Westlaw Today
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Why the *Amgen* case might be about more than enablement

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MAY 26, 2023

For months now, patent practitioners around the country have been closely watching *Amgen v. Sanofi*, a Supreme Court case concerning patent law's enablement requirement, codified at 35 U.S.C.A. § 112(a). The enablement requirement mandates that a patent specification describe "the invention" and "the manner and process of making and using it" with sufficient detail to "enable" a person with ordinary skill in the relevant field "to make and use" the invention.

Prior to the grant of certiorari in *Amgen*, the Supreme Court had not considered the enablement requirement in well over 50 years (since before the modern Patent Act was passed). The patent world — having no indication of how the modern Supreme Court might view enablement law — thus had to be prepared for anything.

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For those hoping for a sea change in enablement doctrine, however, the Court's unanimous decision may have come as somewhat of a disappointment. The Court affirmed the Federal Circuit's ruling that Amgen's patent claims at issue are not enabled and, in doing so, largely endorsed the approach to enablement that the court of appeals has been following for some time now. In some sense, then, the case ended with a whimper rather than a bang.

That is not to say, though, that the decision is not important — far from it. The decision is of course important for enablement law, because we now have a recent and definitive pronouncement from the Supreme Court on the legal standard. But the opinion's impact could reach far beyond enablement to other patent law doctrines as well. Indeed, it could alter the very edifice of patent law as we know it.

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To understand why, a bit of background on the case and the Court's opinion is in order. The patents at issue in *Amgen* claim a genus of antibodies that bind to a particular region of a protein called PCSK9 — referred to in the parties' briefing as the "sweet spot" — and thereby block PCSK9 from binding to LDL receptors.

PCSK9 degrades LDL receptors when it binds to them, which in turn impairs the body's ability to remove LDL cholesterol (the "bad" cholesterol) from the bloodstream. The claimed antibodies are useful in treating high cholesterol because they prevent PCSK9 from binding to LDL receptors and thus make it easier for the body to rid itself of harmful LDL cholesterol.

Antibodies can be described in multiple ways. The claims at issue in *Amgen* describe the antibodies *functionally* — that is, by what they do. Antibodies may also be described *structurally* in two ways relevant here.

First, they can be described by amino-acid sequence, which is referred to as "primary structure." Second, they may be described even more specifically by three-dimensional topography, which is referred to as "tertiary structure."

The patent specification at issue in *Amgen* describes the primary structure of 26 antibodies that have the claimed binding profile (i.e., antibodies that perform the claimed function), and it further describes the tertiary structure of two of those 26 antibodies. The specification also identifies routine laboratory techniques that scientists can use to generate additional antibodies that have the claimed binding profile.

Sanofi argued that Amgen's claims failed the enablement requirement because the specification's description of 26 example antibodies was insufficient to enable a skilled artisan to make and use the full scope of the claimed genus — a genus, Sanofi argued, that encompassed potentially millions of antibodies.

Sanofi contended that the laboratory techniques identified in the specification were insufficient for enablement purposes because they were effectively trial-and-error methods, such that a scientist using those methods to discover new antibodies with the claimed binding profiled would effectively have to redo the inventive work all over again.

The Supreme Court held that Amgen's claims were not enabled as a matter of law.

The Court premised its analysis on three of its own old enablement precedents, all of which concerned inventions from very different technological contexts:

- *O'Reilly v. Morse*,[1] which held invalid Samuel Morse's claim to all means of communication via electric current because Morse's specification described only one such method (the telegraph);

- *The Incandescent Lamp Patent*,[2] which held invalid a claim to an electric lamp with a conductor made of "carbonized fibrous or textile material" because the patent specification identified only one such conductor (carbonized paper); and
- *Holland Furniture v. Perkins Glue*,[3] which held invalid a claim to starch glues that "have substantially the same properties as animal glue" because the specification described only one particular starch (cassava starch) that made glue with the claimed properties.

"While the technologies in these older cases may seem a world away from the antibody treatments of today," the Court explained, "the decisions are no less instructive for it." The Court summed up its precedent as holding that a patent claiming a genus must enable the full scope of that genus: "[t]he more one claims, the more one must enable."

Relying on its equally old holdings in *Wood v. Underhill*[4] (an 1847 case involving claims to making bricks by mixing coal dust into clay) and *Minerals Separation v. Hyde*[5] (a 1916 case involving claims to separating metal from mineral ores), the Court emphasized that genus claims can be permissible in some circumstances.

Specifically, a patent can enable an entire genus by identifying a "general quality" common to the claimed genus that "gives it a peculiar fitness for the particular purpose," such that skilled artisans can determine whether a given species possesses that general quality with a "reasonable amount of experimentation." "What is reasonable," the Court explained, "will depend on the nature of the invention and the underlying art."

Amgen's patents, the Court held, do not satisfy this standard. The specification enables the 26 example antibodies described by primary structure, but it does not enable anything beyond that because the laboratory techniques identified in the patent are no more than "research assignments."

The Court specifically analogized Amgen's claims to those in *Morse*, *Incandescent Lamp*, and *Holland Furniture*: "Much as Morse sought to claim all telegraphic forms of communication, Sawyer and Man sought to claim all fibrous and textile materials for incandescence, and Perkins sought to claim all starch glues that work as well as animal glue for wood veneering, Amgen seeks to claim sovereignty over an entire kingdom of antibodies."

