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Legal Sidebar

Amgen v. Sanofi: Supreme Court Holds Patents Claiming Antibody Genus Invalid as Not Enabled

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In *Amgen v. Sanofi*, the Supreme Court held that Amgen's patent on a class of antibodies used to treat high cholesterol was invalid under patent law's *enablement* requirement. Justice Neil Gorsuch's unanimous opinion held that while Amgen could (and did) patent the specific antibodies it discovered, it could not patent an entire antibody class (known as a "genus") unless the patent disclosure contained enough technical information to enable a scientist skilled in the field to make and use every antibody in the genus with reasonable experimentation. On the facts, the Court held that Amgen's patents were not enabled because the techniques it offered to generate each of the potentially millions of antibodies in the claimed genus would not reliably yield a desired antibody without "painstaking experimentation."

Amgen has significant implications for patents on biological products (biologics) and for innovation and competition in the pharmaceutical industry. While *Amgen* strove to leave the blackletter law of patent enablement unaltered by relying heavily on its enablement precedents, its application of those cases to modern medical treatments will likely make it harder in practice to patent functionally described genus claims, particularly for biologics.

Legal and Factual Background

The dispute in *Amgen* concerns antibody treatments for high low-density lipoprotein (LDL) cholesterol, commonly called "bad" cholesterol because of its association with heart disease. Because a naturally occurring protein called PCSK9 binds to and degrades the body's LDL receptors—which extract LDL from the bloodstream—an antibody that inhibits (i.e., blocks) PCSK9 can be used to lower levels of LDL cholesterol.

In the early 2000s, scientists at Amgen developed a PCSK9 inhibitor known as Repatha (evolocumab), while Sanofi developed a different PCSK9-inhibiting antibody now marketed as Praluent (alirocumab). In 2011, Amgen obtained a patent claiming Repatha as described by its specific amino acid sequence, and Sanofi did the same for Praluent. Amgen also obtained patents claiming the broader genus of antibodies to

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which both Repatha and Praluent belong, that is, any antibody that (1) binds to a specific region of PCSK9 (the so-called "sweet spot"); and (2) inhibits PCSK9 from binding to LDL receptors.

Amgen subsequently sued Sanofi for patent infringement, alleging that Praluent infringed its genus patents. A jury found that Sanofi had infringed, but the district court held that the genus patents were invalid as a matter of law. Specifically, the lower court held that the genus claims were not "enabled" under 35 U.S.C. § 112, which requires the patent to describe the "manner and process of making and using [the invention] in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use" the patented invention. While Amgen's patents disclosed several dozen specific examples of antibodies in the claimed genus, the lower court ruled that producing the other antibodies in the genus would require either de novo discovery or a tedious "trial and error" process. On appeal, the Federal Circuit affirmed, agreeing that the patent was invalid because enabling the full scope of Amgen's claims required "undue experimentation."

The Supreme Court's Decision

Beginning with the Patent Act of 1790, Congress has required patent applicants to provide sufficient technical disclosures to enable others in the field to make and use the invention, so that the public may have the benefit of the invention after the patent expires. Justice Gorsuch's opinion in *Amgen* first reviewed the Court's applications of that enablement requirement in the Court's 19th- and 20th-century cases. In *O'Reilly v. Morse*, for example, the Court held that while Samuel Morse could patent the specific telegraphic systems he famously invented, he could not patent *all* means of using electric current for communication at a distance, because "he had not described how to make and use them all." Similarly, in the *Incandescent Lamp Patent* case, the Court invalidated a patent claim to an electric lamp using *any* "carbonized fibrous or textile material" as an incandescent conductor, because the patentee had not disclosed "a common quality" to all fibrous and textile substances that made them particularly suited to incandescent lighting (most such materials did not work at all). It was only later, through "painstaking experimentation," that Thomas Edison discovered that bamboo worked "brilliantly" for this purpose.

Applying these precedents to Amgen's patents, the Court did not doubt that Amgen's technical disclosure enabled the twenty-six antibodies its patents gave as examples; these were described not by their function (as PCSK9-inhibiting), but by their precise amino acid sequence. The genus claims presented "a challenge" for the Court, however, because "if [the Court's] cases teach anything, it is the more a party claims, the broader the monopoly it demands, the more it must enable." Here, as Amgen acknowledged, it sought to broadly claim "for itself an entire universe of antibodies" that perform a particular function.

The result in *Amgen* thus hinged on whether the two methods for antibody generation that Amgen described in its patents sufficed to enable the genus claims. The first method, which Amgen called the "roadmap," directs scientists to generate a range of candidate antibodies and then test them to determine whether they bind to the PCSK9 sweet spot and block PCSK9 from binding to LDL receptors. The second method, called "conservative substitution," directs scientists to start with a known antibody in the genus (e.g., one of the twenty-six antibodies that Amgen's patents describe by amino acid sequence), replace selected amino acids, and then test the resulting antibody to see if it is an effective PCSK9 inhibitor.

The Court found Amgen's methods to be no more than "two research assignments" that did not fully enable the genus claims. While not disputing that the two methods would theoretically create all antibodies in the genus, the Court characterized them as little more than "trial-and-error" processes. Key to the Court's conclusion was the "unpredictable" state of antibody science: a researcher would not know, without testing, whether the substitution of a particular amino acid in a known a PCSK9-inhibitor would change the resulting function. Because the Court found that making all the antibodies in the genus would thus require "painstaking experimentation," it held that Amgen's claims were invalid as not enabled.

The Court sought to tie its holding closely to particular facts of the case, noting that its opinion neither foreclosed genus claims in principle nor changed the legal bar for them. It also rejected Amgen's arguments that its ruling would undermine incentives to develop breakthrough therapies like PCSK9 inhibitors, insisting that those policy considerations were matters for Congress. The Court's only duty, it explained, was to faithfully apply the Patent Act's enablement requirement.

Considerations for Congress

Although the Court disavowed the consideration of policy implications in its decision, the legal line it drew in *Amgen* impacts the fundamental balance in patent law between encouraging innovation without unduly dampening competition or inhibiting follow-on innovation.

Critics of *Amgen* argue that it will undermine incentives to achieve "fundamental breakthroughs" in science, such as the discovery of an entire class of antibodies useful for treating disease. On this view, the fact that Amgen's innovation was "so important and fundamental" that it covered a lot of antibodies effectively undermined its patent claims, and the Court's ruling will create uncertainty as to whether innovators can actually patent all that they have invented. Other commentators critiqued the decision as reflecting an imperfect understanding of antibody science.

Supporters of the Court's decision argue that the ruling properly aligned the enablement requirement in the biotech field with its application to other technologies. On this view, the decision reflects "a growing emphasis on promoting innovation and competition by limiting the scope of patent monopolies," including "more focused and narrowly tailored [patent] claims." In colloquial terms, *Amgen* reflects a rule that "you get [a patent on] what you actually did, not what someone could do."

Federal patent law is a creation of Congress, and Congress could amend the Patent Act in response to *Amgen*, should it choose to. For example, Congress could consider adjusting the statutory enablement requirement, or explicitly permitting (or disallowing) the patenting of certain types of genus claims.

As a practical matter, companies are already altering their patenting and litigation strategies in response to *Amgen*. These changes include defendants invoking the decision to invalidate patents asserted against them; attempts to reissue existing patents to narrow genus claims in accord with *Amgen*; and changes to patent prosecution to provide more specific technical disclosure and include both broad and narrow claims.

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