"The more one claims, the more one must enable" — Supreme Court confirms full scope enablement standard in *Amgen v. Sanofi*

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This month, the Supreme Court issued its opinion in *Amgen Inc. v. Sanofi*, the closely watched case involving the enablement standard for patent claims, particularly as applied to functionally defined genus claims. Genus claims are typically used in patents for biological, pharmaceutical, chemical technologies to cover an entire group of related chemicals, rather than one specific chemical.

The question raised by Amgen's petition was whether the U.S. Court of Appeals for the Federal Circuit's long-standing articulation of the enablement requirement — that the specification must enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation — exceeds the statutory requirement that the specification teach the skilled person to "make and use" the invention.

As foreshadowed by the tenor of the oral argument, the Supreme Court affirmed the Federal Circuit's articulation of the standard and confirmed that patent claims must be enabled to their full scope. *See* "Practitioners Mostly Agree Amgen Won't Be a Sea Change, But Some Predict Grim Consequences," IPWatchdog (March 28, 2023, 4:15 PM), https://bit.ly/3BXkuC8.

Background

Amgen developed the cholesterol drug Repatha®, an injection of monoclonal antibodies that reduce low-density lipoprotein ("LDL") or "bad" cholesterol. The antibodies bind to the PCSK9 protein, which prevents the destruction of receptors that extract cholesterol from the bloodstream. Amgen's U.S. Patent Nos. 8,829,165 and 8,859,741 functionally claim antibodies that bind to PCSK9 and block it from binding to LDL receptors, as illustrated by claim 1 of the '165 patent:

1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of [15 amino acid residues], and wherein the monoclonal antibody blocks binding of PCSK9 to [LDL receptors].

The patent specifications list 26 example antibodies and techniques for generating additional antibodies.

Sanofi/Regeneron separately developed the cholesterol drug Praulent®, which also binds to PCSK9 using different antibodies than Repatha. In 2015, Amgen filed suit alleging that Praulent infringes the '165 and '741 patents.

The district court found that the patents were invalid for lack of enablement and the Federal Circuit affirmed on appeal, noting that under its existing case law, broad functional claim limitations "pose high hurdles in fulfilling the enablement requirement."

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It further agreed with the district court that a person of ordinary skill would require "undue experimentation" to practice the invention under the factors put forth in *In re Wands* because, among other things, the scope of the claims cover "millions of antibody candidates" and the "invention is in an unpredictable field of science." The court concluded that "substantial time and effort would be required to reach the full scope of claimed embodiments." Amgen's petition followed.

The holding

Writing for a unanimous Court, Justice Neil Gorsuch relied on a series of Supreme Court opinions from the late 19th and early 20th century that address the enablement requirement.

First, in *O'Reilly v. Morse*, the Court held that a claim seeking to cover *all* means of achieving telegraphic communication using electricity was not enabled because, while Morse's patent had described some such means, it had not "described how to make and use them all." 15 How. 62, 113-14 (1853).

Second, in *Incandescent Lamp* the Court held that a claim to an "electric lamp" with an "'incandescing conductor'" made of

"'carbonized fibrous or textile material" was not enabled because "painstaking experimentation" was required to determine which fibrous and textile materials actually work. 159 U.S. 465, 475-46 (1895).

Finally, in *Holland Furniture Co. v. Perkins Glue Co.*, the Court held that a claim to a "starch glue" defined in terms of its function rather than "physical characteristics or chemical properties" was invalid for a lack of enablement. 277 U.S. 245, 258 (1928).

Summarizing, the Court found that its prior holdings in *Morse*, *Incandescent Lamp*, and *Holland Furniture* reinforce the principle that "[t]he more one claims, the more one must enable." *Amgen, Inc. v. Sanofi, et al.*, 598 U.S. ___, No 21-757, Slip Op. at 13 (2023). "In other words, the specification must enable the full scope of the invention as defined by its claims."

The Court made clear, however, that a patent specification can be enabling without describing "with particularity how to make and use every single embodiment within a claimed class" if, for example, it discloses "some general quality … running through" the class that gives it "a peculiar fitness for the particular purpose."

Furthermore, " a specification [is not] necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing." Although the Court did not discuss the Federal Circuit's use of the so-called *Wands* factors to determine how much experimentation is too much, it effectively affirmed that approach but stated that "a reasonable amount of experimentation" is permissible and that reasonableness "will depend on the nature of the invention and the underlying art."

Having confirmed the existing enablement standard, the Court turned to whether the '165 and '741 patents are enabled. Amgen argued that the specification provided a "roadmap" for persons of skill in the art to create and test a range of antibodies for efficacy in binding to PCSK9, as well as a method of "conservative substitution" of antibody candidates whereby a person of skill in the art can substitute a known antibody and test whether it works to bind to PCSK9.

The Court rejected these arguments, however, calling them "research assignments" and merely a description of "Amgen's own trial-and-error method for finding functional antibodies." The Court concluded that a scientist would be "forced to engage in 'painstaking experimentation' to see what works, and that the claims were consequently not enabled."

Finally, the Court turned to the public policy argument raised by Amgen and a number of amici that the "full scope" requirement applied by the Federal Circuit disincentivizes investment in breakthrough innovations. Without discussing the merits of the argument, the Court explained that "striking the proper balance between incentivizing inventors and ensuring the public receives the full benefit of their innovations is a policy judgment that belongs to Congress." In other words, it is for Congress rather than the Court to correct any misalignment between the costs and benefits flowing from the patent statute.

Impacts

The immediate impact of the Court's holding is to remove the uncertainty created when it granted Amgen's petition over the Solicitor General's recommendation. The Supreme Court has a history of admonishing the Federal Circuit for creating standards that exceed or are at odds with the patent statute, and the speculation was that the Court was gearing up to do the same here.

The holding may also provide innovators with more freedom to operate in the face of overly broad genus claims. Conversely, patentees are well-advised to continue the practice of claiming the specific embodiments they have developed in addition to filing broader genus claims, and further to give strong consideration to the specification disclosures required to support such genus claims.

In litigation, the opinion is already being cited, and may lead to more enablement challenges in technological fields other than life sciences where such challenges have not been particularly prevalent. But the Court noted the consistency of its cases involving enablement: over the past 150 years: "[t]oday's case may involve a new technology, but the legal principle is still the same."

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