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

BRIEF OF *AMICI CURIAE* ELI LILLY AND COMPANY, IPSEN BIOSCIENCE, INC. AND INNOVENT BIOLOGICS, INC. IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "'time and effort.'"

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INTEREST OF *AMICI CURIAE*[1]

Amici are research-based pharmaceutical companies that develop and market innovative medicines for treating a diverse set of diseases.

Patient access to promising medicines like those made by *Amici* is threatened by patents, like Amgen's, that claim medicines not by what they are but instead by what they do to a naturally-occurring therapeutic target in the body after administration to a patient. Such an approach is contrary to the letter and logic of the Patent Act. And although such patents cannot enable those innovative medicines, they nevertheless represent an attempt to preempt their future development in contravention of the fundamental bargain of the Patent Act.

Amici are advocates for a robust patent system that incentivizes high-risk, high-investment drug research. Patents like those at issue, however, overreach and thus hinder this goal. Such patents are not a prerequisite to develop antibodies or any other medicine, nor do they enable a skilled artisan to make and use such medicines; instead, they discourage, tax, and prevent their development, to the detriment of patients, payors, and healthcare professionals. This case provides the Court with an opportunity to clarify the application of 35 U.S.C. § 112 to patent claims set forth as purely functional results, and to make clear

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[1] Pursuant to Rule 37.6, *amici curiae* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici curiae* and their counsel made any monetary contribution to its preparation or submission.

that the right to exclude must be commensurate in scope with enablement of the invention as claimed.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Patent Act requires the specification to teach the "manner and process of making and using" the invention "in such *full*, clear, concise, and exact terms as to *enable*" a skilled artisan to make and use the invention. 35 U.S.C. § 112(a) (emphasis added). In other words, the *full* scope of the claimed invention must be enabled. Otherwise, the essence of the bargain the Patent Act seeks to strike—teaching the public how to "make and use" the invention in exchange for a limited monopoly—is lost. Section 112(a) thereby prevents patent applicants from functionally claiming, and preempting, broadly across an entire field while only teaching how to make and use a narrow subset within the field. Here, Petitioner Amgen Inc. ("Amgen") attempts to do just that by reading the "full" requirement out of § 112(a). *See, e.g.*, Pet. Br. at 29. But that view would thwart the Patent Act's design by granting Amgen a windfall at the public's expense.[2] That risk is particularly

[2] A regime where a company can control all antibody therapeutics to a particular target is indisputably detrimental to the public. It stifles competition from other antibody therapeutics and harms patients receiving the one available therapeutic, particularly where a patient develops tolerance to that antibody, leading to "treatment failure or reduced efficacy." *See* Ellen Q. Wang, et al., *Assessing the Potential Risk of Cross-Reactivity Between Anti-Bococizumab Antibodies and Other Anti-PCSK9 Monoclonal Antibodies*, 33 BioDrugs 571, 575 (2019); *see also* Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent*

acute here, where Amgen seeks to remove competition from the market entirely.

Here, Amgen concedes that it did not invent or discover PCSK9—a naturally-occurring protein. Amgen also did not invent or discover PCSK9's natural role in cholesterol metabolism or that antibodies binding PCSK9 could lower cholesterol. What Amgen did do is make 26 antibodies that bind to PCSK9 and block its natural function. The claims at issue here, however, are not directed to the antibodies Amgen invented,[3] but instead are directed to *any and all* antibodies that bind and block PCSK9.

The boundaries of Amgen's claim are unbounded, both in terms of size as well as biological and molecular diversity. The number of antibodies that could be preempted by Amgen's claims are in the millions, if not billions or more.[4] Moreover, by

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Paradox, 132 Yale L.J. (forthcoming 2023) (manuscript at 57-58) (available at bit.ly/3XnCpKx) ("Amgen's and Sanofi's anti-PCSK9 antibodies are not structurally identical, but they bind the same antigen and compete in the same market for lowering persistently high cholesterol. That competition can lower prices, which is a good thing.").

[3] *Cf.* U.S. Patent No. 8,030,457 (filed Aug. 22, 2008), an earlier patent from the same patent family as those at issue, claiming Amgen-developed antibodies including REPATHA® by structure (*i.e.*, its full amino acid sequence).

[4] The potential structural variation within just the complementarity determining regions (CDRs) of human antibodies is approximately 20^{60} (representing each antibody having six CDRs, each comprised of approximately 10 amino acids, and there being twenty different naturally-occurring human amino acids). This value does not even consider potential structural variations of other regions of human antibodies.

defining its claimed antibodies purely by their functional effect, through a natural mechanism on a naturally-occurring protein, Amgen intentionally seeks to lay claim to all PCSK9 antibody therapeutics. But claims expressed as purely functional effects have been recognized by this Court as violative of multiple statutory requirements of the Patent Act, including enablement and written description under 35 U.S.C. § 112, as well as patent-eligible subject matter under 35 U.S.C. § 101.

