

21-757 AMGEN INC. V. SANOFI

DECISION BELOW: 987 F.3d 1080

LOWER COURT CASE NUMBER: 2020-1074

QUESTION PRESENTED:

Section 112 of the Patent Act provides that a patent's "specification shall contain a written description of the invention, and of the manner and process of making and using it," sufficient "to enable any person skilled in the art * * * to make and use the" invention. 35 U.S.C. § 112(a). The requirement that the specification teach skilled artisans "to make and use" the invention is referred to as the "enablement" requirement. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996).

The questions presented are:

1. Whether enablement is "a question of fact to be determined by the jury," *Wood v. Underhill*, 46 U.S. (5 How.) 1, 4 (1846), as this Court has held, or "a question of law that [the court] review[s] without deference," Pet. App. 6a, as the Federal Circuit holds.

2. Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "*to reach the full scope* of claimed embodiments" without undue experimentation-i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "time and effort," Pet.App. 14a (emphasis added).

LIMITED TO QUESTION 2 PRESENTED BY THE PETITION

CERT. GRANTED 11/4/2022