

[Amgen Inc. v. Sanofi, 21–757, 98 U. S. ____ \(5/18/2023\).](#)

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This is a decision of the Supreme Court, on certiorari from the Federal Circuit’s decision holding Amgen’s claims invalid for lack of enablement, *see Amgen Inc. v. Sanofi*, 20-1074 (Fed. Cir. 2/11/2021). The Court affirmed.

Legal issue: 35 USC 112, enablement, scope of claim.

This decision is a tour de force, stating and solidifying the law of enablement.

The Court held that the specification must enable the full scope of the invention as defined by its claims. And despite recognizing prior case allowing specifications requiring some experimentation to determine how to make and use embodiments within the scope of the claim, the Court reiterated that all embodiments within the scope of claim required enablement, for the claim to be valid.

The Court began with the constitutional authority for patent laws, the quid pro quo of the patent bargain.

The Constitution vests Congress with the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Art. I, §8, cl. 8. Right there in the text, one finds the outline of what this Court has called the patent “bargain.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U. S. 141, 150 (1989). In exchange for bringing “new designs and technologies into the public domain through disclosure,” so they may benefit all, an inventor receives a limited term of “protection from competitive exploitation.” *Id.*, at 151; see also *The Federalist* No. 43, p. 272 (C. Rossiter ed. 1961) (J. Madison) (explaining that in such cases “[t]he public good fully coincides . . . with the claims of individuals”). [*Amgen Inc. v. Sanofi*, 21–757, 98 U. S. ____ (5/18/2023).]

The Court then noted that Congress had maintained the enablement requirement, despite having revised other requirements for patents over the years.

Even as Congress has revised the patent laws over time, it has left this “enablement” obligation largely intact. See 35 U. S. C. §§111, 112. Section 111 of the current Patent Act provides that a patent application “shall include . . . a specification as prescribed by section 112.” §111(a)(2)(A). Section 112, in turn, requires a specification to include “a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same.” §112(a). So today, just as in 1790, the law secures for the public its benefit of the patent bargain by ensuring that, “upon the expiration of [the patent], the knowledge of the invention [i]nures to the people, who are thus enabled without

restriction to practice it.” *United States v. Dubilier Condenser Corp.*, 289 U. S. 178, 187 (1933); *see also Grant v. Raymond*, 6 Pet. 218, 247 (1832) (Marshall, C. J.) (“This is necessary in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue a patent.”); *Whittemore v. Cutter*, 29 F. Cas. 1120, 1122 (No. 17,600) (CC Mass. 1813) (Story, J.) (“If therefore [the disclosure] be so obscure, loose, and imperfect, that this cannot be done, it is defrauding the public of all the consideration, upon which the monopoly is granted.”). [*Amgen Inc. v. Sanofi*, 21–757, 98 U. S. ____ (5/18/2023).]

The Court then specified the rule that enablement must be for all embodiments within the scope of the claim.

Our decisions in *Morse, Incandescent Lamp*, and *Holland Furniture* reinforce the simple statutory command. 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. See §112(a); *see also Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U. S. 405, 419 (1908) (“[T]he claims measure the invention.”). [*Amgen Inc. v. Sanofi*, 21–757, 98 U. S. ____ (5/18/2023).]

The Court went on to clarify that enablement of all embodiments within the scope of the claim did not require express disclosure of all embodiments within the scope of the claim, so long as each embodiment was enabled by what was expressly disclosed.

That is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class. For instance, it may suffice to give an example (or a few examples) if the specification also discloses “some general quality . . . running through” the class that gives it “a peculiar fitness for the particular purpose.” *Incandescent Lamp*, 159 U. S., at 475. In some cases, disclosing that general quality may reliably enable a person skilled in the art to make and use all of what is claimed, not merely a subset. *See id.*, at 475–476. [*Amgen Inc. v. Sanofi*, 21–757, 98 U. S. ____ (5/18/2023).]

The Court went on to clarify that a claim could be enabled even when there was some amount of testing or experimentation required to make and use a covered embodiment.

Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing. In *Wood*, a patent claimed a process for making bricks by mixing coal dust into clay. 5 How., at 4. The patent included “a general rule” about the proportion of dust and clay to use

and offered two alternative proportions “where the clay has some peculiarity.” *Id.*, at 5. The Court upheld the claim, recognizing that “some small difference in the proportions must occasionally be required” given the varieties of clay. *Ibid.* Similarly, in *Minerals Separation*, the Court dismissed a challenge to a claimed process for separating metal from mineral ores. 242 U. S., at 270. The record showed that “preliminary tests” were required to adapt the process to any particular ore. *Ibid.* Once more, the Court explained that “the certainty which the law requires in patents is not greater than is reasonable.” *Ibid.* And because the “composition of ores varies in finitely,” it was “impossible to specify in a patent the precise treatment which would be most successful and economical in each case.” *Id.*, at 271. [*Amgen Inc. v. Sanofi*, 21–757, 98 U. S. ____ (5/18/2023).]

The Court went on to specify that, while the specification might leave some one skilled in the art to perform some experimentation to make and use all embodiments within the scope of the claim, it had to meet the statutory mandate to provide full, clear, concise, and exact terms as to enable any person skilled in the art to make and use all the covered embodiments.

Decisions such as *Wood* and *Minerals Separation* establish that a specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art. *See Minerals Separation*, 242 U. S., at 270–271; *see also Mowry v. Whitney*, 14 Wall. 620, 644 (1872) (“[T]he definiteness of a specification must vary with the nature of its subject. Addressed as it is to those skilled in the art, it may leave something to their skill in applying the invention.”). But in allowing that much tolerance, courts cannot detract from the basic statutory requirement that a patent’s specification describe the invention “in such full, clear, concise, and exact terms as to enable any person skilled in the art” to “make and use” the invention. §112(a). Judges may no more subtract from the requirements for obtaining a patent that Congress has prescribed than they may add to them. *See Bilski v. Kappos*, 561 U. S. 593, 602–603, 612 (2010). [*Amgen Inc. v. Sanofi*, 21–757, 98 U. S. ____ (5/18/2023).]

The Court noted that mere advice in the specification to engage in trial and error did not provide enablement.

Failing in its primary argument that it has enabled all of the antibodies it claims, Amgen tries a few alternative lines of attack. First, it suggests that the Federal Circuit erred by applying an enablement test unmoored from the statutory text. As Amgen sees it, that court conflated the question whether an invention is enabled with the question how long may it take a person skilled in the art to make every embodiment within a broad claim. *See* Brief for Petitioners 24–29; *see also id.*, at 2, 19–20, 30–36. We do not see it that way. While we agree with Amgen

that enablement is not measured against the cumulative time and effort it takes to make every embodiment within a claim, we are not so sure the Federal Circuit thought otherwise. That court went out of its way to say that it “do[es] not hold that the effort required to exhaust a genus is dispositive.” 987 F. 3d, at 1088 (emphasis deleted). Instead, the court stressed, the problem it saw is the same problem we see: Amgen offers persons skilled in the art little more than advice to engage in “trial and error.” *Ibid.* (internal quotation marks omitted). In any event, we review judgments of the lower courts, not statements in their opinions. See *Black v. Cutter Laboratories*, 351 U. S. 292, 297 (1956). [Amgen Inc. v. Sanofi, 21–757, 98 U. S. ____ (5/18/2023).]

The Court noted that a claim defining a genus or embodiments by a particular function was insufficient to meet requirement to disclose how to make and use those embodiments.

Taking a similar tack, Amgen next argues that the Federal Circuit erroneously “raise[d] the bar” for enablement of claims that, like Amgen’s, encompass an entire “genus” of embodiments defined by their function. Brief for Petitioners 25 (internal quotation marks omitted). This is impermissible, Amgen argues, because the Patent Act “provides a single, universal enablement standard for all invention[s].” *Ibid.* (internal quotation marks omitted). Here, too, we agree with Amgen in principle: There is one statutory enablement standard. But, once more, we do not understand the Federal Circuit to have thought differently. Instead, we understand that court to have recognized only that the more a party claims for itself the more it must enable. As we have seen, that much is entirely consistent with Congress’s directive and this Court’s precedents. [Amgen Inc. v. Sanofi, 21–757, 98 U. S. ____ (5/18/2023).]

The Court summarized pre-existing Supreme Court law, before addressing the issues in this case. That summary follows.

