

Hold That Generic, Please: Supreme Court Grants Emergency Request to Stay Federal Circuit's Mandate

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In a rare action by the Supreme Court of the United States, Chief Justice Roberts granted Novartis's emergency request for a stay of a mandate from the US Court of Appeals for the Federal Circuit, which had found a Novartis patent invalid for lack of adequate written description and would have permitted generic versions of Novartis's multibillion-dollar blockbuster drug Gilenya to enter the market. For more information on the Federal Circuit's prior decisions, click [here](#) and [here](#). *Novartis Pharms. v. HEC Pharm. Co.*, Misc. Docket 21A272 (Supr. Ct. Sept. 29, 2022) (Roberts, Chief Justice).

Novartis sued HEC and several other generic companies for infringement of a patent directed to methods of treating remitting multiple sclerosis with fingolimod or a fingolimod salt at a daily dose of 0.5 mg without an immediately preceding loading dose. In a split panel decision issued in January 2022 and authored by former Judge O'Malley with current Chief Judge Moore dissenting, the Federal Circuit affirmed the district court's ruling that the patent was not invalid for insufficient written description of the claimed 0.5 mg daily dose or the no-loading dose negative limitation. HEC petitioned for panel rehearing. Judge O'Malley retired in March 2022, and a new panel granted HEC's petition. The new panel now included Judge Hughes, who joined with Chief Judge Moore in the majority opinion. Judge Linn (who had joined with now retired Judge O'Malley in the original panel majority) was now the dissenter. The split panel vacated its prior decision and reversed the district court's judgment. The new majority held that silence cannot support a later-added claim limitation that precludes loading doses. In dissent, Judge Linn argued that the majority applied a heightened written description standard requiring, not only a "reason to exclude," but also a showing that the negative limitation was "necessarily excluded."

On September 27, 2022, the Federal Circuit denied Novartis's motion to stay the mandate pending a forthcoming decision on a petition for *certiorari*. Novartis filed an emergency application directed to Chief Justice Roberts, and two days later Justice Roberts issued an Order staying issuance of the Federal Circuit mandate (which would have issued on October 4, 2022) and ordered HEC to respond to Novartis's emergency application.

Practice Note: The Supreme Court is currently considering another petition for *certiorari* resulting from a divided Federal Circuit decision on the question of whether a patent specification must expressly disclose a claim limitation to satisfy the written description requirement. [Juno Therapeutics](#).

[Inc. v. Kite Pharma., Inc., Case No. 21-1566.](#)

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