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## MEDIA & INVESTOR RELEASE

# Novartis plans to petition the U.S. Court of Appeals for the Federal Circuit for further review to uphold validity of the Gilenya® (fingolimod) dosing regimen patent

**Ad hoc announcement pursuant to Art. 53 LR**

**Basel, June 21, 2022** — Today, Novartis announced that the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a new, negative decision regarding the validity of US Patent No. 9,187,405, covering a dosing regimen for Gilenya. Novartis plans to file a petition seeking further review of this decision.

In August 2020, the U.S. District Court for the District of Delaware issued a favorable decision in the Gilenya patent litigation and a permanent injunction was granted against HEC Pharma until the expiration of the '405 patent in December 2027 (including pediatric exclusivity). HEC Pharma was the only remaining Abbreviated New Drug Application (ANDA) filer challenging this patent.

In January 2022, a three-judge panel of the CAFC issued a decision upholding the validity of the dosing regimen patent. HEC filed a petition for rehearing with the CAFC, which today issued a decision from a modified panel reversing its previous decision and now finding the patent invalid.

Novartis intends to vigorously defend the validity of the patent and is considering all available options, including current plans to seek review of this decision by the full CAFC, a process which may take several months.

Previously, Novartis entered into settlement agreements with a number of ANDA filers. Those ANDA filers will be able to launch a generic version of Gilenya on an agreed upon date that is prior to the expiration of the dosing regimen patent or earlier under certain circumstances. As the formal mandate closing the appeal process has not been issued from the CAFC, the permanent injunction granted against HEC remains in place and Novartis believes that HEC and other ANDA filers are not permitted to launch a generic version of Gilenya at this time.

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