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 THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines (AAM) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 20% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

AAM and its members have an interest in combatting overbroad patents that claim a result, rather than a particular means of obtaining that result. In this case, Amgen invented particular antibodies that bind to a protein known as PCSK9. But rather than claim the antibodies that it actually invented, Amgen obtained patent claims on *all* antibodies that bind to PCSK9. Those overbroad patent claims allowed Amgen to sue Sanofi for patent infringement, even though Sanofi developed a structurally different antibody that Amgen did not invent and never knew about.

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[1] Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

"[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). Patents like Amgen's violate that bargain by allowing patentees to obtain a monopoly on products without disclosing how to make and use them. Further, such patents ban competitors from inventing new ways of achieving a desirable outcome by monopolizing the outcome itself, thus stifling innovation with no countervailing social benefit. AAM has an interest in ensuring that patents confer monopolies on what patentees have actually invented—and nothing more.

INTRODUCTION AND SUMMARY OF ARGUMENT

Section 112(a) of the Patent Act is a key component of the bargain at the center of patent law. It requires that before society will grant an inventor a patent for an invention—and thus eliminate competition in the market for that invention for two decades—the inventor must disclose enough about her invention to enable those skilled in the art to "make and use" it. 35 U.S.C. § 112(a). This enablement requirement "enforces the essential *quid pro quo* of the patent bargain by requiring a patentee to teach the public how to practice *the full scope* of the claimed invention." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1099-100 (Fed. Cir. 2020) (emphasis added) (internal quotation marks omitted). The requirement thus ensures that the monopoly granted to the inventor is no broader than what is

warranted. Simply put, the inventor only gets the exclusive rights to that which she has actually made and disclosed.

The bargain effectuated by Section 112(a) gives patentees a choice. An inventor can choose to prosecute narrow claims, lowering the burden of disclosure but accordingly giving the inventor a narrower monopoly. An inventor can also choose to prosecute a broad claim that endows a broader monopoly. But if the inventor makes that choice, Section 112(a) requires that the specification disclose enough to put the claim's full scope within the reasonable reach of a skilled artisan.

Amgen's patent claims at issue here do not comport with patent law's bargain. Amgen made the choice to seek a monopoly over *all* antibodies that bind to PCSK9 and inhibit it from binding to LDL receptors. But Amgen does not claim to have invented all antibodies that perform those two functions; it has discovered and disclosed only some of them. Nonetheless, it seeks a decades-long monopoly over *every* antibody that inhibits PCSK9 in the same way as the antibodies it has discovered. Amgen's gambit must be rejected because its patents do not meet Section 112(a)'s requirement. And its overbroad claims deprive the public—specifically, American patients—of access to valuable medical treatments.

The Federal Circuit's decision below correctly rejected Amgen's effort to capture the rights to all PCSK9-inhibiting antibodies despite having invented just a small number of them. Its conclusion reflects a proper reading of the Patent Act's text, accords with the

Act's structure and purpose, and is consistent with a long line of this Court's precedent.

Section 112(a) of the Patent Act provides that a patent's specification must contain sufficient detail about "the invention" so as "to enable any person skilled in the art . . . to make and use" it. 35 U.S.C. § 112(a). And the Act explains that "the invention" is that which the inventor asserts as its own in the patent's claims. *See id.* § 112(b). The text is thus clear: everything that the patentee claims must be enabled in the specification. Accordingly, when a patentee, like Amgen here, claims an entire genus, it must enable skilled artisans to "make and use" not just "the limited number of embodiments that the patent discloses, but also the full scope of the claim," Pet. App. 11a. And because skilled artisans must be enabled both to "make" and "*use*" the invention, a genus patent must disclose both how to generate all the members of the genus *and* how to distinguish between those that serve the claimed function and those that are useless.

The claims at issue in Amgen's patents fail this straightforward textual standard. Amgen claimed the entire genus of antibodies—literally millions of them—that bind to and inhibit PCSK9. But as the lower courts determined based on the trial evidence, a skilled artisan following the patents' teachings would still need years of experimentation to make some of the claimed antibodies. Amgen's patents cannot be said to enable such antibodies, but Amgen claims them all the same. Because the claims cover embodiments of the invention that the patent fails to enable, the claims are invalid.

The Patent Act's structure confirms this analysis. After this Court held in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), that functional claiming at a patent's point of novelty is impermissible, Congress enacted what is now Section 112(f) of the Act, which allows claims to be expressed in terms of a function without specifying the precise mechanism for achieving that function. *See* 35 U.S.C. § 112(f). The Act now permits so-called "means-plus-function" claims, but it limits their scope to those "adequate corresponding structure[s]" disclosed in the specification. *Traxcell Techs., LLC v. Sprint Commc'ns Co.*, 15 F.4th 1121, 1134 (Fed. Cir. 2021).