Amgen and its *Amici* assert these extraordinarily broad claims are enabled by Amgen's patent specification that provides 26 example antibodies and a proposed "roadmap" for others to go search for additional ones. Amgen's claims are not limited in any way, however, by their proposed "roadmap." And even if a skilled artisan tried to follow Amgen's disclosed roadmap to find other antibodies, Amgen's patent is nothing more than a "hunting license"—a "reward for the search" rather than "compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966). Such a hunting license, however, is not the "successful conclusion" of the search the public is entitled to receive in exchange for the patent's limited monopoly, especially in the life sciences, where despite great strides and now well-known methods, research remains highly unpredictable.

Across all art classes, patent law has consistently held that § 112 requires that a patentee teach how to make and use its invention across its full scope without undue experimentation. *See, e.g.*, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Amgen argues that "disclosing thousands more examples of

variations that achieve the same result contributes nothing to the store of human knowledge." Pet. Br. at 37. But that is a red herring. The "result" Amgen refers to is blocking PCSK9's function, and to say all therapeutic antibodies that bind to the same target are "the same" such that patentees only need to enable one or a few to fill "the store of human knowledge" is a gross distortion of scientific reality. It also misapprehends the rationale requiring "full" enablement of a claim. Amgen cannot merely enable one small part of its claimed invention while handwaving away its duty to enable subject matter that it asserts falls within its claims—*i.e.*, all PCSK9 antibody therapeutics. It must *at least* enable those examples that contribute to the store of human knowledge commensurate with the scope of its claims. Otherwise, it fails the patent bargain.

In essence, Amgen seeks the Court's endorsement of an exception to the requirements of § 112 for antibodies—permitting them to be claimed by reciting their naturally-occurring therapeutic target and their effect on that target instead of by their structure. Patent law is agnostic to technology and Amgen cannot have an antibody-specific rule. Claims like Amgen's—defined solely by a functional result and devoid of any structural limitation—are and should remain invalid under 35 U.S.C. § 112.[5]

Ultimately, Amgen and its *Amici* rest their overbroad arguments on a faulty premise. That is, Amgen argues that its claims should be viewed as

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[5] This is true whether analyzed under § 112(a) or § 112(f). *See infra* Section III.

"genus claims"—claims that "cover a group of *structurally* related products." *See, e.g.*, Pet. Br. at 24 (emphasis added; citation omitted). While *Amici* do not dispute that genus claims of structurally-related compositions are important for innovation, Amgen's claims are not such genus claims, as no distinguishing structural relationship is discernible from Amgen's claims. Instead, and conveniently for Amgen, its claims are tautological: no matter how structurally related or unrelated an antibody is, if it works, it falls within the claim; if it doesn't work, *i.e.*, doesn't have the recited therapeutic function, Amgen doesn't claim it.

By requiring a patentee to teach 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 same," § 112(a) protects against overbroad claims like Amgen's and ensures the public receives adequate consideration for the bargain of the patent monopoly. When a patentee takes more via his patent claims than he invents, the public loses the benefit of the patent bargain while the patentee reaps the windfall of an undue monopoly. Indeed, antibodies like Respondents' are not "embodiments" of Amgen's invention, as Amgen would like the Court to believe. They are separate inventions that are available to patients because of, not in spite of, § 112. The Court should affirm the decision below and make clear that claims like Amgen's—limited solely by functional results with no structural limitations whatsoever—are invalid under § 112. Doing so will not only ensure that the Patent Act is applied according to its legislative design—it will sustain this country's

leadership in the biotech and pharmaceutical industries.

ARGUMENT

I. Claims Like Amgen's, Expressed as Purely Functional Results Having an Unknown and Unknowable Scope, Violate the Letter, Logic and Purpose of the Patent Laws.

Section 112 provides guardrails to protect the public against overbroad patent scope. In short, a patentee may not claim more than what he has invented. Rather, a patentee must place in the hands of the public *the invention* as defined by the patent claims. But having "an invention" requires some knowledge of its metes and bounds; "simply a wish to know the identity of any material with [a] biological property" is insufficient. *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). A patentee who cannot envision the metes and bounds of his invention and cannot distinguish it from that which he did not invent has failed to place the invention in the hands of the public—and thus has no right to a monopoly.

That is the issue here. Amgen's claimed monopoly is defined solely by a description of a region of the naturally-occurring therapeutic target, PCSK9, and highly-general functional results, "binding" and "block[ing]." As such, Amgen "regards as [its] invention" the entire field of therapeutic PCSK9 antibodies. But it has claimed that all-encompassing functional "invention" without articulating (or, in fact, knowing) any particular features of what it has purportedly invented. Put plainly, whenever anyone

discovers any PCSK9 therapeutic antibody—no matter how different that antibody is from those Amgen has developed and disclosed—Amgen claims to own it.[6] But Amgen's improperly broad functional claiming contradicts the design of the Patent Act and is intended to prevent innovative antibody products like Respondents' product from reaching the market.

