No. 21-757

IN THE
Supreme Court of the United States

AMGEN INC., ET AL.,

Petitioners,

v.

SANOFI, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONERS

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TABLE OF CONTENTS

	Page
Introduction	1
Argument	3
I. The Federal Circuit Applied a Reach-the-Full-Scope Enablement Test	3
II. The Court Should Restore the Statutory "Make and Use" Standard for Enablement	6
A. Section 112 Provides a Practical Standard of Reasonableness	6
B. Sanofi-Regeneron's "Specific Undisclosed Embodiments" Standard Is Unsupported	9
C. Sanofi-Regeneron Cannot Prevail Under Its Own Test	11
III. The Government's Arguments Fail	15
IV. Genus Claims Promote, Rather Than Stifle, Innovation	21
Conclusion	24

TABLE OF AUTHORITIES

Page(s)

CASES

Amgen Inc. v. *Sanofi*,
143 S. Ct. 399 (2022) 3

Amgen Inc. v. *Sanofi*,
872 F.3d 1367 (Fed. Cir. 2017) 14

AstraZeneca AB v. *Mylan Pharms. Inc.*,
No. 1:18CV193, 2022 WL 16857400
(N.D. W. Va. Nov. 9, 2022) 5

Atlas Powder Co. v. *E.I. du Pont De Nemours & Co.*, 750 F.2d 1569
(Fed. Cir. 1984) 9

Auto. Techs. Int'l, Inc. v. *BMW of N. Am., Inc.*, 501 F.3d 1274 (Fed. Cir. 2007) 8

Baxalta Inc. v. *Genentech, Inc.*,
579 F. Supp. 3d 595 (D. Del. 2022) 5

Beidler v. *United States*,
253 U.S. 447 (1920) 8

Béné v. *Jeantet*,
129 U.S. 683 (1889) 9

Carver v. *Braintree Mfg. Co.*,
5 F. Cas. 235 (C.C.D. Mass. 1843) 8

Consol. Elec. Light Co. v. *McKeesport Light Co.*,
159 U.S. 465 (1895) 8, 10, 18, 21

Cont'l Paper Bag Co. v. *E. Paper Bag Co.*, 210 U.S. 405 (1908) 6

Diamond v. *Chakrabarty*,
447 U.S. 303 (1980) 18

eBay Inc. v. *MercExchange, L.L.C.*,
547 U.S. 388 (2006) 23

TABLE OF AUTHORITIES—Continued

Page(s)

Holland Furniture Co. v. *Perkins Glue Co.*, 277 U.S. 245 (1928) 9, 17, 18

Human Power of N Co. v. *Heartbeet Ltd.*, No. PGR2021-00110, 2022 WL 683124 (P.T.A.B. Feb. 25, 2022) 5

Lockheed Martin Corp. v. *Space Sys./Loral, Inc.*, 324 F.3d 1308 (Fed. Cir. 2003) 22

McRO, Inc. v. *Bandai Namco Games Am. Inc.*, 959 F.3d 1091 (Fed. Cir. 2020) 3

Microsoft Corp. v. *i4i Ltd. P'ship*, 564 U.S. 91 (2011) 11, 16

Minerals Separation, Ltd. v. *Hyde*, 242 U.S. 261 (1916) 2, 6, 7, 10, 15, 16, 19, 20

Mowry v. *Whitney*, 81 U.S. (14 Wall.) 620 (1872) 7, 8

Neilson v. *Harford* (1841) 151 Eng. Rep. 1266 (Exch.) 18

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Schriber-Schroth Co. v. *Cleveland Tr. Co.*, 305 U.S. 47 (1938) 6

Smith v. *Snow*, 294 U.S. 1 (1935) 16

Teva Pharms. Int'l GmbH v. *Eli Lilly & Co.*, No. 18-cv-12029, 2022 WL 4824318 (D. Mass. Oct. 3, 2022) 22

TABLE OF AUTHORITIES—Continued

Page(s)

In re Wands,
858 F.2d 731 (Fed. Cir. 1988) 5, 19, 21

Westinghouse v. *Boyden Power Brake Co.*, 170 U.S. 537 (1898) 23

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46 U.S. (5 How.) 1 (1846) 8

STATUTES

21 U.S.C. § 355(j) 23

35 U.S.C. § 112 ..... 1, 2, 6, 7, 9, 23

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INTRODUCTION

Sanofi-Regeneron abandons the Federal Circuit's view that enablement depends on the cumulative time and effort to "reach the full scope" of an invention's embodiments. It does not contend that the effort required to find all embodiments is even *relevant*. The government concedes "such a test has no foundation in the text [of § 112] or this Court's precedent." U.S. Br. 29.

It was Sanofi-Regeneron, however, that pressed the find-all-embodiments test on the Federal Circuit. Abandoning that test, Sanofi-Regeneron now makes up another: A patent with functional elements is not enabled, it says, if there are "specific undisclosed embodiments of the

claimed invention" skilled artisans "cannot predictably produce." Resp. Br. 44. That test has no more basis in § 112's text or this Court's precedent than the reach-the-full-scope test Sanofi-Regeneron repudiates.

There is only one test for enablement—§ 112's "make and use" standard. That requires a practical inquiry into what skilled artisans can do using the patent's disclosures. If those disclosures are "sufficiently definite to guide those skilled in the art to" the "successful application" of "the invention," the patent is enabled. *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 271 (1916). The standard is the same whether there are 5 embodiments of the invention or 5,000. Where there are meaningfully distinct types of embodiments within the claims, the patent must "reasonabl[y]" enable skilled artisans to make and use "variation[s]" across the claims' scope, without subject-matter gaps skilled artisans would consider significant with due "regard to [the patent's] subject-matter." *Id.* at 270.

