

Broad Functional Claim Limitations Raise the Bar for Fulfilling Enablement Requirement

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Amgen Inc. v. Sanofi, No. 20-1074 (Fed. Cir. Feb. 11, 2021)

The patents at issue describe antibodies that purportedly bind to the PCSK9 protein and lower low-density lipoprotein (LDL) cholesterol levels by blocking the protein from binding to LDL receptors. The parties stipulated to infringement of certain claims, and the district court granted judgment as a matter of law (JMOL) of nonobviousness and no willful infringement. The alleged infringer appealed, and the Federal Circuit remanded for a new trial on issues of written description and enablement.

The alleged infringer again moved for JMOL and, in the alternative, a new trial, after a jury found that it failed to prove invalidity for lack of written description and enablement. The district court granted JMOL for lack of enablement but denied for lack of written description, as well as the motion for a new trial. The Federal Circuit affirmed.

Proving invalidity for lack of enablement requires clear and convincing evidence that a person having ordinary skill in the art (PHOSITA) would not be able to practice the claimed invention without “undue experimentation”—determined by weighing eight factual considerations (the *Wands* factors). Since *Wands*, the Federal Circuit has repeatedly explained that, for claims including functional requirements, the enablement inquiry can particularly focus on the breadth of such requirements, especially where predictability and guidance are insufficient.

Each appealed claim was a composition claim defined by meeting functional limitations, rather than by structure, and the specification did not enable preparation of the full scope of the claims without undue experimentation. The binding limitation was itself enough to require undue experimentation. The court was concerned not just with the number of embodiments but also their functional breadth, noting that using broad functional claim limitations raises the bar for enablement.

The amount of effort required to obtain embodiments beyond those disclosed is another consideration. Because the functional limitations were broad and the disclosed examples and guidance narrow, a reasonable jury could only conclude that substantial time and effort would be required to reach the full scope of claim embodiments.

Read the Federal Circuit’s opinion [here](#).

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