A. Purely Functional Claims Like Amgen's Cannot Be Enabled.

Defining the metes and bounds of a patent solely by a functional result, in an unpredictable art, makes it impossible to know how far the patentee's "invention" extends, or where its property line ends. As the Federal Circuit recognized, "it is clear that the claims are far broader in functional diversity than the disclosed examples. If the genus is analogized to a plot of land, the disclosed species and guidance 'only abide in a corner of the genus.'" *Amgen, Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1087 (Fed. Cir. 2021) (footnote omitted) (quoting *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299–1300 (Fed. Cir. 2014)). As such, Amgen has "merely recite[d] a description of the problem to be solved"—binding an antigen to block binding to the

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[6] Amgen and its *Amici* argue that such a regime results in more efficient allocation of R&D dollars. *See, e.g.*, Pet. Br. at 40; Brief of *Amicus Curiae* GSK PLC in Support of Petitioners at 9-12. But that presupposes without foundation that the patent holder and the alleged patent infringer are equally efficient at discovering and developing drugs. In an extreme case, Amgen's take on enablement would allow a "Non-Practicing Entity" to act as the proverbial troll extracting a toll to cross the bridge and would dramatically *undermine* resource allocation efficiency.

antigen's receptor—"while claiming all solutions to it and … cover[ing] any compound later actually invented and determined to fall within the claim's functional boundaries." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc). But, as noted by Sir Gregory Paul Winter, "[i]t is a fundamental tenet of basic antibody science that an antibody's structure, as determined by its sequence, further determines its function [and] equally fundamental that the reverse is not true." Brief of Sir Gregory Paul Winter and Interested Scientists as *Amici Curiae* Supporting Respondents, at Summary of Argument (Feb. 10, 2023). In fact, Amgen espoused this very view as *amicus* before the Federal Circuit in *Ariad*, stating: "[I]t is also important to ensure that such innovation is not preempted by those who provide no solution but only describe a problem and attempt to claim in a patent any or all solutions to the problem." Brief for Amgen Inc. as *Amicus Curiae* Supporting Affirmance, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 08-1248, 2009 WL 4616154, at *16 (Nov. 19, 2009).

Indeed, the claimed subject matter here is not analogous to a plot of land bound by property lines. Rather, Amgen's claims are boundless and encompass land anywhere in the world that yields working PCSK9 "antibody fruit." But Amgen's current characterization of § 112 misses the "boundary" requirement entirely.[7] Instead, Amgen strains to

[7] Amgen's *Amici*, however, seem to understand. *See, e.g.*, Brief of Diversified Researchers and Innovators in Support of Petitioners at 19 (noting that claims "which impose *no*

analogize this case to the Wright Brothers' flying machine, arguing that the Federal Circuit's textually-rooted standard would render the flying machine wholly "unpatentable." *See* Pet. Br. at 2–3. But the issue here is not whether Amgen's "invention" is patentable, but rather whether Amgen can use purely functional claiming (devoid of any structural limitations) to morph its invented compositions into a patent that monopolizes an entire field.

If Amgen's characterization of § 112 were correct, a patentee could enable a claim to *any* vehicle capable of flying by merely disclosing Bernoulli's principle of fluid dynamics, first published in the 18th century, as applied to winged flight, along with a description of the Wright Brothers' flying machine. Under Amgen's theory, such a claim could encompass the *entire field* of vehicles capable of flight, including a jet-propelled rocket, helicopter, hang glider, ornithopter, dirigible, or wingsuit. The scope of such a claim, defined by a purely functional result, would stretch the Patent Act's contemplated bargain far beyond its purpose by granting exclusive rights beyond what the patent has enabled.

The above hypothetical—which like Amgen's claim is defined solely by a broad functional result—highlights the perennial preemption problem with

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requirements as to *any* structural characteristics … are unlikely to pass scrutiny"); Brief of Intellectual Property Professors as *Amici Curiae* Supporting Petitioners ("IP Professors Br.") at 16 (similar).

functional claims having no structural limitations.[8] By attempting to claim a product or process solely by what it *does*, rather than what it *is*, a patentee can lay claim to an entire field by describing a few species that achieve the claimed result rather than describing the genus in such a way that its members become reasonably predictable, if not specifically disclosed. Such a claim cannot stand.

B. Claims Like Amgen's Are Nothing More than Pretext for Preempting an Entire Field of a Naturally-Occurring Protein.

This Court has long recognized that allowing a patent to monopolize basic tools of scientific work "would be at odds with the very point of patents" and risks impeding innovation as opposed to promoting it. *E.g.*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013). Amgen's claims have the veneer of being directed to non-natural compositions of matter—monoclonal antibodies. But, upon inspection, they are nothing more than claims that preempt the entire field of therapeutic PCSK9 antibodies—precisely the type of overbreadth that Congress designed § 112 to prevent.

Amgen's claims outline the invention by first defining the field of its monopoly: "monoclonal

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[8] *See, e.g.*, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1853) ("[S]ome future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. … *But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.*" (emphasis added)).

antibod[ies]."[9] However, instead of defining a genus of antibodies in a manner that limits them to Amgen's invention, Amgen's claims recite something else entirely—portions of the naturally-occurring human protein, PCSK9, to which the claimed antibodies must bind.

More specifically, the term "monoclonal antibody" is a generic term which provides no meaningful or structure-limiting description of any antibody falling within the scope of Amgen's claim. *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 223–24 (2014) (noting that such a claim offers no "meaningful limitation" (citation omitted)). The sole limitation defining the claimed genus of antibodies is the functional results of "binding" and "blocking" the naturally-occurring protein PCSK9. Thus, Amgen's claims amount to nothing more than a recitation of an abstract idea similar to "apply it with a computer." *Id.*

Moreover, with respect to antibodies like Respondents', which are indisputably not "conservative" derivatives of Amgen's,[10] there exists no correlation between a description of PCSK9 and any antibody falling with Amgen's claimed genus. Put

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[9] *But see Bilski v. Kappos*, 561 U.S. 593, 610 (2010) (prohibition against patenting an abstract idea to preempt an entire field "cannot be circumvented by attempting to limit the use … to a particular technological environment" (citation omitted)).