Sanofi-Regeneron obfuscates with false narratives about issues (like inventiveness) with no relevance to *enablement*. While Sanofi-Regeneron and its *amici* attempt to manufacture factual disputes over whether skilled artisans can "make and use" the invention across the "full scope," *e.g.*, U.S. Br. 22-28, the jury was instructed on that standard, C.A. App. 2906-2907, and found for Amgen, C.A. App. 3630-3632. Sanofi-Regeneron's and the government's contrary arguments operate in an evidence- and law-free zone, divorced from the trial record and a standard of review they cannot overcome.

Sanofi-Regeneron and its *amici* decry the idea of genus claims. Yet Sanofi, Regeneron, and *amici* (from Genentech to Sir Gregory Paul Winter) protect *their own* inventions through broad genus claims. If someone invents and enables a pioneering advance, the "patent bargain" enti-

tles her to a patent covering the genus. The Court should not distort enablement law to serve those who would prefer a patent system different from the one Congress enacted.

ARGUMENT

I. THE FEDERAL CIRCUIT APPLIED A REACH-THE-FULL-SCOPE ENABLEMENT TEST

A. Rather than defend the Federal Circuit's reach-the-full-scope standard, Sanofi-Regeneron denies the Federal Circuit "relies on any such cumulative-effort standard." Resp. Br. 32; see U.S. Br. 29. Sanofi-Regeneron made the same argument to oppose certiorari. Br. in. Opp. 29. This Court nonetheless granted certiorari on the petition's "Question 2," *Amgen Inc.* v. *Sanofi*, 143 S. Ct. 399 (2022), which addresses the reach-the-full-scope standard, Pet. i. Amgen thus properly addresses that issue "[f]rom its Question Presented to the last page." Resp. Br. 32.

The Federal Circuit's opinion plainly turns on the effort required to identify and make all or nearly all the antibodies within Amgen's patent claims. The court invoked its heightened enablement standard for "'claims that state certain structural requirements and also require performance of some function.'" Pet. App. 11a (quoting *McRO, Inc.* v. *Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 n.2 (Fed. Cir. 2020)). That test "consider[s] the quantity of experimentation that would be required to make and use, *not only* the limited number of embodiments that the patent discloses, *but also the full scope of the claim*." *Ibid.* (emphasis added). In doing so, courts ask whether "'*identifying*'" which of the "'*many*'" potential embodiments "'satisfy'" the genus's "'requirement[s]'" would necessitate "'undue experimentation.'" Pet. App. 11a-12a (quoting *McRO*, 959 F.3d at 1100 n.2) (emphasis added).

Applying that cumulative-effort standard, the Federal Circuit posited that Amgen's "claims encompass[ ] millions of candidate[ ]" antibodies, and that "it would be necessary to first generate and then screen *each* candidate antibody" to determine whether those antibodies fell within the claims. Pet. App. 15a (emphasis added). That is an inquiry into the effort to find *all* antibodies within the claims—Sanofi-Regeneron cannot explain what else that would be. And the court found that "no reasonable jury could conclude * * * that anything but 'substantial time and effort' would be required *to reach* the full scope of claimed embodiments," Pet. App. 14a (emphasis added), and that "undue experimentation would be required *to practice the full scope* of these claims," Pet. App. 15a (emphasis added).

B. While Sanofi-Regeneron downplays the "cumulative-effort standard" as a "straw man," Resp. Br. 31-32, it was *Sanofi-Regeneron* that pressed that standard below. It repeatedly argued that "the number of *potential* antibodies over the full scope of the claims that artisans would have to make and test" was "'millions.'" Resp. C.A. Br. 36; see Resp. Br. 1-2, 17-18, 22-25, 27-29, 34-35, 37-40. "Someone instructed to * * * dig[ ] for gold," Sanofi-Regeneron thus urged, "might eventually find *all* the gold in the world, but not without extraordinary trial-and-error efforts." Resp. C.A. Br. 43 (emphasis added).

Three times in its Federal Circuit brief, Sanofi-Regeneron invoked its expert's assertion that Amgen's claims were non-enabled because "'you could be immunizing mice for a hundred years' and not find *all* of the claimed antibodies." Resp. C.A. Br. 22 (emphasis added); Resp. C.A. Br. 36 ("all of the claimed antibodies"), 43-44 (similar). That looks to the cumulative effort to find *all* antibodies within the claim. Sanofi-Regeneron now recharacterizes its expert as testifying that "a skilled artisan 'could be im-

munizing mice for a hundred years' and still not create *a particular desired antibody*." Resp. Br. 14 (emphasis added). That blatant switch gives away the game. Sanofi-Regeneron cannot pretend the cumulative-effort standard *it* pressed is a figment of *Amgen's* imagination.

The PTO's Patent Trial and Appeal Board understands the decision below as assessing the "effort required to screen and identify *all*" antibodies within the claims. *Human Power of N Co.* v. *Heartbeet Ltd.*, No. PGR2021-00110, 2022 WL 683124, at *9 (P.T.A.B. Feb. 25, 2022) (emphasis added). District courts likewise read it to impose "'high hurdles in fulfilling the enablement requirement,'" *Baxalta Inc.* v. *Genentech, Inc.*, 579 F. Supp. 3d 595, 616 (D. Del. 2022) (quoting Pet. App. 12a), striking down genus claims "given [their] breadth," *id.* at 619; see also *AstraZeneca AB* v. *Mylan Pharms. Inc.*, No. 1:18CV193, 2022 WL 16857400, at *8 (N.D. W. Va. Nov. 9, 2022). Commentators recognize the Federal Circuit "imposes a new requirement" for enablement "that a patentee teach [skilled artisans] how to identify *every* working [embodiment] in a genus." M. Lemley & J. Sherkow, *The Antibody Patent Paradox*, 132 Yale L.J. 994, 1031 (2023) (emphasis added). *Amici* agree. *E.g.*, NYIPLA. Br. 16; Diversified. Rschrs. Br. 5.

