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 FOR HIGH TECH INVENTORS ALLIANCE AND THE COMPUTER & COMMUNICATIONS INDUSTRY ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICI CURIAE*[1]

High Tech Inventors Alliance ("HTIA") is a consortium of some of the world's most innovative technology companies: Adobe, Amazon, Cisco, Dell, Google, Intel, Micron, Microsoft, Oracle, Salesforce, and Samsung. It supports fair and reasonable patent policy by publishing policy research, providing testimony and comments to Congress and government agencies, and sharing industry's perspective with courts considering issues important to technology companies.

HTIA's members annually invest more than $140 billion in research and development and have received nearly 350,000 patents. Due to their products' complexity and success, HTIA's members also are frequent targets of patent-infringement claims, giving them a unique perspective as both patent owners and defendants in high-stakes patent litigation.

The Computer & Communications Industry Association ("CCIA") is an international, nonprofit association representing a broad cross-section of communications and technology firms.[2] For more

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[1] Pursuant to Rules 37.2 and 37.6, HTIA and CCIA affirm that no counsel for a party authored this brief in whole or in part and that no person other than HTIA, CCIA, their members, or their counsel made a monetary contribution to its preparation or submission. All parties have filed blanket consents to the filing of amicus briefs with the Clerk's office.

[2] CCIA's members are listed at http://www.ccianet.org/members.

than fifty years, CCIA has promoted open markets, open systems, and open networks. CCIA members employ more than 1.6 million workers, invest more than $100 billion in research and development, and contribute trillions of dollars in productivity to the global economy. CCIA regularly files amicus briefs in this and other courts to promote balanced patent policies that reward, rather than stifle, innovation.

As their members are industry participants developing and offering to the public real products embodying important technologies, HTIA and CCIA have a strong interest in curbing patent claims that use purely functional language to preempt future innovations.

SUMMARY OF ARGUMENT

The Question Presented addresses Section 112 of the Patent Act, which codifies essential requirements for the disclosure and claims of a U.S. patent, including the full-scope enablement mandate. Section 112 is the linchpin of the patent system's delicate balance, and fosters innovation in the fields of computers, electronics, telecommunications, and software in which *Amici* innovate. For several reasons, this case is an exceptionally poor vehicle for the Court to disturb this delicate balance.

First, this case is particularly ill-suited for altering Section 112's full-scope enablement requirement, which mandates that the patent disclosure sufficiently describe the claimed invention to enable skilled artisans to make and use the claimed embodiments upon expiration of the patent. While Petitioners' Question Presented mentions "full scope," their Brief does not challenge this fundamental

requirement that dates back to the mid-19th Century. On the contrary, Petitioners acknowledge that a patent claim must not "truly exceed[] what the patent enables." Pet. Br. at 21. Therefore, this case is a poor vehicle for disturbing the unchallenged and longstanding mandate of full-scope enablement.

Second, the Question Presented is based on a false premise. It presumes that the three patent claims before the Court have been construed to define their "claimed embodiments," and asks how fully the patents' disclosure must identify those claimed embodiments. But there has been no such claim construction in this case and, therefore, no definition of the "claimed embodiments." Instead, these claims define functions, which functions *might* be performed by "millions and millions" of mostly *unidentified* antibody embodiments. *See* BIO at 8. Neither the Patent Office nor any court has construed the claims to be limited to a particular set of antibody embodiments. Without this threshold step of claim construction, the "claimed embodiments" mentioned in the Question Presented mostly are undetermined. Therefore, this procedurally peculiar case is an exceptionally inappropriate vehicle for the Court to disturb any existing law under Section 112.

Third, the patent claims at issue are naked functional claims, by which we mean they recite what the invention *does* rather than what it *is*. The claims do not recite the structures, materials, or acts that perform their recited functions. "The claimed antibodies are defined by their function: binding to a combination of sites (residues) on the PCSK9 protein, in a range from one residue to all of them; and blocking the PCSK9/LDLR interaction." *Amgen Inc. v.*

Sanofi, Aventisub LLC, 987 F.3d 1080, 1083 (Fed. Cir. 2021). Such naked functional claims—which expressly encompass and thus preempt the future inventions of others—plague the computer, electronics, telecommunications, and software fields, but are relatively rare in life sciences. For good reason, they are banned by this Court's precedents.

The patent statutes have long placed demands on both patent disclosures and patent claims that preclude naked functional claims. These demands are codified in Section 112 of the Patent Act, and include mandates that the invention be described in "full, clear, concise, and exact terms," 35 U.S.C. § 112(a), and that the claims "particularly point[] out and distinctly claim[]" the invention, *id.* § 112(b). The Court, interpreting very similar predecessors to Sections 112(a) and 112(b), repeatedly ruled naked functional patent claims invalid.