[10] A "conservative" derivative is obtained from an Amgen "anchor" antibody when the anchor is changed in a manner that is expected to retain its function. To the extent Amgen is arguing that *any* antibody that has the claimed function is a conservative derivative of Amgen's, that argument fails as circular.

another way, an antibody that binds the naturally-occurring portions of PCSK9 as recited in Amgen's claims could have a near-infinite number of unpredictably different structures. *See supra* n.4. Thus, unlike *structural* genus claims which provide metes and bounds defining *the invention*,[11] Amgen's claims describe a naturally-occurring protein—PCSK9—and provide only a *generic* linkage to a *technological field* (therapeutic antibodies). As a result, such claims preempt, rather than promote, progress in the field of therapeutic PCSK9 antibodies.

This Court has warned against claims precisely like those at issue, which preempt all uses of a building block of nature,[12] and has rejected such claims for overbreadth.[13] Amgen's claims overreach, serving as clever cover for preempting the field of therapeutic PCSK9 antibodies. Where, as here, the scope of the monopoly is delineated only by a description of the naturally-occurring protein (which is not itself claimed) applied to a specific technological field (antibodies), the public has not received the

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[11] *See, e.g.*, U.S. Patent No. 8,030,457 (to Amgen; claiming a genus of antibodies, including REPATHA®, by reciting CDRs (*i.e.*, structural elements common to antibodies within the claimed genus that impart the recited function)).

[12] *See, e.g.*, *Mayo Collaborative Services v. Prometheus Labs, Inc.*, 566 U.S. 66, 69 (2012).

[13] *See, e.g.*, *O'Reilly*, 56 U.S. (15 How.) at 112-13, 119-20; *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 371 (1938) (finding claim-at-issue "vividly illustrates the vice of a description in term of function. 'As a description of the invention it is insufficient and if allowed would extend the monopoly beyond the invention.'" (quoting *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 258 (1928))).

proper return in exchange for the monopoly granted. Absent that meaningful return, where the monopoly is commensurate with the actual invention disclosed to the public, the claims are invalid.

This Court should thus reject Amgen's assertion that an entire therapeutic field can be preempted by a patent claim that recites the therapeutic target limited only by the therapeutic field itself (monoclonal antibodies). Purely functional claims, like Amgen's, which lack any structure-limited construction, cannot suffice to disclose and enable the public to "make and use" the entire preempted field. *See Amgen Inc. v. Sanofi Aventisub LLC*, 850 F. App'x 794, 796 (Fed Cir. 2021) ("Drawing a broad fence around subject matter, without filling in the holes, is not inventing the genus."). Without the proper check served by § 112 on the preemptive breadth of Amgen's claims, the patent system risks "foreclos[ing] more future invention" surrounding that naturally-occurring target "than the underlying discovery could reasonably justify." *Mayo*, 566 U.S. at 86.

C. Amgen's Claims Fail Either Interpretation of § 112(a) Put Forward in the Question Presented.

In an attempt to sidestep the issues with its claims' undue breadth, Amgen presents its question to this Court as a dispositive (but false) dichotomy of statutory interpretation.[14] But where purported

[14] Amgen does not deny "that a patent must reasonably enable the entire scope of the claim." Pet. Br. at 28. Rather, it takes issue with the Federal Circuit's requirement that skilled artisans

genus claims encompass an unknown and unknowable scope in both size and structural diversity, such claims are not enabled under either posited interpretation of § 112.

First, by Amgen's own definition, its claims are not in fact "genus" claims, *i.e.*, claims that "cover a group of *structurally related* products that incorporate the basic advance of the patented invention." *See, e.g.*, Pet. Br. at 24 (alteration adopted; citation omitted). No structural relationship, in any way, defines Amgen's claimed genus—the only structural elements recited are those of the naturally-occurring protein PCSK9. Amgen, however, posits the Federal Circuit has "failed to identify any actual problem skilled artisans face in *practicing* the invention." Pet. Br. at 26. This charge misses the point precisely because Amgen's claims, limited only by a functional result, are designed to preempt everything that works, while discarding everything that doesn't. The Patent Act does not countenance that tautological approach.

Second, Amgen's interpretation of the Federal Circuit's standard as requiring a patentee "to cumulatively identify and make all or nearly all embodiments of the invention" is contrary to the Federal Circuit's actual holding below. Pet. Br. at 5; *see Amgen*, 987 F.3d at 1088 ("We do not hold that the

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be able "to reach the full scope of claimed embodiments." *Id.* at 27. But in the context of a claim like Amgen's, where the full scope of the claimed embodiments can only be ascertained by making and testing each purported embodiment and the public has no other way of knowing whether a particular antibody falls within or outside the claims, that is a distinction without a difference.

effort required to *exhaust* a genus is dispositive. It is appropriate, however, to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance."); Resp. Br. at 32–36. And, because Amgen's disclosure brings the skilled artisan no closer to knowing the size and scope of the genus claimed, it is clear that Amgen's claims cannot meet either enablement standard posited.