C. The government says the court's "reach the full scope" language "appears to mean" only that skilled artisans must be able to "'make and use' embodiments beyond" the specification's "exemplars." U.S. Br. 30. The Federal Circuit never suggested that making and using individual embodiments beyond Amgen's 26 examples "'would require undue experimentation.'" Resp. Br. 28 (quoting *In re Wands*, 858 F.2d 731, 736-737 (Fed. Cir. 1988)); see U.S. Br. 26-27; pp. 15-17, *infra*. Instead, the Federal Circuit *varied* the *Wands* factors by asking

whether there would be "'undue experimentation in identifying,'" from "millions of" potential embodiments, those that "'satisfy'" the genus's "'requirement[s],'" Pet. App. 11a-12a, 15a, *i.e.*, the effort to "reach the full scope," Pet. App. 14a; see Pet. Br. 24-25.

Sanofi-Regeneron invokes the Federal Circuit's assertion that "'the effort required to exhaust a genus'" is not "'dispositive.'" Resp. Br. 32 (quoting Pet. App. 14a). But it was here. Besides, the court held that the effort required to generate and test all candidates is an "appropriate," Pet. App. 14a, and "important," Pet. App. 11a, consideration. Sanofi-Regeneron and the government do not defend that consideration as even *relevant*.

II. The Court Should Restore The Statutory "Make And Use" Standard For Enablement

A. Section 112 Provides a Practical Standard of Reasonableness

1. Section 112(a) is clear: The specification must "enable any person skilled in the art * * * to make and use" "the invention." 35 U.S.C. § 112(a). That is a practical test, focused on the ability of skilled artisans to do something concrete—to make the invention and to use it. The requirement's purpose is similarly practical. Section 112's "object * * * is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent." *Schriber-Schroth Co.* v. *Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938). Patent disclosures thus "satisf[y] the law" if they are "sufficiently definite to guide" skilled artisans to "successful application" of "the invention." *Minerals Separation*, 242 U.S. at 271.

The standard does not change where "the modes of" the claimed invention's "embodiment * * * may be numerous and * * * different from each other." *Cont'l Paper Bag Co.* v. *E. Paper Bag Co.*, 210 U.S. 405, 418-419 (1908). The

"certainty which the law requires" for enabling "variation[s]" of the invention "is not greater than is reasonable, having regard to [the patent's] subject-matter." *Minerals Separation*, 242 U.S. at 270. The government agrees that enablement "generally depend[s] not on any bright-line rule but on a flexible inquiry that takes into account the nature of the claimed invention and the field in which it arises." U.S. Br. 14.

Contrary to Sanofi-Regeneron's accusation, Resp. Br. 37, Amgen agrees patents "must reasonably enable the entire scope of the claim," Pet. Br. 28. Where an invention has many embodiments, the patent enables the invention's "full scope" if skilled artisans can "reasonabl[y]" make and use "variation[s]," without gaps in subject matter skilled artisans would consider significant with "regard to [the patent's] subject-matter." *Minerals Separation*, 242 U.S. at 270. If the patent's instructions are "sufficiently definite to guide" skilled artisans to "successful application" across the scope of the "invention," the claims are enabled. *Id.* at 271; see Pet. Br. 41-42. In such cases, the "enabling disclosure" is "'commensurate with the scope of the claims.'" Resp. Br. 30; see U.S. Br. 7. But cataloging every embodiment is a task for "the mechanic, not the inventor." 2 W. Robinson, *The Law of Patents for Useful Inventions* § 485 (1890).

2. Sanofi-Regeneron characterizes that standard's origin as "entirely unclear." Resp. Br. 37. But it comes from § 112's text and the cases Sanofi-Regeneron discusses. Resp. Br. 37-42. In *Mowry* v. *Whitney*, 81 U.S. (14 Wall.) 620 (1872), for example, the patent claimed a method for manufacturing railway wheels. It was "[p]lainly * * * impossible to describe" the specific timing and temperature parameters for every type of wheel skilled artisans might make. *Id.* at 645. But the patent was enabled

because, "in following" the specification's "directions," skilled artisans "would be taught by [their] practical knowledge" how to apply the method to any wheel in the course of their work. *Id.* at 646. In *Wood* v. *Underhill*, 46 U.S. (5 How.) 1 (1846), there were "exceptions" where the formula for mixing clay and coal dust to make bricks needed variation, but those "peculiarit[ies]" did not defeat enablement where it "appear[ed]" artisans would be able to apply the formula to most types of clay. *Id.* at 5-6; see also *Carver* v. *Braintree Mfg. Co.*, 5 F. Cas. 235, 237 (C.C.D. Mass. 1843) (patent enabled where "a skilful mechanic could from [the patent's] description make a proper rib for any particular kind of cotton"). Those cases show that, if skilled artisans can reasonably employ the invention across the relevant field, the claim is enabled. See Pet. Br. 30-36.[1]

3. There are various ways defendants can disprove enablement. Skilled artisans may be unable to make the invention at all. *Beidler* v. *United States*, 253 U.S. 447, 453 (1920). Defendants can show a distinct category of embodiments within the claim's scope cannot be made following the patent's disclosures. *Auto. Techs. Int'l, Inc.* v. *BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007). Or they can demonstrate that the patent's teachings force skilled artisans on a labor-intensive hunt for working embodiments that exceeds what skilled artisans typically do, like searching for a working needle in a haystack of failures. See Pet. Br. 45-47 (discussing *Consol. Elec. Light Co.*

[1] Sanofi-Regeneron attacks Amgen's use of the phrase "as needed." Resp. Br. 36-44. But saying skilled artisans must be able to make "versions of the invention as needed" merely distinguishes the effort to make *individual* embodiments from making "every possible variation of the invention *in succession*," as the reach-the-full-scope test requires. Pet. Br. 28.

v. *McKeesport Light Co.*, 159 U.S. 465, 472-475 (1895); *Béné* v. *Jeantet*, 129 U.S. 683, 684-686 (1889); *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245, 250-251, 257 (1928)). That precedent amply addresses any concerns about patentees claiming more than they enable. See Pet. Br. 44-48.