> The language of the claim . . . describes this 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. We have held that a claim with such a description of a product is invalid.

Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1, 9 (1946).

Two bedrock principles of patent law are violated by naked functional claims like those at issue in this case. First: give inventors what they contributed *and no more*. *Schriber-Schroth Co. v. Cleveland Trust Co.*,

305 U.S. 47, 57 (1938) ("[T]he patent monopoly does not extend beyond the invention described and explained as the statute requires . . . ."). Second: grant patents on inventive structures, materials, and acts, not functions or results. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) ("A claim covers and secures a process, a machine, a manufacture, a composition of matter, or a design, but never the function or result of either . . . ."); *Cochrane v. Deener*, 94 U.S. 780, 787–88 (1877) (explaining that a patentable process "is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing"); *Corning v. Burden*, 56 U.S. 252, 268 (1853) (noting that patents are granted "for the discovery or invention of some practicable method or means of producing a beneficial result or effect . . . and not for the result or effect itself"). But as the Patent Office here did not apply these precedents banning naked functional claims, and Respondents did not directly assert them in the lower courts, the Court now is being asked to address a prohibited type of patent claim which preempts innovation in large swaths of industry in which the parties do not participate, and without the benefit of any application of that precedent by the Patent Office or lower courts.

Finally, the parties have ignored the special claim-construction provision in Section 112 enacted in response to *Halliburton Oil* having invalidated naked functional claims. It saves from invalidity some patent claims drafted in the *form* of a naked functional claim, but only by mandating that they be construed to be limited to structures, materials, or acts disclosed in the patent, and equivalents—so that they do not claim naked functions.

> 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, patent drafters wanting their claim to recite a function have two options.

First, a claim using functional words may recite the particular way the function is performed (*i.e.*, particular structure, material, or acts), thereby limiting the patent to a particular thing or process. Petitioners have another patent on the same subject matter with claims of this type, specifying antibody structures, but the three claims before the Court are not of this type.

For the second option, a claim using functional words may recite only a function without a particular way of performing it, but then it "shall be construed" under Section 112(f) if it satisfies two conditions: (1) it is a "combination" claim, *i.e.*, one with at least two elements, and (2) the functional claim element is supported by the patent specification's disclosure of one or more particular structures, materials, or acts that implement the function or result recited in the claim. For example, Petitioners' "pharmaceutical composition" claim 29 (Pet. at 4a) might qualify as a

"combination" claim qualifying for construction under Section 112(f), while their two "antibody" claims 7 and 19 (Pet. at 4a–5a) likely do not.

Otherwise, if a patent claim recites a function without a way and fails either of these two conditions of Section 112(f), it is a naked functional claim and invalid under Sections 112(a) and 112(b). The Patent Office has described such naked functional claims not saved by Section 112(f) as being in a "dead zone." *Sanada v. Reynolds*, 67 U.S.P.Q.2d 1459, 1460 (B.P.A.I. Mar. 19, 2003) (informative).

But the Patent Office did not analyze or construe these naked functional claims under these rules. Had it (or the lower courts) done so, the Question Presented would not exist. Each claim would either have been rejected under Sections 112(a) and 112(b) and *Halliburton Oil*, or construed under Section 112(f) to be limited to the particular antibody embodiments performing the claimed functions that are actually disclosed in the patent, and equivalents. Either way, the claims as they now stand before the Court, presumed to cover *perhaps* "millions and millions" of mostly unidentified antibodies, would not exist and neither would the Question Presented.

For the above reasons, *Amici* ask the Court either to dismiss *certiorari* as improvidently granted or to expressly circumscribe its opinion to be limited to the peculiar procedural posture of this case in which the claims are assumed to have an illegitimate, purely functional claim scope. Issuing any broader opinion risks upsetting the carefully crafted patent system in a way that harms innovation and competition in multiple fields outside of the life sciences.

ARGUMENT

I. SECTION 112 CODIFIES THE PATENT SYSTEM'S DELICATE BALANCE FOSTERING INNOVATION

We do not need a patent system to dream of future innovations, from time-travel machines to Star Trek transporters. Nor do some entrepreneurs need a patent system to create commercially successful products based on secret inventions, from Coca-Cola to Listerine. The genius of the U.S. patent system is that it induces inventors not only to invent real, working inventions—as opposed to mere ideas—but also to fully and clearly disclose them to the public so that they enter the public domain upon the patent's expiration.

