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# Supreme Court Affirms Federal Circuit's Decision in *Amgen v. Sanofi*

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This morning, the US Supreme Court issued its opinion in *Amgen v. Sanofi*, a closely watched case concerning patent law's enablement requirement. Under that requirement, codified at 35 U.S.C. § 112(a), a patent specification must enable a person skilled in the relevant art "to make and use" the invention. In a unanimous decision, the Court affirmed the Federal Circuit's ruling that the Amgen patent claims at issue are not enabled.

Those patents claim the entire genus of antibodies that bind to a particular region of a protein called PCSK9 and block PCSK9 from binding to LDL receptors. PCSK9 degrades LDL receptors when it binds to them, which in turn impairs the body's ability to remove LDL cholesterol from the bloodstream. The claimed antibodies are therefore useful in treating high cholesterol.

The patents' specification identifies the amino-acid sequence of 26 example antibodies that fall within the claimed genus and depicts the three-dimensional structure of two of those 26 antibodies. The specification further describes routine laboratory techniques that scientists can use to generate additional antibodies falling within the claims' scope. The parties agreed that the claimed genus extended well beyond the 26 examples recited in the specification—in other words, there are more antibodies other than those the patent describes that can bind to the desired region of PCSK9 and have the desired effect. The exact size of the genus, however, was hotly disputed. Amgen argued that only a few hundred antibodies fall within the claim scope, whereas Sanofi contended that the claimed genus might encompass millions of distinct antibodies.

The Federal Circuit held that Amgen's claims were not enabled as a matter of law, concluding that no reasonable juror could find that Amgen had provided sufficient guidance to allow skilled artisans to make and use the claimed genus of antibodies. The Supreme Court affirmed.

The Court began its analysis with a detailed description of three of its seminal enablement cases—*O'Reilly v. Morse*, which concerned Samuel Morse's telegraph patent, *The Incandescent Lamp Patent*, which concerned a patent on an electric lamp asserted against Thomas Edison, and *Holland Furniture v. Perkins Glue*, which concerned a patent on starch glue. These cases, the Court explained, stand for the proposition that, "[i]f a patent claims an entire class [i.e., genus] of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims."

The Court emphasized that the specification need not necessarily "describe with particularity how to make and use every single embodiment within a claimed class"; it can be sufficient simply to identify a "general quality" common to the claimed genus that "gives it a peculiar fitness for the particular purpose." And a specification may permissibly require the skilled artisan to do some experimentation to determine whether a given species

possesses that general quality, so long as the amount of experimentation is “reasonable.” “What is reasonable,” the Court explained, “will depend on the nature of the invention and the underlying art.”

Amgen’s patents, the Court held, do not pass muster under this standard. The patents describe only 26 antibodies but claim “a vast number of additional antibodies.” And the laboratory techniques that the patent identifies as allowing for the generation of the un-described antibodies, the Court concluded, “amount to little more than . . . research assignments” that would require “painstaking experimentation” and simple “trial and error” to successfully implement.

The Court did agree with Amgen “that enablement is not measured against the cumulative time and effort it takes to make every embodiment within a claim” and that genus claims are subject to the same enablement standards as other types of claims. But, the Court held, these principles did not save the claims at issue here, because Amgen had claimed a genus far beyond what it had described and had provided “little more than advice to engage in trial and error” to skilled artisans seeking to make other claimed embodiments. Finally, the Court dismissed Amgen’s policy arguments, concluding that “the proper balance between incentivizing inventors and ensuring the public receives the full benefit of their innovations is a policy judgment that belongs to Congress.”

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