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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Justices Told Horizon's IP Loss 'Casts A Pall' On 32K Patents

By **Tiffany Hu**

Law360 (July 30, 2020, 9:47 PM EDT) -- Horizon is urging the U.S. Supreme Court to take up its appeal of a divided Federal Circuit decision that struck down part of its patented arthritis drug Pennsaid, saying the ruling "casts a pall of uncertainty" over the validity of tens of thousands of patents with similar phrasing.

In a July 24 petition for a writ of certiorari docketed Wednesday, Horizon told the justices that the Federal Circuit erred in **upholding** a New Jersey federal court's decision that several claims in Horizon's patents for Pennsaid were invalid for being indefinite. The appeals court had ruled that when a patent claim uses the phrase "consisting essentially of," the written description must identify the patent's "basic and novel properties" or it is indefinite.

But Horizon argued that this 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, it argued.

"The Federal Circuit's 8-4 majority deviates from decades-old established construction of 'consisting essentially of,'" Horizon wrote. "The majority articulates a new standard, which requires identification of 'basic and novel properties' for the purposes of evaluating them under the definiteness standard as if they were claim limitations. This was legal error."

Pennsaid is a topical formulation used to treat osteoarthritis of the knees. Horizon sued Teva Pharmaceuticals unit Actavis and others in late 2014, claiming that their planned generic versions of the drug infringe its patents.

In August 2016, the district judge **ruled** that some claims in five of Horizon's patents did not inform skilled artisans of the scope of the invention with "reasonable certainty," making them indefinite under the high court's Nautilus Inc. v. Biosig Instruments ruling.

The panel majority agreed in October, finding he was correct that "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.

U.S. Circuit Judge Pauline Newman dissented from the panel's decision at the time, saying 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.

One of the properties of the patent is a "better drying time" for Pennsaid, and the majority agreed with the judge that a skilled artisan would not know how to tell if it is "better," rendering the claim indefinite.

However, the majority also upheld the validity of a claim in one of the patents, effectively blocking Actavis from selling its generic until that patent expires in October 2027.

In February, the appeals court **rejected Horizon's petition for rehearing en banc** by a vote of 8-4. Judge Newman was again part of the dissent, joined by U.S. Circuit Judges Alan D. Lourie, Kathleen O'Malley and Kara F. Stoll. The judges argued that the majority incorrectly based its indefiniteness finding on the conclusion that the patent specification was inconsistent in how it defined "better drying time," a

purported advantage of the claimed invention.

Counsel for Horizon and a Teva spokeswoman did not immediately respond to requests for comment Thursday.

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.

Counsel for Actavis was not immediately available Thursday.

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 Alanna Weissman.