Our patent system achieves this with its two engines of innovation. The first is the promise of monopoly profits or royalties, which incentivizes everyone to invent new solutions *and describe them in exact detail* in patent applications that will be published so that the public may practice the invention when the patent expires, or sooner under license. Its second engine of innovation begins once a patent issues on a first solution: it incentivizes others to invent different and often better solutions outside the clearly delineated boundaries of the patent, to bring additional innovations to market for the benefit of the public, without the second inventor paying a royalty to the patent owner.

But this ingenious system is delicate and if its mandates are not strictly observed, it can become a brake on innovation. "Patent protection is, after all, a two-edged sword. On the one hand, the promise of

exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention . . . ." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 92 (2012). Our patent laws therefore are carefully crafted to get this delicate balance right.

> [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. The balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception.

Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998).

The key to this delicate balance is for each patent claim to have clear boundaries—so others may identify inventions for which a license is needed or confidently invent outside those boundaries—and to limit those clear boundaries to the particular inventions (structures, materials, and acts) fully and clearly described and enabled in the patent. Thus, a bedrock principle of U.S. patent law is to give inventors what they contributed *and no more.*

Schriber-Schroth, 305 U.S. at 57 ("[T]he patent monopoly does not extend beyond the invention described and explained as the statute requires . . . ."). Another bedrock principle is that patents are granted on structures, materials, and acts, not functions or results. *Markman*, 517 U.S. at 373 (1996) ("A claim covers and secures a process, a machine, a manufacture, a composition of matter, or a design, but never the function or result of either . . . .").

These bedrock principles are codified throughout Section 112 of the 1952 Patent Act, from the mandate that the invention be described in "full, clear, concise, and exact terms," 35 U.S.C. § 112(a), to the demand that the claims "particularly point[] out and distinctly claim[]" the invention, *id.* § 112(b), and to the provision that "combination" claims facially reciting a function without specifying the way in which it is performed shall be interpreted to be limited to the particular "structure, material, or acts" described in the patent for performing the function, and their equivalents, *id.* § 112(f).

Sections 112(a) and 112(b) are linked by the word "invention," the former mandating how that invention is disclosed and the latter mandating how it is claimed.

A patent claim is "the portion of the patent document that defines the scope of the patentee's rights." *Markman*, 517 U.S. at 372. Because the patentee is granted "the right to exclude others from making, using, offering for sale, or selling" the invention claimed, 35 U.S.C. § 154(a)(1), "[i]t has long been understood that a patent must describe the exact scope of an invention," *Markman*, 517 U.S. at 373.

Otherwise, a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention." *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

Section 112(b) is "the statute's clarity and precision demand." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). It mandates that the claims must both "distinctly claim[]" and also "particularly point[] out" the invention. 35 U.S.C. § 112(b). This requires that a patent claim delineate a clear boundary between what is inside versus outside the claimed monopoly, which was required even before the 1952 Patent Act. *E.g.*, *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938) ("The limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.") (internal citation omitted).

But Section 112(b) requires more than clear boundaries. It also requires that the invention inside those boundaries be defined with particularity, not in a purely functional way. *See Markman*, 517 U.S. at 373. This reading of the "particularly pointing out" mandate is reinforced by Section 112(f), which clarifies that claims must specify structures, materials, or acts, not merely functions or results. Although Section 112(f) is limited to only "combination" or multi-element claims, courts have recognized it would make no sense for Congress to require every element in a "combination" claim to be limited to particular structures, materials, or acts, yet permit a single-element, non-combination claim to

define the invention as a mere function or result. *In re Hyatt*, 708 F.2d 712, 713–15 (Fed. Cir. 1983) (Judge Giles Rich) (holding single-element functional claim unpatentable for lack of full-scope enablement).

Section 112(a), in turn, makes several parallel demands on a patent's disclosure of the clearly delineated structures, materials, and acts of the claimed invention. *Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (explaining that under Section 112, "the patent application must describe, enable, and set forth the best mode of carrying out the invention").

First, the "specification shall contain a written description of the invention." 35 U.S.C. § 112(a). Importantly, the statute does not require a written description of merely *part* of the claimed invention. Instead, the specification must describe the entirety of the structures, materials, and acts recited in the claims. This is patent law's full-scope written description requirement, and it too predates the 1952 Act. *E.g.*, *Schriber-Schroth*, 305 U.S. at 57 ("[T]he patent monopoly does not extend beyond the invention described and explained as the statute requires . . . .").

Second, the description must be in "full, clear, concise, and exact terms." 35 U.S.C. § 112(a). This precludes partial descriptions, vague descriptions, and descriptions of mere functions and results, again in harmony with Sections 112(b) and 112(f).

