

Supreme Court Upholds Patent Law Precedent

by Erik Nyre

The case of Amgen Inc. v. Sanofi, U.S., No. 21-757 dealt with patent law's "enablement" requirement. Essentially, the Court affirmed 150 years of precedent requiring the invention to be described "in such full, clear, concise, and exact terms as to enable any person skilled in the art' to 'make and use' the invention" notwithstanding that antibody technology is unlike any of the technologies in that precedent. Justice Gorsuch delivered the opinion for a unanimous Court.

Amgen's patents had broadly claimed all "antibodies that (1) bind to specific amino acids on a naturally occurring protein known as PCSK9, and (2) block PCSK9 from impairing the body's mechanism for removing . . . ["bad"] cholesterol from the bloodstream." The Court rejected Amgen's argument that disclosing a "roadmap" for identifying these antibodies, in combination with providing amino acid sequences for 26 of those antibodies, was sufficient for Amgen to claim to a genus, enlarged by "conservative substitution," encompassing "millions" of related antibodies.

In upholding the US Court of Appeals for the Federal Circuit's decision finding Amgen's patents invalid as a matter of law, the Court maintains an interpretation of enablement that requires patent applicants to disclose enough information to enable someone with expertise in the relevant field to make and use the invention. While the Court accepted the fact that, especially for antibodies, applicants need not specify every potential embodiment, they endorsed the idea that "the more one claims, the more one must enable."

Here, Amgen was attempting to expand the scope of their claim to encompass "millions of candidate" antibodies. While conceding that antibody technology "is thoroughly modern" in comparison to the precedent for the enablement requirement, the Court stated that "from the law's perspective Amgen's claims bear more than a passing resemblance to those this Court faced long ago."

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This decision is likely to have little effect on current best practices for drafting of antibody claims, which tends not to rely heavily on functional claiming. However, the decision is likely to force Applicants to spend more time thoroughly characterizing and disclosing as many alternative embodiments as possible. Indeed, one of the questions posed to Amgen during oral argument centered on why, if it is so easy to create and characterize the full scope of claimed antibodies, Amgen had not seen fit to sequence more than 26 of the hundreds of antibodies it had identified.