B. Sanofi-Regeneron's "Specific Undisclosed Embodiments" Standard Is Unsupported

1. Abandoning the cumulative-effort standard it pressed below, Sanofi-Regeneron proposes another bespoke test: It argues a patent is not enabled "when skilled artisans cannot *predictably* produce *specific undisclosed embodiments* of the claimed invention." Resp. Br. 44 (emphasis added). Section 112, however, refers only to "enabl[ing]" skilled artisans to "make and use" the "invention." 35 U.S.C. § 112(a). It does not mention "embodiments," "specific" or "undisclosed." It imposes no requirement that every "specific embodiment" one can hypothesize be "predictably produced."

Sanofi-Regeneron identifies *no* case holding that a patent must enable skilled artisans to easily make all hypothetical variations of the invention. Defendants can always theorize about specific embodiments that do not work or cannot be made. But the law recognizes that "inoperative embodiments" within a genus do not alone invalidate a claim. See *Atlas Powder Co.* v. *E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). Only when "the number of inoperative combinations becomes significant, and in effect forces" skilled artisans "to experiment unduly" to find ones that do exist or operate, does that suggest "the claims might indeed be invalid." *Id.* at 1576-1577. Thus, in *Consolidated Electric*, the defendant prevailed by presenting clear-and-convincing *evidence* that months of experimentation, with thousands of mate-

rials, was necessary to find one fiber (bamboo) that would function as claimed. 159 U.S. at 472-474; Pet. Br. 45-46. Such evidence is absent here.

Nor can Sanofi-Regeneron's "specific undisclosed embodiments" standard be squared with a standard of "reasonable[ness]" in view of the patent's "subject-matter." *Minerals Separation*, 242 U.S. at 270. Sanofi-Regeneron abandons a practical focus on whether the specification "guide[s] those skilled in the art to" the "successful application" of "the invention," *id.* at 271, for a fixation on speculative outliers skilled artisans may never want or need.

2. This case illustrates the folly of Sanofi-Regeneron's "specific undisclosed embodiments" test. Suggesting certain antibodies within Amgen's claims are more "desirable," Resp. Br. 13, or "coveted," Resp. Br. 51, Sanofi-Regeneron insinuates that, if an antibody binds at more points in PCSK9's sweet spot, it is more "medically effective," Resp. Br. 43; see Resp. Br. 15, 21-22, 49, 51. That insinuation is unsupported by any *evidence*. Sanofi-Regeneron's own expert said the *opposite*, testifying that "there's *no correlation* between the *number* of amino acids that are bound and the [antibody's] blocking" of PCSK9's interaction with LDL receptors. C.A. App. 3787 (462:1-15) (emphasis added). The undisputed testimony was that, "if an antibody has a structure that allows it to bind to one or more residues on the sweet spot"—no matter which ones or how many—"it will block" PCSK9's interaction with LDL receptors. C.A. App. 3876 (629:10-18).

Sanofi-Regeneron states that "only Praluent is FDA-approved in a low-dose version." Resp. Br. 1, 8-9, 21, 47. But there is nothing about the Praluent *antibody* that makes it amenable to a "low dose." Praluent is the only FDA-approved antibody for a low dose because only Sanofi-Regeneron *sought FDA approval* for both a full dose

and a "low" dose with half the amount of antibodies in the container. And Sanofi-Regeneron failed to prove Praluent would not be made by following the roadmap in Amgen's patents.

C. Sanofi-Regeneron Cannot Prevail Under Its Own Test

Sanofi-Regeneron's invocation of a "specific undisclosed embodiments" standard is ironic: Neither Sanofi-Regeneron nor the Federal Circuit identified *any* actual antibody that could not be made following the patents' teachings. Pet. Br. 49; see Pet. Br. 19, 25. Sanofi-Regeneron tried to convince the jury that Amgen's patents were not enabled by arguing that the roadmap in Amgen's patents would not produce four specific competitor antibodies—Sanofi-Regeneron's Praluent, Pfizer's J16, and Merck's 1D05 and AX132 antibodies, C.A. App. 3681 (191:2-21), 3989-3990 (912:21-913:7)—but the jury *rejected* that contention, and Sanofi-Regeneron never challenged that rejection on appeal or in its brief in opposition here.

1. Without mentioning those failures, Sanofi-Regeneron reprises its failed factual argument here. Resp. Br. 51. But Sanofi-Regeneron bore the burden of proving non-enablement by clear-and-convincing evidence. *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). To overturn the jury's verdict, it must show that *every reasonable juror* would be compelled to find it proved non-enablement by *clear-and-convincing* proof. See Pet. Br. 48 (citing 9B Wright & Miller, *Federal Practice & Procedure* § 2535 (3d ed.)). Sanofi-Regeneron does not come close to meeting that standard for any of its "specific undisclosed embodiments."

While Amgen disclosed 26 example antibodies by amino-acid sequence, the patents disclosed that Amgen had made 384 antibodies within the claims using just two pan-

els of mice. C.A. App. 234 (Tbl. 3), 237 (80:22-23); see pp. 19-20, *infra*. Amgen's expert explained how the four competitor antibodies Sanofi-Regeneron identified would be made following Amgen's roadmap.[2] Sanofi-Regeneron never rebutted that testimony, and Sanofi-Regeneron never argued on appeal that the jury could not credit it. See Pet. C.A. Reply. Br. 3. Sanofi-Regeneron now makes the unexplained assertion that *Amgen's* expert's testimony was "conclusory," Resp. Br. 51 n.9, a meaningless assertion from the party that bears a clear-and-convincing burden.