Under a proper reading of *Halliburton* and Section 112(f), a patentee may include functional language in a claim only if the patentee complies with Section 112(f)'s constraints. But if Amgen's position prevails, a patentee could obtain a functional claim even without complying with Section 112(f). That outcome would effectively overrule *Halliburton* and render Section 112(f) a nullity.

This Court's precedents also support the court of appeals' conclusion. This Court has repeatedly held that broad claims covering all methods of achieving a function are not supported by disclosure of just a small number of methods. And though Amgen invokes a number of this Court's decisions in support its interpretation of Section 112(a), those cases merely stand for the proposition that a patent can permissibly leave some degree of reasonable gap-filling to a skilled artisan as to how to make a disclosed embodiment. This Court has never held that by disclosing one structure that achieves a

function, a patentee may obtain a monopoly over the entire class of structures performing that function.

ARGUMENT

The Federal Circuit correctly concluded that Amgen's patents fail to enable the claims at issue. The court of appeals' decision hews to the text, structure, and purpose of Section 112(a) of the Patent Act, follows this Court's precedent, and reflects sound public policy. This Court should affirm.

I. THE FEDERAL CIRCUIT'S DECISION ALIGNS WITH SECTION 112'S TEXT.

This case can be resolved by a straightforward application of the text of Section 112(a) of the Patent Act. Section 112(a) requires a patent to enable a skilled artisan "to make and use" "the invention." 35 U.S.C. § 112(a). The "invention" encompasses all that the patentee asserts as its own in the patent's claims. The patentee must therefore enable skilled artisans to make and use *all* claimed embodiments of its invention. But as the lower courts found, a skilled artisan following the direction of Amgen's patents could spend years of experimentation trying to make some of the claimed antibodies. Those claims are therefore not properly enabled.

A. Section 112 Requires a Patent to Teach Both How to "Make" and "Use" the "Invention," Which Is Defined by the Scope of the Claims.

Section 112 of the Patent Act requires a patent's specification to "contain a written description of *the*

invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to *make and use* the same." 35 U.S.C. § 112(a) (emphasis added). The enablement requirement covers the entirety of "the invention"—everything within its claims. And it demands that a patent teach *both* how to "make" and "use" everything that is claimed. In light of these requirements, the enablement burden for a patent claiming an entire genus of pharmaceutical compounds performing a common function is quite substantial.

1. Section 112 requires enablement of "the invention." 35 U.S.C. § 112(a). In determining whether a patent is properly enabled, the key threshold question therefore is: what is "the invention"?

The answer turns on the scope of the claims. Section 112 provides in the next subparagraph that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor . . . *regards as the invention*." 35 U.S.C. § 112(b) (emphasis added). The Patent Act thus leaves the patentee to define the scope of its "invention" through the patent's claims, and then imposes a requirement that the "invention"—so defined—be enabled in the specification. Accordingly, the broader the claims, the broader the "invention," and the more onerous Section 112(a)'s enablement requirement.

This straightforward rule makes sense in light of a patent's "bargain," *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). The public will be prohibited from making or using all that is within the scope of the patent's claims. *See Markman v. Westview Instruments, Inc.*, 517 U.S.

370, 373-74 (1996). If the patent claims—and thus seeks a monopoly over—thousands or millions of different variations on an invention, the inventor has a concomitant responsibility to explain how to make and use each of those thousands or millions of distinct products.

2. Section 112(a) requires the specification "to enable" a skilled artisan both to "*make*" and to "*use*" the invention—*i.e.*, the entirety of what is claimed. 35 U.S.C. § 112(a) (emphasis added). As applied to claims for pharmaceutical compounds, each of these two requirements carries independent significance.

First, the specification must teach a skilled artisan how to "make" the invention. If a patent's claims cover one particular molecule, the specification must enable the skilled artisan to synthesize that molecule. Likewise, if the claims cover thousands of molecules, the specification must enable the skilled artisan to synthesize *all* of those molecules, each of which the inventor purports to have invented.

Second, the specification must teach the skilled artisan how to "use" what she has made. In light of the general principle that an invention must be both "new and useful" to be patentable, 35 U.S.C. § 101, a specification must shed light on the usefulness of the invention—including instructing a skilled artisan how to determine *whether* something she has made is useful. *See McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 & n.2 (Fed. Cir. 2020).