Third, Section 112(a) requires "a written description . . . of 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 which it pertains, or with which it is most nearly connected, to make and use the same." This is the full-scope enablement requirement, mandating that the disclosure enable skilled artisans to make and use the entirety of the structures, materials, and acts of the claimed invention, so that the full scope of the patent's monopoly enters the public domain upon expiration of the patent.

Judge Giles Rich co-authored the bill which became the 1952 Patent Act, while practicing patent law in New York. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 206 (1980). In the first year of existence of the Court of Appeals for the Federal Circuit, Judge Rich authored an opinion addressing this full-scope enablement requirement in the context of functional claims—the same context as here. *In re Hyatt*. The patent application claim before the court recited a single element and described that element by its function, not its structure, material, or acts. More specifically, it recited a processor having a means for generating Fourier transformed incremental output signals in response to incremental input signals. 708 F.2d at 712–13. The court rejected the claim under Section 112(a)'s full-scope enablement requirement, namely: "the requirement of the first paragraph of § 112 that the enabling disclosure of the specification be commensurate in scope with the claim under consideration." *Id.* at 714 (footnote omitted). Citing to this Court's seminal opinion in *O'Reilly v. Morse*, 56 U.S. 62, 112 (1853), Judge Rich explained: "The long-recognized problem with a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those

means known to the inventor." *In re Hyatt*, 708 F.2d at 714. This mandate that "the enabling disclosure of the specification be commensurate in scope with the claim," *i.e.*, the full-scope enablement requirement, remains the law in 2023, just as it was with equal force in 1983 and 1853.

When strictly observed, these statutory provisions ensure that the inventor's reward is no greater than his or her contribution to the public store of knowledge, and that follow-on inventors can—without fear of an expensive lawsuit—freely invent new and better solutions outside the patent's clear boundary.

Section 112, thus, is the linchpin of the system carefully crafted by Congress and maintained by this Court to promote science and the useful arts. Without these mandates and their zealous enforcement, much of the science that is today commonplace would remain science fiction. This case is an exceptionally poor vehicle in which to disturb such an important part of our nation's patent system.

II. THE CLAIMS ARE NAKED FUNCTIONAL CLAIMS

To appreciate just how poor a vehicle this case is for disturbing the delicate balance of Section 112, it is essential to appreciate the preemptive nature of the patent claims before the Court.

Petitioners have another patent on this same subject matter, not asserted here, which specifies in the claim both a function to be performed (underlined below) *and* the structure and material necessary to perform that function (italicized below):

15

> 15. An isolated neutralizing human monoclonal antibody that binds to a PCSK9 protein comprising:
>
> *a heavy chain polypeptide comprising the following complementarity determining regions (CDRs): a heavy chain CDR1 that is a CDR1 in SEQ ID NO: 67; a heavy chain CDR2 that is a CDR2 in SEQ ID NO: 67; a heavy chain CDR3 that is a CDR3 in SEQ ID NO: 67; and*
>
> *a light chain polypeptide comprising the following CDRs: a light chain CDR1 that is a CDR1 in SEQ ID NO: 12; a light chain CDR2 that a CDR2 in SEQ ID NO: 12; and a light chain CDR3 that is a CDR3 in SEQ ID NO: 12,*
>
> *wherein each CDR is defined in accordance with the CDR definition of Kabat.*

U.S. Pat. No. 8,168,762, claim 15.

But the claims before the Court are fundamentally different. They claim not only Petitioners' specific discovery of a limited number of antibodies but all antibodies that *others* may discover that perform the same functions. The claims do this by claiming two functions without specifying the antibody sequences or other biochemical structure necessary to perform those functions, with claim 19, depending from claim 1, being an example:

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.
>
> 19. The isolated monoclonal antibody of claim 1 wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3.

U.S. Pat. No. 8,829,165, claims 1 and 19 (Pet. at 4a) (underlining added to identify the function).

Petitioners defend these naked functional claims by calling them "genus claims" and discussing enablement of *structurally* defined genus claims. *E.g.*, Pet. Br. at 18. But the essential defect remains. The claims define their genus entirely by the functions performed by the antibodies, not by their structures, materials, or acts which perform those functions. They claim not what the invention *is*, but only what it *does*. And so, whether or not styled as genus claims, they are invalid—if not saved by a structurally limiting construction under Section 112(f)—based on an unbroken chain of this Court's precedents.

III. NAKED FUNCTIONAL CLAIMS LIKE THESE PREEMPT INNOVATION IN THE FIELDS IN WHICH *AMICI* INNOVATE

Amici do not have special knowledge or concerns about antibody patents but do have special knowledge and concerns about naked functional patent claims, because they are a blight on the industries in which *Amici* operate and innovate.