Sanofi-Regeneron cites a footnote in the Federal Circuit's decision, Resp. Br. 51, but that footnote merely compares the claims with certain "disclosed examples" in Amgen's patents, Pet. App. 13a n.1. The Federal Circuit did not posit, much less identify evidence, that the antibodies identified in Sanofi-Regeneron's chart would not be generated using the patents' roadmap. Amgen explained that, Pet. Br. 51 n.6, and Sanofi-Regeneron has no response. The Federal Circuit theorized that there *might* be "far corners of the claimed landscape" that *might* be "inaccessible," Pet. App. 65a, but that fails to identify a "specific undisclosed embodiment"—it is generalized speculation.

2. Sanofi-Regeneron's argument that Amgen failed to make a single antibody within a class variously called "EGFa mimics," "middle binders," or "the missing epi-

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[2] Amgen's expert testified that Praluent ("alirocumab") could be made "follow[ing] the road map" because the transgenic mouse system contained "the gene pieces that are put together to make alirocumab." C.A. App. 3908 (757:12-758:18). He testified that Praluent likely was among 384 antibodies Amgen initially produced, C.A. App. 3918-3919 (798:25-799:5), and that Pfizer's and Merck's antibodies could be made following the roadmap too, C.A. App. 3908-3909 (758:19-760:21, 762:10-20).

tope," see Resp. Br. 51, is frivolous. The documents Sanofi-Regeneron cites in support, see *ibid.*, were *excluded* from evidence at trial, see Resp. Br. 13; see also Winter Br. 13 n.9 (quoting excluded document), or never even offered as evidence, see Pet. C.A. Reply. Br. 32 n.13. Sanofi-Regeneron argued that the documents showed Amgen had unsuccessfully attempted to make EGFa mimics, Resp. C.A. Br. 42-43, 59-60, but the district court refuted the argument, finding that the documents "did not actually show that," Pet. App. 47a.

The documents actually show Amgen's initial set of 384 antibodies included *at least 20* such "middle binders." See C.A. App. 9529-9534; C.A. Oral. Arg. 32:28-34:10 (discussing excluded documents). The jury saw data showing that Amgen antibody 9C9 binds in the middle of the sweet spot, antibody 21B12 binds a residue right in the middle of the sweet spot, and antibody 1A12 sits on PCSK9 almost indistinguishably from the competitor antibodies. See D. Ct. Dkt. 866 at 932:6-933:22; D. Ct. Dkt. 1059-1 at 148-150 (demonstratives).

3. Sanofi-Regeneron and the Federal Circuit hypothesized there might be "millions of" potential "candidates" for antibodies within Amgen's claims. Pet. App. 15a. They theorized that, applying the well-established technique called "conservative substitution" to each of the patents' 26 example antibodies, scientists could produce "millions" of variants. See Pet. C.A. Br. 42-43. But all those structures are disclosed in the patents. See C.A. App. 51-116 (Figs. 2A-3JJJ) (26 antibodies), 211 (Tbl. 1) (listing amino-acid substitutions). The "millions" is relevant only under the reach-the-full-scope test Sanofi-Regeneron abandoned—it is undisputed that making individual variants was routine. And there is no needle-in-the-haystack problem. The patents disclose conservative substitutions

that "retain a similar biological activity" as the reference antibody. C.A. App. 211 (27:60-62, 28:1-3, Tbl. 1); Pet. Br. 14-15. Sanofi-Regeneron concedes it did not identify even *one* example of a conservative substitution to a disclosed antibody that stopped the antibody from binding to PCSK9 and blocking LDL receptors, Resp. Br. 52—failing its own "specific undisclosed embodiment" test.

4. Sanofi-Regeneron changes the topic from enablement to false narratives. Implying Amgen did nothing innovative, it urges that Amgen was "[s]purred by" a November 2006 article proposing that antibodies could prevent PCSK9 from destroying LDL receptors. Resp. Br. 7. But the record shows Amgen's research started *nearly two years earlier* and had *already generated* PCSK9 antibodies *before* that article appeared. See C.A. App. 3795 (494:2-6); D. Ct. Dkt. 342 at 261:1-18, 264:6-265:8. Sanofi-Regeneron's contention that Amgen's invention was obvious in light of the prior art, Resp. Br. 35, was thus rejected by the courts long ago, *Amgen Inc.* v. *Sanofi*, 872 F.3d 1367, 1379-1380 (Fed. Cir. 2017).

Using a misleading timeline that mixes publication dates with invention dates, Sanofi-Regeneron implies it discovered Praluent before Amgen applied for its patent. Resp. Br. 8-9, 46-47 n.7. But Amgen *filed* its patent application in August 2007, C.A. App. 3800 (514:3-18), *over a year before* Sanofi-Regeneron filed its first provisional application on Praluent in December 2008, Resp. Br. 8.[3] Amgen generated PCSK9 antibodies before Regeneron gen-

[3] The government's timeline likewise erroneously describes Amgen as "*fil[ing]*" for its patents on dates (U.S. Br. 4-5) that are actually when the PTO *issued* the patents. Those patents "relate back to" (U.S. Br. 4), at the latest, the January 9, 2008 priority date of Amgen's third provisional patent application, which Sanofi-Regeneron did not dispute. See *Amgen*, 872 F.3d at 1371-1372; C.A. App. 3801 (520:2-4).

erated anything. Compare D. Ct. Dkt. 342 at 261:1-18, 264:6-265:8, with C.A. App. 3766 (379:1-9). Regeneron also sought genus claims, but was a year too late. See Prov. Appl. No. 61/122,482 (claims 1-5). It concededly used Amgen's anchor antibodies to confirm that Praluent binds PCSK9's sweet spot. Pet. Br. 15 & n.3; Resp. Br. 46-47 n.7.