Again, the scope of this requirement will turn on the scope of the claims. If the claim covers one molecule, the specification must teach the skilled artisan how to use

that molecule. Likewise, if a claim covers thousands of molecules, some of which are useful for treating an illness and some of which are useless, the specification must enable the skilled artisan not only to make each molecule, but to identify and use the *useful* ones. Without such a teaching, the specification does not enable a skilled artisan to "use" the invention.

To be sure, a specification does not have to explain how to "make" and "use" aspects of the claim that do not reflect the patent's inventive contribution. Suppose, for instance, that a patentee claims to have invented a new formulation of a particular pharmaceutical compound that is stable at high temperatures. The claim recites that the new formulation is stored in a "bottle," but the invention itself has nothing to do with bottles.

In such a case, the specification would not need to explain how "to make," 35 U.S.C. § 112(a), a bottle. Similarly, although the full scope of the invention would cover the new formulation when stored in *any* type of "bottle"—including theoretical and as-yet unavailable types of bottles not currently on the market—the specification need not teach how to make and use every theoretical variant of bottle. This is because the inventor does not claim to have invented bottles. Bottles are not the "invention," *id.* § 112(b), so the enablement requirement does not extend to bottle technology, even though "bottle" appears in the claims.

By contrast, if the "new and useful" aspect of the invention, 35 U.S.C. § 101, were the new formulation's stability at high temperatures, and the claim language purported to cover *all* formulations of the compound that are likewise "stable at high temperatures," then the

specification would need to "teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (internal quotation marks omitted). Here, the inventor would claim to have invented *all* formulations of the compound that are stable at high temperatures, so under the Patent Act's plain terms, the specification must enable a skilled artisan "to make and use," 35 U.S.C. § 112(a), all stable formulations.

B. The Specification in Amgen's Patents Does Not Enable a Skilled Artisan to Make and Use Its Claimed Invention.

Applying these principles, Section 112's plain text requires the conclusion that the patent claims at issue in this case are invalid.

The relevant claims in the '165 and '741 patents cover *any* monoclonal antibody that "binds to PCSK9" and that, when so bound, "blocks binding of PCSK9" to LDL receptors. Pet. App. 5a; *see id.* at 4a. The Federal Circuit accurately characterized these claims as "double-function claims," *id.* at 12a, in that they cover all monoclonal antibodies that perform these two functions. In particular, Amgen asserts that these claims read on the active antibody in Sanofi's Praluent—*i.e.*, Amgen believes that antibody to be within the scope of its "invention." Because Amgen purports to have invented this antibody (as well as all other antibodies satisfying the claims' dual functional limitations), the Patent Act requires that the specification teach a skilled artisan how to make and use Praluent and every other antibody that binds to and inhibits PCSK9.

The specification that appears in the '165 and '741 patents, however, fails to meet Section 112's requirements. Though it describes how "to make and use," 35 U.S.C. § 112(a), a few of the antibodies within the scope of the claims, it does not describe how to make and use *all of them*. And because the "invention," *ibid.*, comprises *all* such antibodies, the specification's failure to enable the entire class of antibodies that bind to and inhibit PCSK9 means that it does not enable the "invention"—and thus does not comply with Section 112(a). Indeed, there is no indication in the specification that Amgen was even aware of the antibody used by Sanofi in Praluent, much less an explanation of how to make and use it.

Nor can the full scope of the antibodies covered by the claim language—that is, the full range of antibodies Amgen claims to have "invented"—be inferred from the specification. The undisputed trial evidence showed that the claim's full scope "encompasses millions of candidate[]" antibodies. Pet. App. 15a. And though the specification provides a methodology for generating those candidates, it offers no way to distinguish between functioning and nonfunctioning antibodies without "first generat[ing] and then screen[ing] each candidate antibody to determine whether it meets the double-function claim limitations." *Ibid.* (citing *id.* at 30a-44a). Further, even the methodology for generating *candidates* is suspect: as the court of appeals explained, "this invention is in an unpredictable field of science" and there was a "conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods." *Id.* at 13a.

In short, the specification in Amgen's patents does not enable a skilled artisan to make and use the "invention," which includes *all* antibodies satisfying the functional limitations set forth in the claims. The Federal Circuit was correct to conclude that the claims were not enabled, and thus invalid.

C. Amgen's Textual Argument Lacks Merit.

Amgen frames the decision below as "impos[ing] limitations on the Patent Act that are inconsistent with the Act's text," Pet. Br. 1 (quoting *Bilski v. Kappos*, 561 U.S. 593, 612 (2010)), and urges this Court to instead "read the enablement requirement to mean what it says," *id.* at 2. But in reality, it is the Federal Circuit's interpretation of Section 112's enablement requirement, not Amgen's, that hews to the statutory text. The court of appeals' standard accurately takes account of the statutory command that it is the "invention"—as defined by the scope of the patent's claims—that must be enabled. Amgen's approach, by contrast, distorts the statutory text by permitting patents whose specifications enable just a subset of the claimed embodiments.

