

Justices Skip Case Horizon Said Puts 32K Patents At Risk

By **Tiffany Hu**

Law360 (November 2, 2020, 6:47 PM EST) -- The U.S. Supreme Court on Monday refused to take up Horizon's argument that a divided Federal Circuit decision striking down part of its patented arthritis drug Pennsaid "casts a pall of uncertainty" over the validity of more than 32,000 patents.

The high court denied certiorari to Horizon over the Federal Circuit's ruling that its patents for Pennsaid were invalid as indefinite. The appeals court had ruled that when a patent claim uses the phrase "consisting essentially of," which is often found in patents, the written description must identify the patent's "basic and novel properties" or it is indefinite.

Horizon argued in a July petition for a writ of certiorari that the Federal Circuit's ruling flies in the face of the law because indefiniteness only deals with the claims of a patent, not the written description. The ruling creates a new rule that "casts a pall of uncertainty" over the validity of more than 32,000 patents that include the phrase in question, it said.

Generic drugmaker Actavis, for its part, responded that the Federal Circuit correctly applied the high court's 2014 *Nautilus* ruling to find that a skilled artisan could not reasonably tell whether an additional ingredient would affect the drug's "basic and novel" characteristics, making it indefinite.

"Yet Horizon takes ... the incredible position that the claim term 'consisting essentially of' can never be indefinite because it is 'a term of art with a definite legal definition,'" Actavis wrote. "That is a breathtakingly broad proposition, and it is flatly incorrect."

Counsel for the parties did not immediately return requests for comment Monday.

The high court's order closes the book on a case in which Horizon had accused Teva unit Actavis of infringing most of Horizon's patents for Pennsaid 2%, a topical formulation used to treat osteoarthritis of the knees.

A New Jersey federal court ruled that Actavis did not infringe most of Horizon's patents for Pennsaid and that several of the claims were invalid for being indefinite.

The Federal Circuit panel majority in October 2019 sided with the New Jersey judge's determination that the phrase "consisting essentially of" allows for the inclusion of components not listed in the patent, as long as they don't affect the invention's "basic and novel properties."

The majority also upheld the validity of a claim in one of Horizon's patents, however, effectively blocking Actavis from selling its generic until that patent expires in October 2027. The net sales for Horizon's Pennsaid were about \$200.8 million in fiscal year 2019, the company said in its annual report.

U.S. Circuit Judge Pauline Newman dissented from the panel's decision at the time, saying that the majority's holding that the phrase "consisting essentially of" is indefinite "casts countless patents into uncertainty" because those words are used in many patents. The full Federal Circuit **voted 8-4** not to rehear the case in February.

The patents at issue are U.S. Patent Nos. 8,217,078; 9,132,110; 8,618,164; 9,168,304; 9,168,305; 8,546,450; 9,101,591; 8,563,613; 9,220,784 ; 8,871,809; 8,252,838; and 9,066,913.

Horizon is represented by Robert F. Green, Caryn Borg-Breen, Jessica Tyrus Mackay and Benjamin D. Witte of Green Griffith & Borg-Breen LLP.

Actavis is represented by J.C. Rozendaal, Michael E. Joffre, Kristina Caggiano Kelly and William H. Milliken of Sterne Kessler Goldstein & Fox PLLC.

The case is HZNP Finance Ltd. et al. v. Actavis Laboratories UT Inc., case number 20-88, before the U.S. Supreme Court.

--Additional reporting by Ryan Davis. Editing by Steven Edelstone.