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High Court Amgen Patent Ruling Promotes Medical Innovation

By **Irena Royzman** (May 22, 2023, 3:42 PM EDT)


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Last week, in Amgen Inc. v. Sanofi, the U.S. Supreme Court interpreted the patent enablement requirement for the first time in nearly a century.

In a unanimous opinion the Supreme Court sided with the judgment of the U.S. District Court for the District of Delaware and the U.S. Court of Appeals for the Federal Circuit, agreeing that Amgen's claims to antibodies that help reduce low-density lipoprotein or "bad" cholesterol encompassed potentially millions more antibodies than Amgen's patents taught scientists to make and were invalid for lack of enablement.

The Supreme Court's decision, the first to enforce the enablement requirement in a biotech setting, is enormously impactful. It provides meaningful guidance into what enablement requires and the relationship between claim scope and enablement, and explains the trouble with providing research assignments to other scientists to enable claims that encompass every therapeutic with a desired function.

The decision affects litigation, licensing and what patents are prepared. In rejecting claims that extend the patent monopoly far beyond the discovery actually made, the decision also promotes investment in research and development and invention of new, life-changing therapies.

The Enablement Requirement

The Supreme Court began its analysis with the statutory requirement for enablement and discussion of the "quid-pro-quo premise of patent law." The court explained that from the start, since the Patent Act of 1790, Congress required a patent to enable a skilled person to make and use the invention so that the public may have the "full benefit" of the invention once the patent expires. That is part of the bargain of the patent system and "foundation of the power to issue a patent."

The court then marshaled its 19th and early 20th century precedent to illustrate that the claimed invention, whether narrow or broad, must be enabled and the relationship between claim scope and enablement. It emphasized that "the specification must enable the full scope of the invention as defined by its claims." In other words, "[i]f 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." The court explained that Congress' directive and the court's precedents command that "[t]he more one claims, the more one must enable."

The court stressed that there is one universal enablement requirement. It is not higher or different for any area of technology. But, as recognized by the Federal Circuit for functional genus claims, "the more a party claims for itself the more it must enable."

The court discussed its cases involving a telegraph, incandescent light and glue to show that claims that are overbroad and would extend the patent monopoly far beyond the invention do not fulfill the enablement requirement and are invalid.

But the court explained that a specification does not need to "always [] describe with particularity how to make and use every single embodiment within a claimed class." Indeed, "an example (or a few examples)" may suffice if the specification discloses some "general quality [that] may reliably enable a person skilled in the art to make and use all of what is claimed, not merely a subset."

The court also explained that a specification is not necessarily inadequate if "some measure of adaptation or testing" is required and that the court's precedents allow for a "reasonable amount of experimentation to make and use a patented invention." Further, "[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art" and therefore remains a question of fact.

The court emphasized, however, that the "tolerance" for a reasonable amount of experimentation cannot detract from the statutory requirement that the specification enable the claimed invention.

Research Assignments Do Not Suffice

The Amgen patents at issue claim all antibodies by their function of binding to a naturally occurring therapeutic target, PCSK9, and blocking it from interfering with low-density lipoprotein, or LDL, receptors that remove cholesterol from the blood. The patents identify the amino acid sequence of 26 antibodies, but the claims are far broader; they encompass potentially millions of antibodies with the desired binding and blocking function, including those of other pharmaceutical innovators.

The court held that Amgen's broad, functional claims were invalid for the same reasons as in its earlier nonbiotech 19th and 20th century cases. The claims are "vast" and cover "at least millions of candidates." As the court put it, "Amgen seeks to claim 'sovereignty over [an] entire kingdom' of antibodies." It "seeks to monopolize an entire class of things defined by their function — every antibody that both binds to particular areas of the sweet spot of PCSK9 and blocks PCSK9 from binding to LDL receptors."

Amgen did not dispute that "it seeks to claim for itself an entire universe of antibodies." Instead, it argued that methods known in the art could be used to identify the antibodies within the scope of the claims.

The court disagreed. It held that Amgen's two approaches to enable the claims "amount to little more than two research assignments." The first approach merely describes Amgen's own "trial-and-error method for finding functional antibodies" and the second, conservative substitution, requires scientists to make substitutions and test them to see if they work.

The court noted that whether these approaches suffice in other contexts where the inventor identifies a quality common to every functional embodiment, they do not here. Here the research projects leave a scientist to engage in "'painstaking experimentation' to see what works." The court explained that is not

enablement; it is a hunting license.

The court also provided an analogy involving a combination lock with 100 tumblers from one of the amicus briefs, explaining that just because "random trial-and-error discovery" may hit on a successful lock combination or allow scientists to identify antibodies with the desired function that is not enablement. Random trial-and-error discovery does not enable others to make and use the claimed invention.

The court also rejected Amgen's argument that the Federal Circuit measured enablement against the cumulative time and effort it takes to make every embodiment within the claim. Rather, it explained that the Federal Circuit saw the same problem that the Supreme Court sees: "Amgen offers persons skilled in the art little more than advice to engage in 'trial and error.'"

The court explained that "Section 112 of the Patent Act reflects Congress's judgment that if an inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain." It enforced that statutory requirement in its unanimous affirmance of the Federal Circuit invalidating Amgen's claims.

The Implications Now and for the Future

The implications of the court's decision are wide-ranging — from what patents are prepared, litigated and licensed to the inventions that are pursued.

The decision encourages patent owners to prepare patents with more disclosure and more varied and diverse examples in order to enable the full scope of claims. It also encourages drafting patent claims that are narrower in scope and claims that avoid functional limitations.

The decision also repeatedly mentions commonality between embodiments and encourages claims that identify structural, instead of functional, commonality between the members of the claimed genus.

In addition to patent preparation, the court's decision will have a significant impact on litigation and licensing. It makes clear that overbroad, functional claims that attempt to control a therapeutic area are unlikely to survive in court or in proceedings before the Patent Trial and Appeal Board.

Issued patents, however, with such overbroad, functional claims and limited disclosure are common and have been asserted in litigation between pharmaceutical innovators and/or have been licensed to end or avoid litigation. The court's decision should discourage such lawsuits and the licensing of such patents, freeing resources for development of new therapeutics.

The court's decision also has long-term implications for medical innovation. Broad, functional claims that lay claim to a therapeutic target should not impede medical innovation. Just as Amgen's patents do not block marketing of future PCSK9 antibodies that others independently discover, the same should be the case for antibodies or other biotech inventions directed to the myriad other therapeutic targets.

The decision encourages competition and invention. Indeed, there is tremendous value to discovering new treatments that bind to the same, known target as they can be more effective or have fewer side effects. Instead of being impeded by non-enabled claims that lay claim to a therapeutic target, innovators big and small can invest in research and development and discover other and better therapeutics within the scope of non-enabled patent claims.

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