According to Amgen, the Federal Circuit's rule "looks to the number of claimed embodiments and the cumulative 'time and effort' to 'reach' *every* (or nearly every) embodiment within the claim—to identify and make them all." Pet. Br. 28 (quoting Pet. App. 14a). That rule, in Amgen's view (*ibid.*), is "categorically different and exponentially more demanding" than what Section 112's text provides. It contends (*ibid.*) that a claim is sufficiently enabled so long as there are not "large tracts of claimed subject matter that are not enabled."

Amgen's interpretation of Section 112(a) runs counter to the text. The Patent Act's enablement requirement contains no exception for small "tracts," Pet. Br. 28, of claimed subject matter. Rather, it requires that the "invention"—all of it—be enabled. 35 U.S.C. § 112(a). If a claim is drafted broadly to cover all embodiments of an invention, the Act requires that all those embodiments be enabled by the inventor before the public will be precluded from making each embodiment. If the inventor fails to enable a skilled artisan to "make and use," *ibid.*, each claimed embodiment, then it has failed to satisfy the Act's requirements. The claims, in such a case, are too broad.

Amgen therefore errs by faulting (Pet. Br. 24-25) the Federal Circuit for purportedly applying a different (and stricter) test for genus claims. In Amgen's view (*id.* at 25), the Patent Act "provides a single, universal enablement standard," rather than "different tests for different technologies, different claim formats, claim breadth, or the state of the art." That is true, and the Federal Circuit's reasoning conforms to that principle. For every patent, Section 112(a)'s uniform standard must be met: the specification must enable skilled artisans to "make and use" "the invention." 35 U.S.C. § 112(a). The Federal Circuit's approach adheres to that rule by recognizing that the requisite showing turns on the scope of "the invention": the broader the invention, the broader the necessary disclosure in the specification. It is *Amgen's* approach that would introduce a two-track system into patent law by *lowering* the enablement bar for broad genus claims that purport to assert monopolies

over an entire class of substances exhibiting a common behavior.

Amgen is correct, of course, that a patent is not invalid for lack of enablement just because it would cumulatively take a great deal of time and effort to make every claimed embodiment. But the Federal Circuit did not hold otherwise. Indeed, though Amgen repeatedly characterizes (Pet. Br. i, 2, 3, 5, 18, 19, 20, 27, 28, 29) the court of appeals' holding using the words "cumulative" and "cumulatively," Amgen never actually *quotes* the court of appeals when using these words—because the court of appeals *never used them*. Instead, when the court below held that Amgen had failed to enable "the full scope of claimed embodiments," Pet. App. 14a, it meant that there were *individual* claimed antibodies that could not be obtained by following the patents' specification without requiring an unreasonable amount of time and effort. The court did not hold or suggest that enablement turns on how long it would take a skilled artisan to make and use *all* of the claimed embodiments. Rather, it held that each *individual* embodiment must be reasonably achievable by following the patent's specification. By continually mischaracterizing the Federal Circuit's actual holding, *see, e.g.*, Pet. Br. 25 (referring to the court of appeals' standard as a "how-long-to-make-them-all test"), Amgen's argument largely attacks a straw man.

II. THE FEDERAL CIRCUIT'S DECISION ALIGNS WITH THE PATENT ACT'S STRUCTURE AND PURPOSE AND WITH THIS COURT'S PRECEDENT.

The Federal Circuit's decision is also consistent with Section 112's structure, which includes a subsection

specifically addressing patents, like those at issue here, that claim *functions*. It likewise conforms to the statutory purpose of conferring a monopoly upon only those technological advances that have been adequately disclosed to the public—and no others. And it adheres to a long line of this Court's precedents holding that a patent does not satisfy the enablement requirement by merely enabling some embodiments of a broadly claimed function.

A. The Federal Circuit's Interpretation of Section 112(a) Aligns with Section 112(f).

The claims at issue in this case are functional rather than structural—that is, rather than claiming only specific antibodies, they purport to cover all antibodies that perform specified *functions*. Section 112(f) of the Patent Act authorizes functional claiming, but only subject to specific restrictions. *See* 35 U.S.C. § 112(f). Amgen's cribbed reading of Section 112(a)'s enablement requirement, however, would effectively eliminate Section 112(f)'s restrictions on functional claiming. The Act's structure thus demonstrates that functional claims, like the ones here, that fail to meet those restrictions are invalid.