Sanofi-Regeneron's accusation that Amgen "attempt[ed] to corner the market" by adding genus claims "*after* Sanofi/Regeneron developed Praluent," Resp. Br. 1; see Resp. Br. 10, 46, is also false. Amgen's provisional applications from August and December 2007 included genus claims of similar scope that likewise encompassed Praluent. See Prov. Appl. Nos. 60/957,668 (claims 68, 70-71), and 61/008,965 (claims 77, 88-89). That Sanofi-Regeneron devotes so much of its brief to (untrue) assertions having nothing to do with enablement speaks volumes.

III. THE GOVERNMENT'S ARGUMENTS FAIL

The government agrees to the standard of "'reasonable[ness], having regard to [the patent's] subject-matter.'" U.S. Br. 16 (quoting *Minerals Separation*, 242 U.S. at 270). But it then (U.S. Br. 22-28) departs from that standard—and from the record and the rules of procedure and evidence. Contrast Pet. Br. 48-51.

A. Even though its own PTO issued Amgen's patents, the government argues they are not enabled because they cover more antibodies than the "exemplars" in the specification. U.S. Br. 22. It urges that, because Amgen disclosed "only 26 antibodies," the Court should "infer[ ]" that Amgen did "not know how to produce * * * additional" antibodies. U.S. Br. 27. The patents refute that: They disclose that Amgen generated *hundreds* of PCSK9-blocking antibodies. C.A. App. 237 (80:22-37). A century of law refutes any such inference: "[H]aving one [patent] embodiment before them, the public are *presumed* to be able to

construct such others as they may desire." 2 Robinson § 485 (emphasis added). That presumption of enablement can be overcome only through clear-and-convincing evidence. See *i4i*, 564 U.S. at 95. A patent's teachings may "guide" skilled artisans to the "successful application" of a nearly "infinite[ ]" number of embodiments beyond those disclosed in the specification. *Minerals Separation*, 242 U.S. at 271; see Pet. Br. 29-32. The government ignores the rule that it is "not necessary to * * * describe in the specification[ ] all possible forms in which the claimed principle may be reduced to practice." *Smith* v. *Snow*, 294 U.S. 1, 11 (1935).

The government asserts that Amgen's 26 example antibodies "do not capture even the degree of structural variation in their competitors' antibodies." U.S. Br. 27. But the question is what Amgen's patents *enable*, not what the 26 examples look like. Here, the evidence showed that the disclosures in Amgen's patents *enable* skilled artisans to *make and use* the full scope of claimed antibodies, including the competitor antibodies. See pp. 10-14, *supra*. Moreover, presented with the same argument that the competitor antibodies were distinct because they "bind to a greater number" of PCSK9's sweet-spot residues, U.S. Br. 27; see Resp. Br. 15, 51 n.9, the jury rejected it. And rightfully so, as the number of residues an antibody binds has no effect on its function. See p. 10, *supra*. The jury found Amgen's examples "representative of the structural diversity of the genus," and the district court upheld that finding as supported by "substantial evidence." Pet. App. 25a-27a.

The government dismisses that as pertaining only to sufficiency of the patents' "written description." U.S. Br. 28. But whether the examples are "representative" of the genus's "structural diversity" is no different for enable-

ment (which derives from the same sentence of § 112(a) as the "written description" requirement, see Pet. Br. 6 n.1). The jury's factual finding on that issue having not been overturned, the government cannot assert the opposite. And the government appears to concede that, if the 26 example antibodies—which it concedes can readily be made—are structurally representative of the full genus, Amgen has enabled the "full scope" of its claims. U.S. Br. 26-27.

The government erroneously urges that supposedly "obvious gaps in the structural representativeness of petitioners' examples" cannot be ignored "on the theory that all the undiscovered antibodies in the class are likely to be fungible." U.S. Br. 28. But it proves no gaps—and the antibodies *are* fungible. The government's assertion that it does not understand Amgen to "suggest that every PCSK9 antibody that binds the sweet spot blocks LDL receptors," U.S. Br. 23, shows the government does not understand the record. Both parties' experts testified that, "if an antibody has a structure that allows it to bind to one or more residues on the sweet spot, it will block" PCSK9's interaction with LDL receptors. C.A. App. 3876 (629:10-18) (Amgen's expert); C.A. App. 3787 (462:16-22) (Sanofi-Regeneron's expert) (similar). And there is no evidence any antibody or category of antibodies blocks "better" or "differently" than the 26 examples in Amgen's patents, better reduces cholesterol, or is better tolerated by patients. P. 10, *supra*. They all operate by the same mechanism: By parking on PCSK9's sweet spot, they block that spot and prevent it from binding to LDL receptors.

B. The government urges that *Consolidated Electric* and *Holland Furniture* "establish that, when a patent claims a broad class or 'genus' of products, * * * the specification must describe 'some general quality, running

through the whole' genus that 'distinguishe[s]' the products from all others." U.S. Br. 21 (quoting *Consol. Elec.*, 159 U.S. at 475). "That general quality," it urges, must be described in "structural" terms. *Ibid.* (citing *Holland Furniture*, 277 U.S. at 256).

