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U.S. Supreme Court Requires Patents Seeking Broad Scope to Be Fully Enabled

In *Amgen Inc. v. Sanofi*, No. 21-757, 2023 WL 3511533 (U.S. May 18, 2023), the Supreme Court held that broad patent claims covering all antibodies that help reduce low-density lipoprotein (LDL), or "bad" cholesterol, by binding to a key protein in a certain way were not sufficiently enabled. In reaching this conclusion, the Court determined: "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 specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable." *Id.* at *9.

Background

Bad cholesterol has been a target of pharmacology—most notably, statins like Lipitor—for decades. Pharmaceutical companies, including Amgen and Sanofi, have recently developed antibody-based drugs that reduce LDL by binding to a naturally occurring protein called PCSK9. Each drug employs a distinct antibody with its own unique amino acid sequence, and each company obtained a patent protecting its unique antibody. Those patents were not at issue.

Amgen also obtained two other patents for such antibodies. Claims of these patents read much more broadly than on just the 26 antibodies whose amino acid sequences the patents disclosed. The Court described the patents as "claim[ing] a monopoly over 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 LDL cholesterol from the bloodstream." Amgen sued Sanofi for infringement of broad claims of the two patents.

The Enablement Requirement

Sanofi argued that Amgen's broad claims were invalid under 35 U.S.C. 112 "because Amgen had not enabled a person skilled in the art to make and use all of the antibodies that perform the two functions Amgen described in its claims." *Id*. at 6. Critical to Sanofi's argument is that, even today, antibodies are not fully understood because their properties depend not only on their amino acid sequence, but also on their three-dimensional shape. Amgen insisted that its claims were valid because its patents taught methods by which those skilled in the art could identify antibodies within the scope of the claims. Sanofi responded, however, that those methods "required scientists to engage in little more than a trial-and-error process of discovery."

Affirming the decisions of the lower courts, the Supreme Court held that Amgen's patent claims failed to meet the enablement standard because they sought to claim for Amgen the right to exclude others from "potentially millions more antibodies than the company had taught scientists to make." *Id*. at *3. The Court acknowledged that a broad genus claim may be enabled where the specification discloses "some general quality running through the class that gives it a peculiar fitness for the particular purpose," *id*. at *2 (cleaned up), and even that some degree of experimentation may be required, *id.* at *10, but concluded Amgen's disclosure was insufficient given the breadth of its claims. After all, "the more a party claims for itself, the more it must enable." *Id.* at *11.

What *Amgen* Means to You

Those drafting patent specifications must take care to disclose sufficient information to enable those skilled in the art to practice the full scope of the claims without undue experimentation. Because section 112 applies on a claim-by-claim basis, it may be wise to include narrower claims along with broader ones. In the wake of *Amgen*, many genus claims may be suspect.

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