Third, Amgen states that *In re Wands* is the "now-seminal" Federal Circuit decision on enablement and does not dispute that the factors comprising its "undue experimentation" standard are crucial in determining whether the enablement requirement is met. *See* Pet. Br. at 23–24. Yet the *Wands* factors include "the amount of direction or guidance presented" by the patent, "the predictability or unpredictability of the art," and "the breadth of the claims"—factors the Federal Circuit directly employed below to interpret § 112 and to find Amgen's claims invalid. *Wands*, 858 F.2d at 737; *Amgen*, 987 F.3d at 1084–88 (discussing the *Wands* factors). Thus, the Federal Circuit's interpretation of the enablement requirement of § 112 below is exactly in line with three decades of jurisprudence with which Amgen takes no issue. *See* Resp. Br. at 28–31.

Even reading daylight between the allegedly competing interpretations of § 112 in the question presented as Amgen does, the interplay between the amount of guidance presented by Amgen (describing 26 antibodies that bind PCSK9) with the breadth of the claims (claiming the entire field of therapeutic PCSK9 antibodies) is fatal to Amgen's claims under either standard. Amgen's contribution to the field is

nowhere near commensurate with its claim scope—which Amgen concedes includes non-conservatively-substituted antibodies like PRALUENT®. *See* Pet. Br. at 39.

And Amgen's reliance on its "roadmap" is unavailing. Amgen concedes that this supposed "roadmap" comprises techniques that the Federal Circuit over 30 years ago recognized as "'well-known' 'methods for obtaining and screening monoclonal antibodies'" Pet. Br. at 25 (quoting *Wands*, 858 F.2d at 736). As the District Court correctly found, a skilled artisan attempting to find other antibodies within the claims "would have to do essentially the same amount of work as the inventors of the patents-in-suit." *See Amgen Inc. v. Sanofi*, No. 14-1317-RGA, 2019 WL 4058927, at *12 (D. Del. Aug. 28, 2019) (citation omitted). And in any event, Amgen does not claim only its "roadmap" or only antibodies discovered therethrough. While Amgen's patent brings the public no closer to therapeutic PCSK9 antibodies than the prior art, Amgen nevertheless seeks to claim and preempt them all. As a result, Amgen has failed to enable a skilled artisan to make and use *the full scope of the claimed invention*—which includes antibodies unknown and unknowable to Amgen at the time of its invention. Amgen's claims cannot satisfy § 112 under any interpretation thereof and are thus invalid.

II. Enablement Jurisprudence Comports with the Tenets Upon Which § 112 Rests.

This Court has long held that enablement is viewed through the lens of the claimed invention's breadth. For instance, the Court has rejected an argument "that one, who had discovered that a certain fibrous or

textile material answered the required purpose, should obtain the right to exclude everybody from the whole domain of fibrous and textile materials." *Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465, 476 (1895). And it has refused to extend the patent monopoly so far as to permit "the inventor who has discovered that a defined type of starch answers the required purpose to exclude others from all other types of starch." *Holland Furniture*, 277 U.S. at 257. Those holdings make sense: the patent "monopoly is a property right, and like any property right, its boundaries should be clear." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901–02 (2014) (quotation marks omitted). Thus, "[i]t has long been understood that a patent must describe the exact scope of an invention and its manufacture." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996).

Amgen's claims fail these standards. By crafting claims of undefined and indeterminate scope devoid of any structural limitations, Amgen has left it up to others to discover which antibodies inhibit binding of PCSK9 to its receptor and therefore fall within Amgen's unknowably broad "genus." But when others independently invent those other antibodies, Amgen wants to block those inventors from providing them to the public. That anticompetitive behavior impedes the innovation that the Patent Act was designed to promote.[15]

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[15] See IP Professors Br. at 14 ("Claims that are too broad and untethered to working examples would allow patentees to 'jump

Amgen invites the Court to undermine that bargain and undo decades of settled law on the false premise that the Federal Circuit applied a "new" and "high[er]" standard. Pet. Br. at 24, 45 (alteration in original). But contrary to Amgen's assertions, there is no "different standard" for claims directed only to functional results. *Id.* at 19. Rather, the enablement requirement exists uniformly to "ensure[] that the public knowledge is enriched by the patent specification to a degree *at least commensurate with the scope of the claims*." *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195–96 (Fed. Cir. 1999) (emphasis added). It has been true for decades that "[t]he scope of the claims must be less than or equal to the scope of the enablement." *Id.* at 1196. And "[t]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art." *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). Amgen's unbounded claims to all therapeutic PCSK9 antibodies bear no correlation, let alone a reasonable one, to the scope of its disclosure.

Amgen and its *Amici* endeavor to gloss over this discrepancy between the scope of the monopoly it seeks and the disclosure it provides to the public by citing cases where the Court has upheld patent claims supported by a specification that did not disclose every embodiment claimed. But this misses the mark. The patent at issue in *Minerals Separation, Ltd. v. Hyde*, for example, dealt with improved methods of processing and refining ore by adding oil to it and

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the gun' and control unforeseen species that might be dramatic improvements without offering a corresponding benefit.").

agitating the mixture. 242 U.S. 261, 263, 265 (1916). The patent described the amount of oil to be used—0.1 to 0.5%—and the agitation rate—"1,000 to 1,100 revolutions per minute." *Id.* at 267. For one, *Minerals Separation* did not address—and says nothing about—functional claims. *See* Brief of High Tech Inventors Alliance and the Computer & Communications Industry Association as *Amici Curiae* in Support of Neither Party ("HTIA Br.") at 27.