While describing a structure may be *one* way to enable a genus, the Court has never held it is the *only* way, regardless of the nature of the art. The patent to Neilson's improved forge was enabled, even though it did not identify a common structure for the "receptacle" at the invention's core, instead stating that any "size" or "shape" would do. *Neilson* v. *Harford* (1841) 151 Eng. Rep. 1266, 1273-1274 (Exch.). In biological arts, inventions may be implemented by biological generation—not structural assembly—even when described by function. See *Diamond* v. *Chakrabarty*, 447 U.S. 303, 305-306 (1980). This Court's recognition of such claims laid the foundation for the Nation's biotech industry. See A. Mossoff & M. Dowd, *Fearmongering Obscures the Historical, Pro-Innovation Role of Genus Claims*, Westlaw Today (Mar. 1, 2023), https://bit.ly/3KWxaPo.

Regardless, Amgen's patents provide the relevant "structural" requirement common to each embodiment within the genus: a "monoclonal antibody" with the necessary physical shape and electrochemical properties to "bind[ ] to at least one" of the residues in PCSK9's sweet spot. Pet. App. 4a.[4]

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[4] The claim term "binds to [residues on PCSK9]," C.A. App. 411 (427:47-52), conveys to skilled artisans a genus of antibody *structures* that complement, and thereby bind, the sweet spot's three-dimensional structure, see, *e.g.*, C.A. App. 3876 (629:25-630:13). Sanofi-Regeneron's expert agreed that "structure" and "bind[ing]" are inseparably intertwined. C.A. App. 3789 (470:17-471:2), 3787 (462:20-22).

The government demands that Amgen's patents "identif[y] a *particular chain of amino acids* that every antibody that blocks and binds will share." U.S. Br. 24 (emphasis added). That demand lacks "regard to [the patents'] subject-matter." *Minerals Separation*, 242 U.S. at 270. The jury heard expert testimony that amino-acid sequence is not the metric antibody scientists use for comparing antibodies or predicting their functions. See Pet. C.A. Br. 54-55; Pet. App. 25a-27a. And the tools of antibody science do not require particular amino-acid sequences to *create* the claimed antibodies. See *Wands*, 858 F.2d at 740. Amgen's patents disclose two "anchor" antibodies that, together, bind across PCSK9's entire sweet spot. See Pet. Br. 12. Amgen's expert testified that, following Amgen's roadmap, scientists can use established means (like transgenic mice) with those anchor antibodies as tools for identifying "all" other antibodies that bind anywhere on the sweet spot, and thus fall within the claims. C.A. App. 3909 (762:10-21), 3908 (757:12-14); see Pet. Br. 13-14.

C. Sanofi-Regeneron, the government, and *amici*, see, *e.g.*, Resp. Br. 35; Winter. Br. 27, flatly err in dismissing the roadmap in Amgen's patents as "little different from petitioners' initial research plan," U.S. Br. 25. The government does not bother discussing the roadmap itself, instead referring to the district court's decision. *Ibid.* (citing Pet. App. 40a). But the district court's analysis was so clearly wrong that Sanofi-Regeneron did not defend it in its Federal Circuit brief. See Pet. Br. 45 n.5. Nor did the Federal Circuit adopt it.

Far from requiring skilled artisans to "retrace" Amgen's "research steps," U.S. Br. 16, the patents allow them to *start* where Amgen's research *ended*. Amgen's patents provide a wealth of previously unknown shortcuts and techniques. Among other things, the patents disclose:

- The region of PCSK9 that binds LDL receptors—the sweet spot—and its precise three-dimensional structure and biochemical properties. C.A. App. 180 (Fig. 21D), 249 (Ex. 31).
- That the sweet spot is antigenic, meaning one can generate an antibody that binds there. C.A. App. 3798 (505:21-506:3).
- The first antibodies that bind there: Amgen disclosed that it had found 384 antibodies that block the interaction between PCSK9 and LDL receptors "well," C.A. App. 237 (80:22-23), 3798 (505:10-12), characterizing 26 by amino-acid sequence, C.A. App. 51-116.
- Two anchor antibodies that—because they together *cover the entire sweet spot*—allow skilled artisans to identify *any antibody* that binds *anywhere* on PCSK9's sweet spot. Pet. Br. 45 n.5; see also Pet. Br. 12-14; Pet. C.A. Br. 62-63.
- Super-immunization protocols to produce robust responses in transgenic mice. Pet. C.A. Br. 14.
- Assays to identify antibodies that bind the sweet spot. Pet. Br. 14; see also C.A. App. 236-238 (Ex. 3); Pet. C.A. Br. 14-15.
- Proof the antibodies reduce LDL cholesterol in live animals. C.A. App. 242-244 (Exs. 13-16).

The government simply ignores those foundational teachings.

The effort to dismiss Amgen's roadmap as a "trial-and-error process," U.S. Br. 14, 24; Resp. Br. 49, has no "regard to" the field of antibody science, *Minerals Separation*, 242 U.S. at 270. This is not a case, like *Consolidated Electric*, where skilled artisans had to flail blindly, randomly test-

ing plants in hopes of discovering a "fibrous * * * material" suitable "for incandescent conductors" in electric lamps. 159 U.S. at 472. They can make Amgen's 26 examples. And using Amgen's roadmap, skilled artisans *know* they will succeed in making more: They can produce a pool of antibodies from immunized mice, and then use assays taught by Amgen's patents to filter down to antibodies that "compete" with one of Amgen's anchor antibodies and thus bind PCSK9's sweet spot. See Pet. Br. 13-14. That "screen[ing]" is not trial and error, but something antibody scientists "are prepared to" perform in the ordinary course. *Wands*, 858 F.2d at 740.

D. Insofar as the government invokes the "Federal Circuit's application of the *Wands* factors," U.S. Br. 26, the Federal Circuit did not identify any class of antibodies that could not be made using Amgen's patents, Pet. Br. 25-27. The court's *Wands* analysis turned on "the amount of effort" that "would be required to reach the full scope of claimed embodiments," Pet. App. 14a—a cumulative-effort approach the government concedes is improper, U.S. Br. 29.