1. In *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), this Court invalidated a patent that used "conveniently functional language at the exact point of novelty." *Id.* at 8 (quoting *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 371 (1938)). The patentee had improved on the prior art for measuring the surface depth of oil wells by adding a device that would measure the depth by "amplify[ing] . . . echo waves and eliminat[ing] unwanted echoes from other obstructions."

Id. at 7; *see id.* at 6-7. But rather than obtaining a patent on a specific device that would accomplish this goal, the patentee's claim extended to any "means . . . to clearly distinguish the echoes . . . from each other." *Id.* at 8-9 (internal quotation marks omitted).

This Court held that the claim was invalid. As the Court explained, "[t]he language of the claim . . . describes th[e] most crucial element in the 'new' combination in terms of what it will do rather than in terms of its own physical characteristics or its arrangement in the new combination apparatus." *Halliburton*, 329 U.S. at 9. The patent purported to capture "any device heretofore or hereafter invented" that "performs the function of clearly and distinctly catching and recording echoes" in the described manner. *Id.* at 12. The Court observed that "[j]ust how many different devices there are of various kinds and characters which would serve to emphasize these echoes, we do not know." *Ibid.* The Court therefore held that the claims were invalid because they "fail[ed] adequately to describe the alleged invention." *Id.* at 14.

When Congress enacted the modern Patent Act in 1952, it added a new provision (now codified as Section 112(f)) to abrogate the decision in *Halliburton*. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 27 (1997) (explaining that this provision was enacted "in response to *Halliburton*"); *see also* P.J. Federico, *Commentary on the New Patent Act* (West 1954), *reprinted in* 75 J. Pat. & Trademark Off. Soc'y 161, 186-87 (1993). Section 112(f) provides:

> An element in a claim for a combination may be expressed as a means or step for performing a

> specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112(f). Under this provision, "an applicant can describe an element of his invention by the result accomplished or the function served, rather than describing the item or element to be used." *Warner-Jenkinson*, 520 U.S. at 27. But while Section 112(f) allows such claims, it includes "the proviso that application of the[ir] broad literal language . . . must be limited to only those means that are 'equivalen[t]' to the actual means shown in the patent specification." *Id.* at 28 (third alteration in original).

Claims falling within Section 112(f) have come to be known as "means-plus-function" claims. *See, e.g.*, *Rain Computing, Inc. v. Samsung Elecs. Am., Inc.*, 989 F.3d 1002, 1006 (Fed. Cir.), *cert. denied*, 142 S. Ct. 579 (2021). Under Section 112(f), "[a] means-plus-function claim is indefinite if the specification fails to disclose adequate corresponding structure to perform the claimed function." *Traxcell Techs., LLC v. Sprint Commc'ns Co.*, 15 F.4th 1121, 1134 (Fed. Cir. 2021); *see Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1352 (Fed. Cir. 2015) ("[I]f a person of ordinary skill in the art would be unable to recognize the structure in the specification and associate it with the corresponding function in the claim, a means-plus-function clause is indefinite."). In other words, under Section 112(f), purely functional claiming is not permissible. The patentee instead has two options: either (1) include structural language in the claims, in

which case the patent covers only the structure disclosed in the claims; or (2) assert claims in purely functional language, in which case the patent extends only to the structure(s) set forth in the specification. *See Dyfan, LLC v. Target Corp.*, 28 F.4th 1360, 1365 (Fed. Cir. 2022). In the latter case, the patent is invalid for indefiniteness if a structure is not adequately disclosed in the specification. *See Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311-12 (Fed. Cir. 2012).

2. The Federal Circuit did not consider Section 112(f) here because that court applies a "presumption" that "a claim limitation is not drafted in means-plus-function format in the absence of the term 'means'" in the claim, *Dyfan*, 28 F.4th at 1365—and Amgen's claims do not use the word "means." This Court has never addressed whether this presumption applied by the Federal Circuit is correct, and the principle has proven controversial even within that court. *See Williamson*, 792 F.3d at 1358 (Reyna, J., concurring in part, dissenting in part, and offering additional views) ("[*Halliburton*'s] rationale applies to functional claiming generally, not just to claims that recite 'means.' Indeed, the *Halliburton* Court relied on precedent invalidating functional claims that did not recite the term 'means.'" (citing *Halliburton*, 329 U.S. at 9)).