Naked functional claims like these are rare in life sciences. The Patent Office generally does not permit such claims to issue, in view of the mandates of Section 112. But they proliferate, unfortunately, in the fields in which *Amici* innovate. *See generally* FTC, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* 10, 11, 84–85, 100–102 (2011) (noting the proliferation of functional claiming in software arts and their harm to the notice function of patents) (https://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf).

Software-related patent claims, for example, often describe a function or result, with no accompanying structure, materials, or acts other than a general-purpose computer or processor. It is common today for *Amici* and other high-technology innovators to be sued on such patents claiming, for example, a processor executing "a program configured to" perform a function, or a computer-readable medium with "instructions for" performing a function, or a "method" consisting of functions to perform—all without specifying the way in which the function is performed. Such purely functional claims are asserted against

technologies (structures, materials, and acts) not even remotely invented by the patent applicants and, unsurprisingly, not even remotely described in their patents. *See, e.g.*, *IBM v. Zillow Grp., Inc.*, 50 F.4th 1371, 1375, 1378 (Fed. Cir. 2022) (asserting claims that are "result-oriented, describing required [computer] functions (presenting, receiving, selecting, synchronizing), without explaining how to accomplish any of the tasks"); *Free Stream Media Corp. v. Alphonso Inc.*, 996 F.3d 1355, 1363–64 (Fed. Cir. 2021) (asserting claims that "provide for how [the claimed result] is achieved only by stating that the mechanism used to achieve this communication is by piercing or otherwise overcoming a mobile device's security sandbox" but "do not at all describe how that result is achieved"); *Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317, 1328 (Fed. Cir. 2020) ("The claims are silent as to how access is controlled [by a computer]. They merely make generic functional recitations that requests are made and then granted."); *Innovation Scis., LLC v. Amazon.com, Inc.*, 778 F. App'x 859, 864 (Fed. Cir. 2019) (non-precedential) ("The claim seeks to capture the broad concept of switching to a more secure server, rather than a specific way to do so."); *Univ. of Fla. Research Found., Inc. v. Gen. Elec. Co.*, 916 F.3d 1363, 1368 (Fed. Cir. 2019) (explaining that "[n]either the . . . patent, nor its claims, explains *how* the drivers do the conversion," and that in a claim, the driver is "recited in purely functional language").

Granting patents on functions without limitation to particular ways (structures, materials, or acts) for performing the function violates patent law's bedrock principles protected by Section 112 and preempts future innovation. Such naked functional claims

undermine every important mechanism by which the patent system is designed to promote innovation.

First, allowing naked functional claims incentivizes dreamers to file aspirational patent applications before they have contributed anything to the public store of knowledge. If patent monopolies are granted on all ways of performing a function, rather than only the particular ways contributed by the patent applicant, no patent-based incentive exists to do the hard work of future invention.

Second, allowing naked functional claims defeats the inherent bargain in the patent system that the full invention for which the inventor is granted a limited monopoly enters the public domain, free for all to make and use, when the patent expires. If a patent claims all ways of performing a function, but discloses only a limited number of ways, then the patent owner gets a windfall monopoly far exceeding his or her contribution to the public, which by definition has not been taught the full scope of the claimed monopoly.

Third, allowing naked functional claims burdens the patent system's second engine of innovation. Instead of a clearly marked and fixed claim boundary defining a particular solution to a problem, outside of which other innovators can freely experiment with other possible solutions, naked functional claims create a monopoly on the future, covering all possible later solutions of others. This preempts the hard work of and investment in future inventions that perform the same functions and achieve the same results in different and often better ways. It deters "efficient investment in innovation":

> The patent laws "promote the Progress of Science and useful Arts" by rewarding innovation with a temporary monopoly. U.S. Const., Art. I, § 8, cl. 8. The monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not. For this reason, the patent laws require inventors to describe their work in "full, clear, concise, and exact terms," 35 U.S.C. § 112, as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights.

Festo, 535 U.S. at 730–31 (citation omitted).

If the Court reaches the Question Presented in this case, *Amici* ask that the Court do nothing to approve or encourage such innovation-choking naked functional claims.

IV. THE CLAIMS HAVE NOT BEEN CONSTRUED TO IDENTIFY THE CLAIMED EMBODIMENTS

The Question Presented rests on a false premise. It presumes that the "claimed invention" and "claimed

embodiments" have been identified in the lower courts:

> 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,'" Pet. App. 14a.

Pet. Br. at i. (emphasis added; original emphasis removed).