IV. Genus Claims Promote, Rather Than Stifle, Innovation

No one defends the Federal Circuit's reach-the-full scope test for enablement of genus claims as consistent with the patent "bargain." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). Sanofi-Regeneron and *amici* decry the idea of genus claims with functional elements. *E.g.*, Resp. Br. 44-48; Eli. Lilly. Br. 7-17. But Sanofi, Regeneron, and *amici* have protected *their own* inventions through claims as broad or broader than Amgen's. See, *e.g.*, U.S. Patent Nos. 8,329,669 (Sanofi); 8,298,532 (Regeneron); 6,331,415 (Genentech); 8,236,931 (Winter); see G. Quinn, *Will the Supreme Court Save Biopharma from*

CAFC Enablement Insanity?, IPWatchdog (Mar. 1, 2023), https://bit.ly/3ZJdDGd.

A. Sanofi-Regeneron suggests that patenting an individual "antibody by amino-acid sequence" is a "long-accepted way to claim a biological discovery." Resp. Br. 1. But genus claims are long-accepted, too. See GSK. Br. 5-8; Lemley. Br. 2-7; Mossoff, *supra*. They are "'critical to protecting and advancing innovation,' especially in the chemical, pharmaceutical, and biotechnological industries." GSK. Br. 5; see D. Karshtedt *et al.*, *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 1 (2021).

Patenting specific antibody sequences offers virtually no "protection," for "the fruits of [an innovator's] investment." Pet. App. 65a. Armed with Amgen's patents, it is easy to make myriad antibodies beyond the disclosed examples. The doctrine of equivalents hardly "address[es] th[e] risk" of copyists avoiding infringement by making minor changes to amino-acid sequences. Resp. Br. 45-46; see U.S. Br. 11, 32. That doctrine does not apply where "even one limitation of a claim * * * is not present in the accused [product]." *Lockheed Martin Corp.* v. *Space Sys./Loral, Inc.*, 324 F.3d 1308, 1321 (Fed. Cir. 2003). Courts thus have refused to apply "the equivalence argument" because it "would read the amino acid sequence limitation out of" the claim and "effectively expand" the claim's scope to encompass any "antibody that has the [claimed] effect." *Teva Pharms. Int'l GmbH* v. *Eli Lilly & Co.*, No. 18-cv-12029, 2022 WL 4824318, at *19 (D. Mass. Oct. 3, 2022). No company would invest billions in researching and developing new antibodies in hopes that the doctrine of equivalents will prevent competitors from evading an amino-acid-sequence claim.

Speculative concerns about hypothetical antibodies in the "far corners of the claimed landscape," Pet. App. 65a,

cannot meet the clear-and-convincing standard required for invalidity. And this Court's precedent provides the answer to any such concerns: If some "different" antibody in a remote corner "has so far changed the principle of the" patent claim that it no longer "represent[s]" the invention in Amgen's patents, the antibody can be deemed *outside* the claims' scope (even if it "literally" falls within the class). *Westinghouse* v. *Boyden Power Brake Co.*, 170 U.S. 537, 568 (1898). The answer is not to rewrite the longstanding enablement standard and the patent bargain itself.

B. Sanofi-Regeneron errs in urging that many "important medical treatments will never reach the market." Resp. Br. 47. The prospect of an *improvement* patent provides an incentive to pursue innovation within a genus. See Pet. Br. 38; Mossoff, *supra*. If someone did invent a particular species more efficacious and beneficial to the public—Sanofi-Regeneron has identified none—courts would have ample discretion to ensure it is not kept off the market through an injunction. See *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). And Congress has created processes for allowing generics and biosimilars at low costs. See 21 U.S.C. § 355(j) (Hatch-Waxman Act); 42 U.S.C. § 262(k) (Biologics Price Competition and Innovation Act). The Court need not distort enablement law under § 112 to protect those interests.

C. *Amici* suggest that allowing claims with functional elements would permit Amgen to monopolize "*all* PCSK9 antibody therapeutics." Eli. Lilly. Br. 4 (emphasis added); see Winter. Br. 23. Not so. This is nothing like Samuel Morse's effort to claim "'the use of * * * electro-magnetism, *however developed*, for making or printing intelligible characters * * * *at any* distances.'" *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 112 (1854) (emphasis added);

see Mossoff, *supra*. Amgen's claims cover only antibodies that block the interaction between PCSK9 and LDL receptors by *binding PCSK9's sweet spot*. Pet. App. 4a. Merck and Novartis developed cholesterol-reducing antibodies that, binding elsewhere, function through different mechanisms.[5] Novartis developed a non-antibody, siRNA-based therapeutic that inhibits PCSK9 production and lowers LDL cholesterol.[6] And Novo Nordisk is developing small-molecule PCSK9 inhibitors.[7] *That* is the type of innovation the patent system should promote—encouraging companies to develop diverse therapies, not minor variations of antibodies performing the same function in the same way. Upholding genus claims for pioneering inventions accelerates the progress of science as inventors seek their own breakthroughs instead of developing "me-too" products (like Sanofi-Regeneron did here).

CONCLUSION

The court of appeals' judgment should be reversed.

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[5] See PCT. Appl. WO 2008/057,458 (Merck); PCT. Appl. WO 2008/125,623 (Novartis).

[6] *FDA Approves Novartis Leqvio® (Inclisiran), First-in-Class siRNA To Lower Cholesterol and Keep It Low with Two Doses a Year*, Novartis (Dec. 22, 2021), https://bit.ly/3EWJevV.

[7] See, *e.g.*, *2021 Annual Report* at 26, Novo Nordisk (Feb. 2, 2022), https://bit.ly/3y9JsvQ.

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