...O’Reilly mounted a number of defenses, including that Morse’s patent was void because it lacked an adequate specification. See *id.*, at 99–101, 112. Morse’s patent included eight claims, and this Court had no trouble upholding seven of them—those limited to the telegraphic structures and systems he had designed. See *id.*, at 85–86, 112, 117. But the Court paused on the eighth. *** The Court held the eighth claim “too broad, and not warranted by law.” *Id.*, at 113. The problem was that it covered all means of achieving telegraphic communication, yet Morse had not described how to make and use them all. See *id.*, at 113–117; see also 3 Chisum on Patents §7.03[1], pp. 7–18 to 7–19 (2021). “[I]f the eighth claim . . . can be maintained,” the Court concluded, “there was no necessity for any specification, further than to say that he had discovered that, by using the motive power of electro-magnetism, he could print intelligible characters at any distance.” 15 How., at 119. “[I]t will be admitted on all hands, that no

patent could have issued on such a specification.” *Ibid.* [Amgen Inc. v. Sanofi, 21–757, 98 U. S. ____ (5/18/2023).]

Enter Thomas Edison. From his laboratory in Menlo Park, Edison and a team toiled to improve upon the prevailing method of incandescent lighting, which tended to employ carbon filaments. *** One sample from Japan worked brilliantly because “[its] fibres [ran] more nearly parallel than in other species of wood.” 159 U. S., at 473. Satisfied, Edison arranged to have a Japanese farmer supply all of the bamboo he would ever need. Stross 110. *** Sawyer and Man alleged that Edison’s lamp infringed their patent because it “made use of a fibrous or textile material, covered by the patent.” *Id.*, at 471. What was that offending material? Bamboo. *** This Court sided with Edison. It held that Sawyer and Man’s patent claimed much but enabled little. “Sawyer and Man supposed they had discovered in carbonized paper the best material for an incandescent conductor.” *Id.*, at 472. But “[i]nstead of confining themselves to carbonized paper, as they might properly have done, and in fact did in their third claim, they made a broad claim for every fibrous and textile material.” *Ibid.* Even that broad claim “might” have been permissible, the Court allowed, if Sawyer and Man had disclosed “a quality common” to fibrous and textile substances that made them “peculiarly” adapted to incandescent lighting. *Ibid.* Had they done so, others would have known how to select among such materials to make an operable lamp. But the record showed that most fibrous and textile materials failed to work. Only through “painstaking experimentation” did Edison discover that bamboo “answered the required purpose.” *Id.*, at 475–476. The Court summed up things this way: “[T]he fact that paper happens to belong to the fibrous kingdom did not invest [Sawyer and Man] with sovereignty over this entire kingdom.” *Id.*, at 476. [Amgen Inc. v. Sanofi, 21–757, 98 U. S. ____ (5/18/2023).]

The Court returned to these principles in *Holland Furniture*. There, the evidence indicated that animal glue has properties that have long made it excellent for wood veneering. See 277 U. S., at 247. Seeking a substitute, Perkins Glue Company had developed and patented a starch glue similar enough to animal glue that craftsmen could also use it for wood veneering. See *ibid.* Yet Perkins’s patent included a claim that went beyond the specific starch glue it manufactured. See *id.*, at 250–251. This claim covered all “starch glue which, [when] combined with about three parts or less by weight of water, will have substantially the same properties as animal glue.” *Id.*, at 251. Perkins’s specification instructed gluemakers to choose a “starch ingredient” with “such qualities” that it would yield a product ““as good as animal glue”” for wood veneering “when combined with three parts of water and with alkali.” *Id.*, at 256. The Court held this broad claim invalid for lack of enablement. *Id.*, at 258. The specification described the key input—the “starch ingredient”—in terms of its “use or function” rather than its “physical characteristics or chemical properties.” *Id.*, 256. And that left gluemakers

in a bind. As the Court put it: “One attempting to use or avoid the use of Perkins’ discovery as so claimed and described functionally could do so only after elaborate experimentation” with different starches. *Id.*, at 257. To be sure, the Court held, Perkins was entitled to its patent on the specific starch glue it had invented. See *id.*, at 255. The specification described that glue’s “characteristic ingredient” with “particularity.” *Ibid.* But just as Morse could not claim all means of telegraphic communication, and Sawyer and Man could not claim all fibrous and textile materials for incandescence, Perkins could not claim all starch glues made from whatever starch happened to perform as well as animal glue. To hold otherwise, the Court said, “would extend the monopoly beyond the invention.” *Id.*, at 258. [Amgen Inc. v. Sanofi, 21–757, 98 U. S. ____ (5/18/2023).]