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Fed. Circ. Casts Doubt On Novartis MS Drug PTAB Win

By **Britain Eakin**

Law360, Washington (January 9, 2020, 7:30 PM EST) -- A Federal Circuit panel appeared skeptical Thursday of Novartis' argument that the written description of a patent covering multiple sclerosis drug Gilenya doesn't need to explicitly say the treatment excludes a loading dose prior to starting a daily dose regimen.

The issue on appeal of a July 2018 Patent Trial and Appeal Board decision, which upheld the validity of a patent challenged by Apotex Inc., Argentum Pharmaceuticals LLC, Teva Pharmaceuticals USA Inc. and Sun Pharmaceuticals Industries Ltd., is whether Novartis Pharmaceuticals Corporation can claim a 2006 priority date for the patent.

The board held that it can, but Apotex and Argentum — the only PTAB petitioners still pursuing the appeal — contend that conclusion was wrong because Novartis amended the patent during prosecution in 2014 to specify that no loading dose should be given, and did so to get around an international patent application that disclosed a range of dosing regimens, including Novartis' dosage. A loading dose is an initial dose given to a patient that is generally larger than the daily dosage.

Apotex and Argentum's attorney, Teresa Stanek Rea of Crowell & Moring LLP, said the problem for Novartis is that its 2006 priority application for the patent doesn't disclose a dosing regimen or any reason to eliminate a loading dose. Rea contended that under the Federal Circuit's precedent, the patent's written description in the 2006 application must explain why no loading dose is required for Novartis to be able to claim that priority date.

Since there is no explanation in the 2006 application, Apotex and Argentum said Novartis can't claim a 2006 priority date and argued the panel should reverse the board and find the claims invalid as anticipated because a 2010 clinical study disclosed the claimed dosing regimen without a loading dose.

Novartis attorney Jane M. Love of Gibson Dunn & Crutcher LLP said that the patent is not required to contain literal support in the written description and that the test should be based on how a skilled artisan would perceive the information conveyed in the patent.

In this case, Love said a skilled artisan would have understood that a loading dose is excluded, in part because it could have the adverse effect of slowing a patient's heart rate.

U.S. Circuit Judge Jimmie V. Reyna pushed back on the assertion that a skilled artisan would

automatically understand that a loading dose should be excluded.

“Doesn’t that leave a person skilled in the art guessing … and searching for the needle in the haystack?” Judge Reyna asked.

Love said expert testimony during the PTAB proceedings backed up her contention.

U.S. Circuit Judge Kimberly A. Moore, meanwhile, said that none of that testimony pointed to language in the patent’s written description to explain how a skilled artisan would understand to exclude a loading dose, and one of the experts had testified that he would read the patent as not calling for a loading dose. The judge said there’s a difference between whether a daily dose implies the existence of a loading dose or excludes the possibility of one.

Love said it means excluding a loading dosage, but Judge Moore wasn't swayed.

“But it doesn’t mean you’re not giving anything else,” the judge said. “That’s what the testimony doesn’t seem to say to me.”

Novartis sued all of the PTAB petitioners for infringement in Delaware federal court, with a bench trial set to begin on March 2.

The patent-in-suit is U.S. Patent No. 9,187,405.

U.S. Circuit Judges Kimberly A. Moore, Alan D. Lourie and Jimmie V. Reyna sat on the panel.

Apotex and Argentum are represented by Teresa S. Rea of Crowell & Moring LLP.

Novartis is represented by Jane M. Love of Gibson Dunn & Crutcher LLP.

The case is Apotex Inc. v. Novartis Pharmaceuticals Corp., case number 18-2209, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Tiffany Hu. Editing by Jack Karp.