# Supreme Court Issues Patent Ruling Curbing Broad Functional Claims in Patents

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As Vorys previewed in January, 2023 is going to be an active year for the Supreme Court as it relates to issues concerning intellectual property. On Thursday, May 18, in addition to its decision in the Andy Warhol case, the Court also issued its unanimous ruling in *Amgen Inc. v. Sanofi*, which was a rare opportunity for the Court to consider the enablement requirement of 35 U.S.C. § 112.

**Background and Issues:** The case centers on Amgen Inc.'s patents for its cholesterol drug Repatha. Those patents broadly claimed patent protection over all antibodies that bind to specific amino acids to block a particular protein from impairing the body's ability to remove LDL cholesterol. Despite claiming patent protection over any antibody that performs this function, the specifications in Amgen's patents provided examples of only 26 such amino acid sequences—changing just one amino acid in the sequence can alter the antibody's structure and function.

After receiving its patents, Amgen sued Sanofi for infringement. Sanofi challenged the validity of Amgen's patents under 35 U.S.C. § 112. Section 112 is the enablement requirement, which provides that a patent applicant must describe the invention in such clear and complete terms so as to enable a person skilled in the art to make and use the invention. Sanofi argued—and both the district court and the Federal Circuit agreed—that Amgen failed to meet this standard because its patents claimed protection over potentially millions of antibodies that could perform the claimed functions, yet only taught those of skill in the art (*i.e.*, scientists) how to construct only 26 such amino acid sequences.

**Enablement:** After a lengthy review of late nineteenth and early twentieth century cases, which it found instructive, the Court indicated that the patent laws have provided a simple, consistent statutory command: "If a patent claims an entire class 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"—*i.e.*, "the specification must enable the full scope of the

invention as defined by its claims."

With this in mind, must a patentee always describe with particularity how to make and use every single embodiment within a claimed class? In short, the answer is no. For example, a patentee may provide an example or examples from the class, so long as the specification also discloses a general quality running through the class that gives it a particular fitness for a particular purpose. Similarly, a specification does not need to remove the need for any experimentation. Rather, a reasonable amount of experimentation to make a patented invention is acceptable, but what is considered reasonable will depend largely on the nature of the invention and the underlying art.

**Outcome:** The Supreme Court agreed with the lower courts that Amgen's patents fail to enable all that those patents claim, even allowing for a reasonable degree of experimentation. Amgen argued that scientists could make and use every undisclosed but functional antibody by simply following the company's roadmap or its list of conservative substitutions. The Court, however, disagreed and found, in essence, that an unreasonable amount of experimentation was necessary to make the claimed, but undisclosed antibodies.

**Moving Forward:** The Supreme Court reiterated on numerous occasions the following maxim: "[T]he more a party claims, the broader the monopoly it demands, the more it must enable." Broad, functional patent claims like those asserted by Amgen are fairly common for antibodies and other biotechnology inventions. In view of this decision and prior existing precedent, courts and the USPTO will now be asked to more closely evaluate whether the scope of the claims is consistent with the scope of the specification.

Please contact your Vorys attorney if you have any questions about the impact this ruling may have on your patent portfolio or patent litigation strategy.