Moreover, unlike Amgen, the patentee in *Minerals Separation* did not purport to invent and claim a genus of oils or ores; rather, it claimed a method employing narrow ranges of operative variables that were described at length in the patent's specification. 242 U.S. at 270–72. The constituents of the method claims—ore, oil, water, and even the agitation machine—were all known in the art and, importantly, no composition of matter had to be invented to practice the claimed invention. Instead, all a skilled artisan had to do was optimize within the narrow ranges claimed. In view of this disclosure and the prior art, the Court found that a skilled artisan could easily and routinely optimize the process within the claimed ranges for each type of ore presented. *Id.* at 271.

Here, by contrast, Amgen has given the public nothing to optimize. While a skilled artisan could arguably use one of Amgen's 26 disclosed antibodies, or "conservative" derivatives thereof, to discover some antibodies within the indeterminate genus, Amgen's claims are not so limited. There is a virtually limitless universe of other, non-conservative antibodies, and paths to discovering those antibodies, of which Amgen itself has no knowledge but nevertheless tries to

claim. Unlike *Minerals Separation*, a skilled artisan armed with the disclosure of Amgen's patent would be no more enabled in creating one of these other therapeutic PCSK9 antibodies than he was prior to that disclosure. To hold such paltry disclosure sufficient to enable claims preempting an entire technological field would turn the patent *quid pro quo* on its head. *See Amgen*, 850 F. App'x at 797 ("It is not the law that one can put forth an idea, or a result or function, and claim all methods of achieving it; one cannot claim everything that works.").

Ex parte Sloane is likewise inapposite. There, the patent disclosed certain mercaptan compounds that could be added to white petroleum oils to have an antioxidant effect, and claimed the genus of such mercaptans. 22 U.S.P.Q. 222, 1934 WL 25325 at *1 (P.O.B.A. Jan. 18, 1934). But the inventor disclosed and claimed a "well-defined" genus, *i.e.*, one with a particular structural motif. *Id.* Similarly, in *In re Angstadt*, the patentee claimed a genus of catalysts having a particular structure, such that a skilled artisan could readily ascertain—without making the compound and testing it for a particular function—whether a compound fell within the genus. *See* 537 F.2d 498, 500, 503 (C.C.P.A. 1976). Finally, the claims in *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.* recited an emulsified mixture of ammonium nitrate, fuel, gas, and an emulsifying agent. 750 F.2d 1569, 1576 (Fed. Cir. 1984). As with *Angstadt*, a skilled artisan would readily know whether a particular mixture fell within the claimed genus; at issue was only the known (and disclosed) inoperability of certain of the claimed mixtures. *See id.* at 1576–77.

The patentees in *Minerals Separation*, *Sloane*, *Angstadt*, and *Atlas Powder* did not seek to preempt an entire technological field as Amgen does here. Nor did they claim unbounded genera defined only by function, such that a skilled artisan could not readily distinguish that which is claimed from that which is not. Far from supporting Amgen's claims, these cases illustrate the very point that claims like Amgen's—which are of unbounded and undefined scope—cannot be squared with the patent bargain, this Court's long-standing enablement jurisprudence, or the tenets upon which § 112 rests.

III. Functional Claims Are Properly Analyzed Through the Lens of § 112(f).

Both this Court and the Federal Circuit have expressed concerns about functional claims "preempt[ing] the future before it has arrived." *See, e.g.*, *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993); *see also* HTIA Br. at 20–28. Those decisions have stressed the importance of balancing the rights of private parties to claim all that they have invented with the public's right to innovate freely—and to benefit from innovation—in the space beyond that which is described and enabled by the patent. *See supra* Section II. And even in the context of pioneering and groundbreaking discoveries,[16] the Court has historically held that using "conveniently functional

[16] The Court should not now carve into § 112 an exception for "pioneering" or "groundbreaking" inventions, for what is "pioneering" or "groundbreaking" is in the eye of the beholder. The enablement standard should be based on objective measures, not a subjective perception of a particular invention.

language at the exact point of novelty" renders the claims invalid as a matter of law. *See Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 8 (1946) (citation omitted).

In response to *Halliburton*, Congress enacted 35 U.S.C. § 112(f),[17] creating a limited exception to this Court's prohibition against functional claiming. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997) ("§112, ¶6 was enacted as a targeted cure to a specific problem.").[18] The statute's limited, claim-saving exception applies when purely functional language is used to define at least one element among a combination of structural and functional elements that make up a claimed invention. *See* 35 U.S.C. § 112(f); *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc) (holding § 112(f) also applies if the means recited is in the form of a "nonce" that fails to connote "sufficiently definite structure" (citation omitted)).[19]

Section 112(f) however, does not save Amgen's claims, because none of Amgen's claims at issue are *a combination* of structural and functional elements. Beyond two functional elements—binding and

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[17] Originally codified as 35 U.S.C. § 112, ¶ 6. Congress did not abrogate *Halliburton*; rather, this section represents a "compromise" for saving certain functional claims. *See* IP Professors Br. at 13 n.4.