As noted, Section 112 restricts claimed inventions to structures, materials, and acts, not mere functions and results. Thus, a patent's "claimed embodiments" are the particular structures, materials, and acts delineated by the claims of the patent.

But the three patent claims here have not been construed to delineate claimed embodiments. Instead, both parties, and the lower courts, took these claims at face value as encompassing whatever performs the dual functions in the claims. Respondents stipulated to infringement of these claims based on that assumed, face-value claim scope. Without such a construction, there has been no identification of the structures, materials, or acts encompassed by the claims. Therefore, the "claimed embodiments"

referenced in the Question Presented mostly are unidentified in this procedurally peculiar case.

Petitioners suggest that it falls upon each interested member of the public, not the patent applicant, to identify which structures, materials, and acts fall inside or outside a patent's claims. Pet. Br. at 19–21. But that is the opposite of the law.

> The statute seeks to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their rights. The inventor must 'inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.'

Gen. Elec., 304 U.S. at 369.

This false premise in the Question Presented is another reason why this case is an exceptionally poor vehicle to modify any of the innovation-protecting mandates of Section 112.

V. THE CLAIMS HAVE NOT BEEN ANALYZED UNDER THE COURT'S LONGSTANDING BAN ON NAKED FUNCTIONAL CLAIMS LIKE THESE

In the 1930s and 1940s, the Court rejected as a matter of law patent claims reciting only a function to be performed without also reciting particular structures, materials, or acts sufficient to perform the function. By covering all possible ways to perform a

function, such functional claims give inventors more than they contributed and preempt others from inventing different and better ways, defeating the whole point of the patent system. This precedent, *Halliburton Oil* and *General Electric*, is discussed below.

In *General Electric*, the Court held the following naked functional claim "invalid on its face":

> A filament for electric incandescent lamps or other devices, composed substantially of tungsten and made up mainly of a number of comparatively large grains of such size and contour as to prevent substantial sagging and offsetting during a normal or commercially useful life for such a lamp or other device.

304 U.S. at 368 (underlining added to identify the function).

The Court assumed that the patent "sufficiently informed those skilled in the art how to make and use [the inventor's] filament." *Id*. at 368. But enabling the disclosed embodiment did not save the claim because it described "the function of the grains to the exclusion of any structural definition." *Id*. at 371.

> A limited use of terms of effect or result, which accurately define the essential qualities of a product to one skilled in the art, may in some instances be permissible and even desirable, but a characteristic essential to novelty may not be distinguished

> from the old art solely by its tendency to remedy the problems in the art met by the patent.

Id. at 371–72.

In *Halliburton Oil*, the invention was an improved technique for measuring the depth of the fluid surface of the oil in an oil well. 329 U.S. at 3–7. The inventor added a mechanical acoustical resonator to existing equipment to better detect certain sound waves used to determine the distance to the oil. *Id.* at 7. Some claims recited the structure of that resonator, but not the asserted claims. *Id.* at 8. The asserted claims recited the desired outcome without reciting how to achieve it, reciting, for example:

> means associated with said pressure responsive device for <u>tuning said receiving means to the frequency of echoes from the tubing collars of said tubing sections to clearly distinguish the echoes from said couplings from each other</u>.

Id. at 9 n.7 (underlining added to identify the function).

The claims did not recite the structure, material or acts by which the recited function is performed. *Id.* at 8. "[T]he claims failed adequately to depict the structure, mode, and operation of the parts in combination." *Ibid.* The Court identified the essential vice of a naked functional claim:

> The language of the claim . . . describes this 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. We have held that a claim with such a description of a product is invalid.

Id. at 9.

The Court focused on the harm to the patent system's second engine of innovation: "[U]nless frightened from the course of experimentation by broad functional claims like these, inventive genius may evolve many more devices to accomplish the same purpose." *Id.* at 12.

These decisions were consistent with earlier decisions of the Court prohibiting naked functional claims.

The Court first rejected naked functional claims as a matter of law in *O'Reilly v. Morse*, 56 U.S. 62 (1853), cited by Judge Rich in *In re Hyatt*. The patent related to Samuel Morse's invention of the single-wire telegraph. While upholding narrower claims directed to the disclosed invention, the Court rejected Morse's claim to "the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing [of] intelligible characters, signs or letters at a distance." *Id.* at 112. Allowing such a functional claim would permit the patent to cover "some future inventor['s]" discovery of a "mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of [Morse's] process." *Id.* at 113.

