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Ruling on Enablement Requirement of the Patent Act Has Wide Implications

On May 18, 2023, a unanimous U.S. Supreme Court decided *Amgen, Inc. v. Sanofi*, a case addressing the enablement requirement of the Patent Act, 35 U.S.C. § 112(a). Section 112(a) requires a patent specification to "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use" the invention. In a ruling that has significant implications, especially for the pharmaceutical, chemical and biotech fields, the Supreme Court held that to satisfy Section 112(a), a patent specification must enable the person skilled in the relevant art to make and use the *full scope* of the claimed invention. It further held that, while a specification may still be enabling if it requires a "reasonable degree of experimentation," a specification that requires "painstaking experimentation" is not.

The case involved a pair of "genus" patents held by petitioner Amgen, which were directed to antibodies that served to help reduce levels of low-density lipoprotein (LDL) cholesterol. Essentially, in the patents at issue, Amgen sought patent protection for broad classes of antibodies, which it defined by their functions: it claimed antibodies that would bind to specific amino acid residues on the protein known as PCSK9 and block PCSK9 in turn from binding to LDL receptors. Its patents identified the amino acid sequences of 26 particular antibodies that performed those two functions but claimed *all* antibodies that performed those functions, not just the 26 disclosed.

The Supreme Court held that Amgen's patent claims were not enabled. Hearkening back to the days of Samuel Morse's invention of the telegraph and Thomas Edison's tinkering with lamps, it held that "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." In other words, the Supreme Court said: "The more one claims, the more one must enable."

The Supreme Court was careful *not* to hold that a specification must always describe with particularity how to make and use every single embodiment in a class. A specification, it held, may call for "a reasonable amount of experimentation." What is "reasonable" in a given case, the Court held, depends on "the nature of the invention and the underlying art." What was *not* reasonable,

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though, was the experimentation required by the Amgen patents' specifications, which instructed persons of skill in the art to engage in what amounted to trial-and-error experimentation, either by generating a range of antibodies and testing them to see if they performed the claimed functions, or by starting with an antibody that *did* perform the claimed functions, replacing amino acids with other amino acids, and testing the result. The Supreme Court held those approaches "amount to little more than two research assignments," and so they did not satisfy Section 112(a), either.

Genus claims are not uncommon, particularly in the pharmaceutical, biotech, and chemical industries. Under *Amgen*, however, those claims are likely to invite intensive Section 112(a) scrutiny in the near future, as will the questions of just how much a patentee has to do in order to enable the full scope of a genus claim, and just how much experimentation is "reasonable."

Those with questions about the requirements of the Patent Act, patent specifications, or claims that may invite Section 112(a) scrutiny should contact Monica Mark, John Paul Kale or another Reinhart attorney.