In any event, *Halliburton* and Section 112(f) lend powerful support to the court of appeals' conclusion that Section 112(a) requires enablement of the "full scope" of a functional claim. Pet. App. 12a. Under *Halliburton*, a patentee may not use functional claiming at a claim's point of novelty, which is exactly what Amgen's claims do here. Section 112(f) creates a narrow exception to

Halliburton: a patentee may use functional claiming, but the patent's scope will then extend only to structures disclosed in the specification and "equivalents thereof." 35 U.S.C. § 112(f). In other words, if Amgen had drafted its claims as means-plus-function claims, its patents would extend only to the specific antibodies disclosed in the specification and "equivalent[]" antibodies, not *all* antibodies that satisfy the claim's functional limitations.

Amgen's proposed interpretation of Section 112(a), however, would effectively wipe out Section 112(f). Under Amgen's view, a patentee could obtain a functional claim that is not limited to the structures disclosed in the specification. So long as the patent avoids using the word "means," a patentee could patent a function that is much broader than the disclosed structures. And if that view prevailed, patentees going forward would never draft a means-plus-function claim—they would *always* be better off drafting a broad functional claim without the word "means," thereby circumventing Section 112(f)'s limitation that cabins patents to structures disclosed in the specification.

By contrast, under Sanofi's position, the entirety of the statute works in harmony. Pure functional claiming at the point of novelty would never be permissible—whether the word "means" appears in the claim or not. Instead, the patentee would be limited to the structure(s) disclosed in the specification. For if a claim is drafted as a "means-plus-function" claim, Section 112(f) will limit the patentee to the structure(s) in the specification, and if the claim is not so drafted, Section 112(a)'s enablement requirement would likewise require the structures comprising the claim's full scope to be

disclosed in the specification. Either way, a patentee cannot patent a function without disclosing the claimed underlying structures. This Court should adhere to *Halliburton* and reject Amgen's effort to revive pure functional claiming.

B. The Federal Circuit's Interpretation of Section 112(a) Aligns with the Patent Act's Purpose.

"[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." *Pfaff*, 525 U.S. at 63. Disclosure is at the core of the patent bargain. The patent is granted "[i]n consideration of [the invention's] disclosure and the consequent benefit to the community." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933). And "the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989).

It therefore stands to reason that a patentee may obtain a monopoly only on what has actually been disclosed. Requiring a specification to enable the full scope of what is claimed advances that purpose. If the patentee discloses an antibody to the public in a specification, the patentee may obtain a monopoly on that antibody as a reward. But the patentee may not monopolize an antibody that the specification does not disclose—thus "stifl[ing] competition" without the countervailing benefit of public "enlightenment." *Pfaff*, 525 U.S. at 63.

The history of the drugs at issue in this case is illustrative. Amgen initially obtained a patent for a specific PCSK9-inhibiting antibody that it had developed, and Sanofi subsequently designed Praluent, a different antibody that undisputedly does not infringe Amgen's original patent. In an effort to suppress Sanofi from competing, Amgen then followed up by obtaining new patents, which had an earlier priority date and purported to cover *all* antibodies that bind to PCSK9, including the one Sanofi had discovered. These new patents added nothing to the state of public knowledge and enlightened no one. They served no purpose other than to stifle competition.

Amgen's interpretation of Section 112(a) is also in tension with the Patent Act's disclosure requirement. The Act generally requires patent applications to be published within 18 months of the filing date. 35 U.S.C. § 122(b)(1)(A). By contrast, the period of monopoly generally lasts for 20 years from the filing date. *Id.* § 154(a)(2). Congress thus required inventors to disclose how to make and use their invention long before other innovators would be able to directly apply that knowledge.

The reason Congress did so is because it understood that the disclosures in a patent specification could immediately spur new innovations beyond the patented invention. For example, an inventor's patent for a new chemical compound would preclude others from making and using that compound for 20 years, but the inventor's *techniques*—disclosed in the patent's specification far earlier than the monopoly's expiration—can spur other inventors, through improvement on the patentee's

methodology, to invent other new compounds. This case is an illustrative example. According to Amgen (Pet. Br. 13), its patents' specification "sets out a step-by-step 'roadmap' for generating antibodies . . . beyond the 26 examples" disclosed in the patent. The immediate disclosure of that "roadmap," long before the patent term expired, should have allowed all innovators (not just Amgen) to use Amgen's techniques to invent new and useful antibodies.

But Amgen's reading of Section 112(a) would undermine that goal of patent law. Under Amgen's interpretation, a patentee could obtain a patent on all methods of performing a particular novel function, rather than the specific methods the patentee itself invented. With respect to such a patent, the benefits of immediate disclosure would be severely limited. New innovators could no longer review the patent's specification and invent a better solution to the problem it solved, because the claim would purport to cover *all* solutions, even those of which the inventor was unaware. This Court should not adopt an interpretation of Section 112(a) that would undermine the Patent Act in this way.