Foreshadowing the later enactment of Section 112(f), the Court sometimes prohibited naked functional claims not by invalidating them but instead by construing them not to be naked functional claims, limiting their scope to the structure, material or acts described in the patent specification rather than taking the claim at face value. In *Holland Furniture Co. v. Perkins Glue Co.*, a claim recited:

> A glue comprising cassava carbohydrate rendered semifluid by digestion and having substantially the properties of animal glue.

277 U.S. 245, 250 (1928) (underlining added to identify function).

The Court limited the claim to the particular starch ingredient described in the specification, holding that the claim otherwise would be invalid for indefiniteness and inadequate disclosure under the Court's precedents:

> A claim so broad, if allowed, would operate to enable 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. The patent monopoly would thus be extended beyond the discovery, and would discourage rather than promote invention. That the patentee may not by claiming a patent on the result or function of a machine extend his patent

> to devices or mechanisms not described in the patent is well understood.

Id. at 249, 257.

Petitioners mostly disregard this body of precedent rejecting (or limiting) naked functional claims and instead rely on *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 263 (1916). Pet. Br. at 2, 6, 23–24, 31–32, 36, 41–42, and 46. But that decision did not concern naked functional claims. Instead, the claims there recited both a function (separating metallic from nonmetallic material in ore) *and* particular acts for performing that function (by agitating the ore in a solution of water and oil). *Minerals Separation*, 242 U.S. at 265. An issue there was whether the patent's disclosure of how to perform those claimed *acts* was sufficiently detailed for a person of ordinary skill in the art to perform them. *Id.* at 270–71. The Court found for the patent owner on that question. *Ibid.* *Minerals Separation* did not speak to naked functional claims and therefore is not pertinent to the three claims here.

The dual-function claims before the Court have not been analyzed under the precedents banning or limiting naked functional claims, including *Morse*, *Holland Furniture*, *General Electric*, and *Halliburton Oil*. Had the Patent Office done so, it would not have granted the two single-element antibody claims and it would not have granted the composition claim, at least not without first construing it as a combination claim limited to the particular antibody and composition structures, materials, and acts disclosed in the specification as performing the claim-recited functions, and equivalents thereof. Respondents did

not assert this body of law, and neither did the lower courts apply this law to these claims. Consequently, this case comes to the Court in a peculiar procedural posture with patent claims assumed to have a purely functional scope prohibited by governing law. This is another reason why this case is a poor vehicle for disturbing the delicate balance of Section 112.

VI. THE CLAIMS HAVE NOT BEEN ANALYZED OR CONSTRUED UNDER THE STATUTE'S LIMITED SAFE HARBOR FOR SOME CLAIMS USING FUNCTIONAL WORDS

In direct response to *Halliburton Oil*, Congress in the 1952 Patent Act codified this case law, but with a twist, in 35 U.S.C. 112, ¶ 6, now 35 U.S.C. § 112(f). This provision allows "[a]n element in a claim for a combination" to be "expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof." But it instructs that "such [a] claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." *Ibid.*; *see Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 27–28 (1997) ("Congress enacted § [112(f)], in response to [*Halliburton Oil*], which rejected claims that 'do not describe the invention but use "conveniently functional language at the exact point of novelty."'") (citation omitted). Thus, while leaving single-element naked functional claims invalid, Congress codified the *Holland Furniture* claim-construction approach for multi-element claims with naked functional claim elements.

Section 112(f) acts as a limited safe harbor against invalidation of naked functional claims. *See In re Hyatt*, 708 F.2d at 715 (Judge Giles Rich) ("The final paragraph of § 112 *saves* combination claims drafted using means-plus-function format from this problem [of non-enablement] by providing a construction of that format narrow enough to avoid the problem of undue breadth as forbidden by the first paragraph.") (emphasis added and removed). It mandates that any facially naked functional claim element, *i.e.*, one that expressly recites a function without expressly reciting the structure, material, or acts for performing the function, in a combination claim, is by statute limited to the particular structure, material, or acts described in the patent—if any—as performing the function. As explained by the en banc Federal Circuit:

> In enacting this provision, Congress struck a balance in allowing patentees to express a claim limitation by reciting a function to be performed rather than by reciting structure for performing that function, while placing specific constraints on how such a limitation is to be construed, namely, by restricting the scope of coverage to only the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof.

Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1347 (Fed. Cir. 2015).

This statutory safe harbor is limited by two conditions. First, the claim must be a "combination,"

a multi-element claim. Second, if the patent specification fails to describe (and link to the function) the required structure, material, or acts for performing the claim-recited function, the claim remains a naked functional claim and is invalid under this Court's (and the Federal Circuit's) precedents. *See, e.g.*, *Ergo Licensing, LLC v. CareFusion 303, Inc.*, 673 F.3d 1361, 1363 (Fed. Cir. 2012) ("Failure to specify the corresponding structure in the specification amounts to impermissible pure functional claiming . . . . If an applicant does not disclose structure for a means-plus-function term, the claim is indefinite.") (citation omitted).

