals for the Federal Circuit sent the case back to the lower court for further proceedings.

The decision offers new precedent that expands the protection of patent claims limited by Markush groups, said Aziz Burgy, an intellectual property attorney and partner at Axinn Veltrop & Harkrider. Markush groups list alternative elements that can be proprietary parts of an invention.

"It's going to make it more challenging for generic drug manufacturers to claim non-infringement when their basis of non-infringement is countenanced on a Markush group limitation," Burgy said. "It is seemingly swinging the pendulum toward the patentee."

Amgen, a biopharmaceutical company, sued Amneal, the Piramal Group, and Zydus Pharmaceuticals in an effort to block the three companies from bringing competing generic versions into the market.

The Federal Circuit affirmed the lower court's ruling that Piramal's product doesn't infringe claims of the Amgen patent, while finding Zydus—which cross-appealed for its own generic product—is infringing the claims.

Claims Defined

The list in a Markush claim is traditionally considered exclusive, meaning that, except in rare instances, if the allegedly infringing product includes an element that's not listed, there is no infringement.

At issue in the case was whether the phrase "consisting of" in the patent's claim construction meant that the language excludes any elements not specified in the two Markush recitations, said Charles L. Gholz, a patent attorney and senior counsel with Oblon.

By saying specifically that the drug consisted of certain disintegrants—ingredients that help a drug dissolve—and drug binders, which help bind active and nonactive ingredients together in a tablet formulation, the court had to decide whether Amgen left the door open for other companies to enter the market with their own variations, he said.

The Federal Circuit said that including the word "comprising" made clear that "the claim doesn't preclude the presence of components or steps that are in addition to, though not inconsistent with those recited in the limitations."

In addition, Amgen's claim included language that explained the formulation "comprises at least one component set forth in the Markush Group," said Kevin Noonan, a patent attorney and partner with McDonnell Boehnen Hulbert & Berghoff LLP in Chicago.

"The 'at least one' phrasing in conjunction with using 'comprising' with regard to the components of the formulation doesn't excuse an accused infringer who adds an additional component to the formulation that falls within the scope of one of the recited Markush groups," Noonan said.

Gholz said the decision will have a significant impact because it reverses the position taken by the lower court.

"A lot of people were in fact interpreting the earlier opinion that the alleged infringers were relying on as deciding this issue," he said. "Now it isn't any more. It's an important opinion."

The case is Amgen Inc. v. Amneal Pharm., Fed. Cir., No. 16-853, 1/7/20.

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