C. The Federal Circuit's Interpretation of Section 112(a) Aligns with This Court's Precedent.

The decision below is also consistent with this Court's cases, which have consistently held that a patent's specification must enable the full scope of the claim and not merely offer example embodiments. In *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928), for example, the patent specification disclosed a "particular starch glue," but the claim purported to

cover "all starch glues" with the same function. *Id.* at 256. The Court held that the claim was invalid because it would impermissibly 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 and so foreclose efforts to discover other and better types." *Id.* at 257. Likewise, in *Béné v. Jeantet*, 129 U.S. 683 (1889), the patent specification disclosed a way of refining coarse hair by using "chlorine salt," but the claim covered refining coarse hair by "subjecting it to the action of chemicals"—*any* chemicals, not just the disclosed chlorine-salt solution. *Id.* at 684 (quoting patent). The Court invalidated the claim, finding that a specification describing a single chemical did not enable a claim directed to chemicals in general. *Id.* at 685-86. The Court explained that "[t]he broad construction claimed for this patent as a pioneer and foundation invention in the art of refining hair cannot extend the rights of the patentee beyond the compositions of matter and processes which, as stated in the patent, embody his real invention." *Id.* at 686.

Amgen fails to identify any decision of this Court supporting a contrary conclusion. None of the decisions it cites (Pet. Br. 30-32) held that a patentee may obtain a patent on a functional claim based on a limited number of embodiments in the specification. Each of those cases instead addressed a different issue—whether the specification contained sufficient information to get the invention to work.

In *Wood v. Underhill*, 46 U.S. (5 How.) 1 (1847), for instance, the invention involved mixing coal dust and clay, but the patent was challenged on the ground that it

did not disclose with sufficient precision the amounts of coal dust and clay to be used in the mixture. *Id.* at 4. This Court held that whether the invention was clear enough in light of the art was a question for the jury. *Id.* at 5-6. Likewise, in *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620 (1871), the invention involved a process for manufacturing railway wheels, and the parties disputed whether the specification contained sufficient information regarding the temperature at which the process should proceed. *See id.* at 639-41. This Court held that the specification contained sufficient information for an operator to determine the appropriate temperature. *Id.* at 646. Finally, in *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261 (1916), the invention involved adding oil to ore and agitating the mixture. *Id.* at 265. This Court held that a skilled artisan could figure out exactly how much ore and agitation to use in any particular case. *Id.* at 270-71.

None of these cases involved functional claiming, and none involved claims that were especially broad. Rather, the issue in each case was that an operator seeking to use the invention would need to fill in some gaps in the patent's instructions to achieve the invention's desired outcome. This Court held in each case that the specification contained sufficient information for a skilled artisan to fill in those gaps. Those cases would be applicable here if, for instance, Amgen claimed a particular antibody, and Sanofi argued that the specification did not contain sufficient detail on how to synthesize that antibody. This line of cases would instruct that as long as the specification contained sufficient information for a skilled artisan to fill in any gaps and synthesize the

antibody without too much effort, the patent is properly enabled.

But this case addresses a fundamentally different type of problem. The problem here is not that the patent fails to explain how to achieve the invention's desired outcome; it is that the patent purports to cover *all possible ways* of achieving that outcome. Under *Halliburton*, *Holland Furniture*, and *Béné*, such patents are invalid as a matter of law.

III. ADOPTING AMGEN'S THEORY WOULD INHIBIT COMPETITION IN THE PHARMACEUTICAL INDUSTRY.

This Court should hold that a patent specification must enable a skilled artisan both to "make" and to "use" all claimed subject matter. Such a holding is necessary to prevent abusive practices among brand-name patent manufacturers that yield overlong or overbroad monopolies providing no social benefit.

First, the Court should restrict overbroad, functional claims because such claims improperly impede generic and biosimilar manufacturers from designing noninfringing variations of drugs or drug-dosing regimes. For example, a company might discover that a specific dose of a drug is required to treat a new indication, yet the resulting patent might use broad, functional language such as "a therapeutically effective amount of drug *X*." Such language would claim *any* dose that works—even doses that the inventor did not contemplate—and deter competitors from designing around patents and developing more effective dosing regimes.

Here, for instance, it is undisputed that Amgen did not discover all antibodies that bind to and inhibit PCSK9. If the scope of Amgen's patent were properly limited to its actual discovery, the landscape would have remained open to other manufacturers to develop different methods of designing the same antibodies that perform the same function—improving on Amgen's invention, spurring further innovation, and easing access to cholesterol drugs. But that process was short-circuited by Amgen's overbroad claim of all antibodies performing the same function as the ones Amgen discovered.