The Board of Patent Appeals and Interferences ("BPAI") followed the above precedents of the Court prohibiting naked functional claims. The BPAI aptly described a claim having "purely functional" claim language that is not saved by Section 112(f) as being in a "dead zone" because the claim is unpatentable under *Halliburton Oil. Sanada v. Reynolds*, 67 U.S.P.Q.2d 1459, 1460 (B.P.A.I. Mar. 19, 2003) (informative); *see Ex parte Catlin*, 90 U.S.P.Q.2d 1603, 1607 n.2 (B.P.A.I. Feb. 3, 2009) (precedential) (explaining that if a claim step reciting "purely functional language" did not invoke Section 112(f), then the step "would impermissibly cover every conceivable act for achieving the claimed result, and the scope of the claimed step would not be enabled"). In another relatively rare precedential opinion, the BPAI explained that a patent application claim is unpatentable for both claim indefiniteness and inadequate disclosure if it contains a "purely functional claim element" with no limitation of structure, unless saved under Section 112(f). *Ex parte*

Miyazaki, 89 U.S.P.Q.2d 1207, 1216–17 (B.P.A.I. Nov. 19, 2008) (precedential).

Because this statutory safe harbor is limited to "combination" claims, single-element claims whose sole element recites a function without a way remain invalid as a matter of law, as the Federal Circuit ruled 40 years ago. *In re Hyatt*, 708 F.2d at 715 (Judge Rich) (rejecting claim with only a single element, which element was a naked functional element, as lacking adequate disclosure, because the safe harbor of Section 112(f) is limited to combination claims).

But neither the Patent Office, the parties, nor the lower courts have applied or addressed Section 112(f) in this case. Had the Patent Office done so, it would have rejected the single-element naked functional "antibody" claims 7 and 19, and either rejected "pharmaceutical composition" claim 29 for the same reason or construed it as a combination claim under Section 112(f) and limited to the specific embodiments disclosed in the specification and their equivalents. Had this law been applied in the Patent Office or lower courts, the three claims before the Court, to date accepted at face value as reciting naked functions possibly encompassing millions and millions of mostly unknown antibodies, would not exist. Instead, Petitioners would be left with their non-asserted patents that claim their actual invention.

This is another reason this peculiar case should not cause the Court to disturb Section 112 or its own precedents protecting innovation.

VII. THE COURT SHOULD NOT WEAKEN THE LONGSTANDING FULL-SCOPE ENABLEMENT REQUIREMENT

As noted, one patent-system goal advanced by Section 112 is to place the claimed invention fully in the public domain upon the expiration of a patent. This requires that a patent's disclosure give skilled artisans all they need to make and use the full extent of the claimed structures, materials, and acts, perhaps in competition with the patent owner or its licensees. This is patent law's full-scope enablement requirement.

The present case would be an exceptionally poor vehicle for the Court to erode this longstanding rule for all of the reasons explained in this brief. But, in particular, the Court should not erode full-scope enablement because Petitioners do not challenge it. They do not challenge the 170-year-old precedent (*O'Reilly v. Morse*) that patent claims reciting a single element by its function alone—which is true of at least the two "antibody" claims in this case—violate patent law's full-scope enablement requirement. Nor do Petitioners challenge this full-scope enablement requirement more broadly. Instead, they acknowledge that a patent claim must not "truly exceed[] what the patent enables." Pet. Br. at 21.

The Court, therefore, should not in this case alter the unchallenged and longstanding mandate of full-scope enablement.

CONCLUSION

This case is an exceptionally poor vehicle for disturbing existing law under Section 112 because (1) Petitioners have not challenged longstanding full-

scope enablement law, (2) the Question Presented is based on a false premise that the claims have been construed to identify the "claimed embodiments," (3) the claims are naked functional claims which plague the computer, electronics, telecommunications, and software fields much more so than the life sciences, and (4) neither the Patent Office nor the lower courts have analyzed, or construed, these claims under this Court's precedents banning naked functional claims, or the limited safe harbor of Section 112(f) enacted in response to those precedents. Moreover, no *certiorari*-stage brief mentioned *Halliburton Oil*, *General Electric*, or Section 112(f).

The Court therefore should either dismiss *certiorari* or expressly circumscribe its opinion to apply solely to the claims and peculiar procedural posture before the Court. Any broader ruling risks serious harm to innovation across a broad range of industries and a vast swath of the American economy.

Respectfully submitted,

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