[18] Professor Lemley believes that §112(f) could be a "middle ground" for analyzing antibody genus claims. *See* Lemley & Sherkow, *supra* n.2, at 60-70.

[19] In the field of antibody therapeutics, "antibody" is such a "nonce" term because it does not convey any meaningful structure.

blocking—Amgen's claims only further recite the term "monoclonal antibody," which serves simply to identify the field of the invention without reciting any structural elements of the antibody itself. Simply put, reciting multiple functional results achieved by the claimed antibodies does not provide a combination of antibody structural elements as required under § 112(f). Thus, Amgen's claims do not fall within § 112(f)'s exception.[20] As a result, under *Halliburton* and its progeny, Amgen's claims are valid *only* if the functional language employed is "sufficiently definite in meaning as the name for structure." *See Williamson*, 792 F.3d at 1348. Because the factual record in this case in no way establishes that binding and neutralizing activity correlates to identifiable distinguishing antibody structure, Amgen's claims are invalid.

IV. The U.S. Biotech and Pharmaceutical Industry's Global Leadership Role Is Fueled, Not Hindered, By Current Law.

Despite Amgen's and its *Amici*'s concerns, U.S. innovation is booming, particularly in the antibody space. And that is in no small part because the lower courts have refused to endorse Amgen's sweeping theory. Over the last three decades, therapeutic

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[20] Amgen's claims that "cover[] every conceivable means for achieving the stated result" and come with a "specification [that] discloses at most only those means known to the inventor" are "single means" claims. *See In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983). "The proper statutory basis for the rejection of a single means claim is … the first paragraph of § 112 that the enabling disclosure of the specification [is not] commensurate in scope with the claim under consideration." *Id.* (footnote omitted).

antibody innovation has represented an important and increasing driver of the U.S. innovation engine. Recently, the U.S. hit an important milestone—the 100th FDA-approved therapeutic antibody.[21] The U.S. has stayed at the forefront of innovation despite the inherent risks of drug development[22] and the compounding risks of patent litigation. Thanks at least in part to a robust and principled U.S. patent system, more new therapies are invented and developed in the United States than in the rest of the world combined.[23]

Amgen attempts to upend the legal regime that has empowered that growth, innovation, and undeniable benefit to the public. Amgen seeks to eliminate the decades old "full scope" enablement standard under the guise of an "innovation" imperative, alleging "devastating consequences" from the Federal Circuit's

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[21] *See* Asher Mullard, *FDA Approves 100th monoclonal antibody product*, 20 Nature Reviews Drug Discovery 491, 491-95 (2021).

[22] For example, for every approved product, many more fail, often after staggering investment. In fact, among antibody products that reach Phase I clinical trials, approximately 80% do not ultimately obtain approval. *See, e.g.*, Suzanne S. Farid, et al., *Benchmarking biopharmaceutical process development and manufacturing cost contributions to R&D*, 12 MAbs e1754999-1, e1754999-4 (2020). Given these failure rates, the average development cost for an antibody drug product is around $2.59 billion. Pet. Br. at 40.

[23] *See* Robert Kneller, *The importance of new companies for drug discovery: origins of a decade of new drugs*, 9 Nature Reviews Drug Discovery 867, 877 Fig. 2 (2010).

enablement standard.[24] *See* Pet. Br. at 39. But reality suggests otherwise. The Federal Circuit's standard has, since its inception, hewn to this Court's guidance and no devastating consequences have arisen.[25] To the contrary, innovation and patient choice have flourished.[26]

But if this Court sanctions claims of the type advanced here by Amgen, antibody innovators will face significant patent-infringement risks from functional genus claims. A functional genus claim like Amgen's is the epitome of the so-called "patent thicket"—there is no way to avoid it or design around it, other than to not enter the space at all. By their design, such patents are intended to exclude investment in competing therapeutic antibody products that act on the same target within the body.

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[24] Contrary to Amgen's assertions, the inability to preempt an entire therapeutic field via a patent claim does not preclude investment to discover and develop therapeutic antibodies. Amgen filed for and obtained the patents asserted here in 2013 and 2014, *i.e.,* about nine years *after* starting the clinical work (and a few weeks *after completing that work*) that led to FDA approval of its antibody product.

[25] *See, e.g.*, Dmitry Karshtedt, et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 70 (2021) ("[T]he fact that the sky hasn't fallen on the pharmaceutical industry even though [purely and semi-functional] genus claims have been systematically invalidated should give us pause, requiring further inquiry into how much patent protection really is necessary.").

[26] Amgen's professed "innovation imperative" also ignores that, as a practical matter, when innovation-investment decisions are initiated and the first patent application is filed, one cannot reliably predict whether the filing will beat any competitor to the Patent Office, as patent applications generally do not publish for at least 18 months. *See* 35 U.S.C. § 122(b).

Endorsing that view would delay development of competing innovative products—which would grant a competitive windfall to the functional patent holders while harming the patients who stand to benefit from robust competition and innovation in this space.