Indeed, this case directly illustrates how Amgen's cribbed view of the enablement requirement would hinder the development of new drugs. Amgen did not obtain its broad functional patents until years *after* Sanofi and its competitors had independently invented other antibodies that bind to PCSK9. *See* Resp. Br. 8-9. Moreover, Sanofi's antibody (Praluent) had the advantage of a low-dose version which Amgen's product lacked. *See ibid.* Having failed to beat Sanofi in the marketplace, Amgen instead turned to the courtroom, seeking millions of dollars in damages and an injunction that would have banned consumers from using Praluent. If Amgen's position prevails, future patentees will ban competitors from developing improved medications, to the detriment of the public.

Amgen's position would further disrupt the process of creating new pharmaceutical formulations for existing

biologic drugs.[2] Both brand-name and biosimilar manufacturers conduct R & D to find the most effective pharmaceutical formulation for particular drugs, even ones for which a different formulation is patented. But if Amgen's position prevails, that R & D would halt. Brand-name manufacturers could obtain patents that cover *all* formulations that serve the *function* of stabilizing the active molecule or rendering it suitable for delivery to a patient. For example, a company might discover that a specific combination of excipients effectively stabilizes a drug in a liquid formulation, yet use functional claim language like "stable, isotonic formulation." Such overly broad claims preclude competitors from designing around patents to develop alternative liquid formulations of old drugs. Biosimilar manufacturers would have no incentive to experiment with new and different formulations—*every* useful formulation, even one that differs from the brand-name company's formulation in meaningful ways, would be infringing. *See generally* Bernard Chao, *USPTO's Lax Policy Leads to Biologic Formulation Thicket* (Feb. 4, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4348038 (describing how the broad scope of formulation patent claims affects competition).

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[2] The term "pharmaceutical formulation" refers to the powder or liquid components used in combination with an active drug to stabilize the drug and extend its shelf life. These components, known as "excipients," may include buffers, stabilizers, detergents, and tonicity agents that stabilize the active ingredient for long-term storage and render it suitable for delivery to the patient.

Biosimilar manufacturers not only provide consumers with improved drugs and formulations, but also save consumers money by increasing competition in drug markets, reducing overhead costs, and thus substantially cutting drug prices. In 2021 alone, use of high-quality, low-cost generic and biosimilar medications generated $373 billion in savings to patients. *See* Ass'n for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* 7 (2022), https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf. Over the past decade, use of generics and biosimilars has saved over $2.6 trillion. *Ibid.* Overbroad patents allow brand manufacturers to suppress competition from those manufacturers, raising costs for consumers.

Second, this Court should make clear that Section 112(a)'s dual requirements—that a specification teach skilled artisans both how to "make" and how to "use" an invention, 35 U.S.C. § 112(a)—carry independent weight. Today, branded drug companies frequently file patents on biologic peptide sequences—the "backbone" of a particular biologic—and hold back details on how to transform those drug peptide sequences into working pharmaceuticals. The claims generally either include broad functional language or simply recite peptide sequences that are not by themselves useful. The drug companies then obtain a secondary patent, covering not only the "backbone" peptide sequence but secondary characteristics such as the glycan profile, charge profile, variants profile, impurity profile, immunochemical properties, and functional activities. This practice violates the enablement requirement because the first patent

fails to explain to the public how to *use* the invented peptide sequence.

The effect of this practice is that brand-name drug companies get monopolies that are much longer than contemplated by the Patent Act. The Food and Drug Administration (FDA) generally requires biosimilars to copy not only a drug's peptide sequence, but also the physiochemical properties that will typically be the subject of a secondary patent. Accordingly, a biosimilar manufacturer will be able to gain approval from the FDA only after the *secondary* patent expires, thereby artificially increasing the period of exclusivity. Strict enforcement of the Patent Act's enablement requirement would avoid this outcome and ensure that brand-name manufacturers get the patent term to which they are entitled, and no more.

In the end, applying the Patent Act's enablement requirement as written benefits the American public as well. Patent law represents a carefully wrought bargain that aims to "balance" competition and innovation—as a reward for innovation, an inventor receives a respite from competition during the patent term. *Pfaff*, 525 U.S. at 63. But blocking competition in the market for products that a patentee has not actually invented upends this bargain, raising prices and reducing innovation. An inventor should enjoy the fruits of her labor, but her monopoly should be coextensive with what she has actually disclosed to the public.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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