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The Court's reliance on these old precedents as the lynchpin of its analysis has subtle but potentially important implications. *Morse*, *Incandescent Lamp*, and *Holland Furniture* were decided in an era when many of the patent law doctrines that we now think of as entirely separate — for example, enablement, written description, subject-matter eligibility, indefiniteness, and claim construction — were more of a unified whole.

Morse, for example, is often viewed as a case about subject-matter eligibility, rather than enablement. One of the Supreme Court's seminal eligibility decisions — *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*[6] — cited *Morse* as standing for the proposition that natural laws are not eligible for patenting.

And the Federal Circuit has on numerous occasions characterized *Morse* as an eligibility case holding that a claim reciting a mere result, as opposed to a means of achieving that result, is not a patent-eligible "method."[7] Other Federal Circuit cases have characterized *Morse* as a written-description precedent.[8]

Or take the *Incandescent Lamp Patent*. The decision certainly contains language that would be right at home in today's enablement jurisprudence: only with "painstaking experimentation," the Court held, could a skilled artisan reading the patent at issue determine which "carbonized fibrous or textile material" would work best in a light bulb.

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But other passages in the opinion suggest that the problem with the patent was one of *indefiniteness*: Sawyer's and Man's claims were "too indefinite to be the subject of a valid monopoly."[9] And still other passages frame the issue as one of claim construction: the Court was unwilling to adopt a "construction of th[e] patent as would exclude competitors from making use of any fibrous or textile material."[10]

Finally, *Holland Furniture* — as with many enablement cases — could just as easily be characterized as a case about written description. The Court found that Perkins' patent contained an "insufficient" "description of the [claimed] invention" and therefore was invalid because it threatened to "extent the monopoly beyond the invention."[11]

And, like in *Incandescent Lamp Patent*, other language in the *Holland Furniture* opinion characterized the problem of the claims of one of vagueness and indefiniteness, rather than one of enablement.

The point of all this is not to suggest that *Morse, Incandescent Lamp*, and *Holland Furniture* are not enablement cases. They certainly are (not least because the Supreme Court has now said so). The point is that they can *also* be read as instructive on other patent law doctrines.

Now that *Amgen* has breathed new life into these old cases, it is possible those precedents will begin to inform courts' analysis of those other doctrines. And if courts begin citing these cases as authority for the proper application of the law on written description, eligibility, indefiniteness, and so on — doctrines now viewed as entirely distinct — those doctrines may begin to merge or, at the very least, overlap.

That would leave us with a very different state of affairs than we currently enjoy, where the Federal Circuit applies quite different legal standards to each of the doctrines discussed above.[12]

Given that Morse's attempt to patent electromagnetism plays such a significant role here, the author will hopefully be forgiven for

closing with a physics analogy. At the time of the Big Bang, it's said, the four fundamental forces — gravity, the strong nuclear force, the weak nuclear force, and electromagnetism — were united as one.

As the universe expanded, gravity split off from the other forces, and then the strong force split as well, and then the weak, until we were left with the physics we know today. And now physicists search for a theory that would unify those four forces to explain the physics that might have existed when our universe began.

As it goes with physics, so it goes with patent law (or something like that). Perhaps *Amgen* is the first step to realizing a Grand Unified Theory of patentability.

Notes

[1] 56 U.S. 62 (1853).

[2] 159 U.S. 465 (1895).

[3] 277 U.S. 245 (1928).

[4] 46 U.S. 1 (1847).

[5] 242 U.S. 261 (1916).

[6] 566 U.S. 66 (2012)

[7] *See, e.g., Chargepoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759 (Fed. Cir. 2019); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019).

[8] *See, e.g., LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005).

[9] *Wood v. Underhill* (also cited in the *Amgen* opinion) likewise framed its discussion in terms more reminiscent of the definiteness requirement. *See* 46 U.S. at 4 ("[T]he only question presented by the record is, whether his description of the relative proportions of coal-dust and clay, as given in his specification, is upon the face of it too vague and uncertain to support a patent.").

[10] *See also Kaumagraph Co. v. Superior Trade Mark Mfg. Co.*, 72 F.2d 417 (2d Cir. 1934).

[11] *See also Wagner Iron Works v. Koehring Co.*, 282 F.2d 317, 321 (10th Cir. 1960).

[12] I should note one exception to this statement — one respect in which the Federal Circuit itself has already largely merged two nominally separate doctrines. The six-factor written-description test of *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005), overlaps almost completely with the eight-factor *Wands* test for enablement, *see In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). So the difference between those two standards has become quite small even under Federal Circuit law. The credit for this observation goes to my partner Jorge Goldstein.

About the author

William H. Milliken is a director in **Sterne, Kessler, Goldstein & Fox**'s trial and appellate practice group. His practice focuses on patent litigation in U.S. district courts and the Federal Circuit, with a particular emphasis on cases arising under the Hatch-Waxman Act. He has experience drafting appellate briefs filed in the U.S. Courts of Appeals, briefing and arguing complex motions before the federal district courts, and assisting with trial preparation in Hatch-Waxman and other patent infringement litigation. He is based in Washington, D.C., and can be reached at wmilliken@sternekessler.com.

This article was first published on Westlaw Today on May 26, 2023.