Moreover, the patentability standards deployed below are not new and, as applied to Amgen's claims, the result cannot be surprising to Amgen. *See, e.g.*, *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) ("A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it."); *see also Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1385 (Fed. Cir. 2013) (claimed genus would have had "tens of thousands of candidates" with no guidelines in the specification "about how to structurally modify" the compound at issue, "let alone in a way that would preserve the recited utility").

Furthermore, innovators have long focused on development of new antibody drugs that inhibit binding to the same target as existing therapies—often with multiple companies independently innovating in the same space at the same time to the benefit of patients. The therapeutic target CD20, a naturally-occurring human protein, provides an instructive example. The first FDA-approved antibody that binds CD20 was Genentech's RITUXAN® (rituximab) for follicular non-Hodgkin's lymphoma in 1997. Since then, four companies have

developed structurally different antibodies targeting CD20:

- Biogen Idec with ZEVALIN® for non-Hodgkin's lymphoma in 2002;
- Corixa with BEXXAR® for non-Hodgkin's lymphoma in 2003;
- Novartis with ARZERRA® for chronic lymphocytic leukemia in 2009; and
- Genentech itself, with GAZYVA® for chronic lymphocytic leukemia in 2013 and OCREVUS® for multiple sclerosis in 2017.

In short, four innovators developed six different antibody therapies for three different illnesses while targeting the same protein.

Even here, Amgen's REPATHA® (evolocumab) and Respondents' PRALUENT® (alirocumab) are products born from independent innovation by two competitors; they are not "biosimilars"—*i.e.*, they are not expected to have the same effect in any given patient. And importantly, new antibodies to the same target often have substantial benefits over the first-in-class compound.

For example, HERCEPTIN® (trastuzumab) was a game-changing HER2 inhibitor for the treatment of breast cancer when it was approved in 1998. But MARGENZA® (margetuximab), approved in 2020, has demonstrated significantly better progression-free

survival statistics than HERCEPTIN® in clinical trials.[27]

Similarly, UCB's CIMZIA® (certolizumab pegol)—approved in 2008 as a TNF inhibitor for the treatment of Crohn's disease—provided substantially improved outcomes for patients who had experienced a loss of response to Janssen's first-line treatment REMICADE® (infliximab), approved in 1998.[28] This type of outcome, where patients respond differently to different antibodies, occurs despite both antibodies binding to the same target. Such differences are impossible to predict at the screening stage; rather, clinicians must generate and study clinical data, as has been done for antibodies like CIMZIA® and REMICADE®.[29]

These examples demonstrate the benefits of a patent system that does not condone preempting an entire field's use of a therapeutic target based on a patent claim that only describes the therapeutic target and not the actual molecules that bind thereto. Amgen's proposed regime would cut off such

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[27] *See* Hope S. Rugo, et al., *Efficacy of Margetuximab vs Trastuzumab in Patients with Pretreated ERBB2-Positive Advanced Breast Cancer: A Phase 3 Randomized Clinical Trial*, 7 JAMA Oncol. 573, 577-80 (2021).

[28] *See* B.G. Feagan, et al., *Randomised clinical trial: improvement in health outcomes with certolizumab pegol in patients with active Crohn's disease with prior loss of response to infliximab*, 33 Alimentary Pharmacol. & Therapeutics 541, 541 (2011).

[29] *See* Yusuf Yazici, *Rheumatoid Arthritis: Evidence-based rather than habit-based treatment options*, 8 Nature Reviews Rheumatol. 374, 374 (2012).

innovation at its knees, remove the incentives to invest in R&D where antibodies to a chosen target are already claimed wholesale, and potentially eliminate multiple treatment options from the market.

Indeed, if Amgen's interpretation of the Patent Act were the law of the land, the first party to obtain a functional claim to all antibodies that inhibit binding to a target could prevent market entry and/or extract rents from all future innovators for twenty years. Such an interpretation would create a race to scoop up, and preempt, as many therapeutic antibody targets as possible without necessarily creating any useful antibodies to those targets, thereby chilling therapeutic antibody innovation. *See supra*, n.2.

That is the opposite of what our patent system was designed to achieve. Competition between innovators in this space is healthy and beneficial to patients, who should be provided as many healthcare options as possible. And considering the extremely high cost to independently invent and develop a new drug of any type, there is little to no incentive to bring forward a therapy that offers no benefits relative to existing therapies. The current robust competition landscape and constantly improving treatment options indicate that the system is working as intended. A decision by this Court holding Amgen's functional claims (and all claims similarly situated) invalid would correctly require patentees to claim the antibodies they have actually invented and enabled consistent with the design of the Patent Act.

CONCLUSION

This case provides the Court with an opportunity to confirm that the disclosure requirements of § 112 apply in a technology-neutral manner and exist to ensure exclusive rights granted are commensurate with an enabling disclosure. *Amici* request this Court affirm the invalidity of Amgen's claims as lacking enablement *and* make clear that claims over unbounded genera, defined only by functional results, are *per se* invalid under 35 U.S.C. § 112(a). Without clarity from this Court, entire fields such as the unpredictable therapeutic antibody arts risk being preempted by claims, like Amgen's, that seek to preempt all uses of a building block of nature within a given field and thereby threaten to limit treatment options available to patients and the doctors who treat them.

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