No. 21-757

IN THE

Supreme Court of the United States

AMGEN INC., AMGEN MANUFACTURING, LIMITED, AND AMGEN USA, INC.,

Petitioners,

v.

SANOFI, AVENTISUB LLC, FKA AVENTIS PHARMACEUTICALS INC., REGENERON PHARMACEUTICALS, INC., AND SANOFI-AVENTIS U.S. LLC,

Respondents.

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

BRIEF OF DIVERSIFIED RESEARCHERS AND INNOVATORS IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Page

TABLE OF AUTHORITIES – continued

CONSTITUTION AND STATUTES

LEGISLATIVE MATERIALS

OTHER AUTHORITIES

TABLE OF AUTHORITIES – continued

INTEREST OF *AMICI CURIAE*[1]

Amici are a diverse group of innovators who rely on the patent system to protect their inventions. They include small and early-stage biotech companies, larger and well-established pharmaceutical companies, companies in materials science and consumer products, research hospitals, and university technology managers. They are for-profit and not-for-profit entities who conduct both basic and applied research in many different fields. *Amici* are also competitors, and they have been directly adverse to one another in litigation over their innovations and patent rights. Their perspectives thus vary enormously.

Despite their diverse interests, *amici* agree that the Federal Circuit's enablement standard for genus claims is wrong as a matter of law and harmful to the innovation process. It unrealistically demands that inventors make and test numerous examples of an invention *before* filing their patent applications, under the guise that doing so is necessary "to reach the full scope" of a claimed genus. But the Federal Circuit's standard effectively demands that inventors eliminate any scientific uncertainty or experimentation incidental to carrying out an invention. That has never been the standard for enablement.

The Federal Circuit's "reach the full scope" standard ignores how innovators actually operate. Innovation-centric entities like *amici* devote significant resources

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[1] Pursuant to Supreme Court Rule 37, *amici* state that no counsel for any party authored this brief in whole or in part, and that no entity or person other than *amici* and their counsel made any monetary contribution toward the preparation and submission of this brief. Both parties filed blanket consent letters.

and personnel to the discovery and development of inventions, but far more resources to the arduous and unpredictable task of delivering products and services based on those inventions to doctors, patients, and consumers. No innovator—large or small, commercially-focused or non-profit— can justify diverting limited resources to the task of performing experiments to fill patent specifications with information skilled artisans know and with test results skilled artisans could readily obtain using routine experimental methods. The Federal Circuit time-and-resource-wasting "reach the full scope" rule is badly out of touch with the innovation economy.

Amici believe that the Federal Circuit's approach cannot be reconciled with the language of the Patent Act or this Court's precedent. They also believe the requirement erodes the ability of innovators to secure and enforce patents with an effective scope of protection for innovations that make possible a wide range of products and services, ranging from new medicines addressing unmet medical needs to remarkable consumer products. If not remedied, the Federal Circuit's inflexible enablement standard diminishes the patent incentives for both innovation and the prompt disclosure of new technologies, all to the detriment of patients and the public at large.

Amicus Association of University Technology Managers, Inc. ("AUTM") is a nonprofit organization dedicated to bringing research to life by supporting and enhancing the global academic technology transfer profession through education, professional development, partnering, and advocacy. AUTM's more than 3,200 members manage intellectual property and technology commercialization for more than 300 universities, research institutions, and teaching hospitals around the

world, as well as numerous businesses and government organizations.

Amicus Bavarian Nordic A/S is a fully integrated vaccines company focused on the development, manufacturing and commercialization of life-saving vaccines, including a smallpox and monkeypox vaccine, an Ebola vaccine licensed to the Janssen Pharmaceutical Companies of Johnson & Johnson, and vaccines against rabies and tick-borne encephalitis. Bavarian Nordic is also committed to the development of an RSV vaccine and a next generation COVID-19 vaccine.

Amicus Biogen Inc. is a global biopharmaceutical company focused on discovering, developing, and delivering innovative therapies.

Amicus Bristol Myers Squibb Company is a global innovator biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.

Amicus Corning Incorporated is one of the world's leading innovators in materials science. For nearly 170 years, Corning has applied its unparalleled expertise in glass science, ceramic science, and optical physics to develop products that transform industries and enhance people's lives. Corning's innovations include the first glass bulbs for Thomas Edison's electric light, the first low-loss optical fiber, the cellular substrates that enable catalytic converters, and the first damage-resistant cover glass for mobile devices.

Amicus Merck Sharp & Dohme LLC is an American multinational pharmaceutical company and one of the largest pharmaceutical innovators in the world.

Amicus 3M Company is a diversified global manufacturer and technology innovator that uses science to improve lives. Today, more than 60,000 3M products

are used in homes, businesses, schools, hospitals, and other industries. About one-third of 3M's sales come from products invented within the last five years.

SUMMARY OF ARGUMENT

The Federal Circuit's heightened enablement standard for genus claims contradicts the governing statute and this Court's precedent, while simultaneously upsetting the patent system's essential bargain.

I. Section 112 of the Patent Act contains a comprehensive set of obligations for inventors: they must "particularly point[] out and distinctly claim[]" their inventions and provide "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, or with which it is most nearly connected, to make and use the same."

Among those strictures, the "enablement" requirement means what it says—and what this Court has interpreted it to say. The specification must be "sufficiently definite to guide those skilled in the art to [the invention's] successful application." *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 271 (1916). What qualifies as "sufficiently definite to guide" a skilled artisan to make and use the invention, moreover, necessarily depends on the skilled artisan's perspective. An inventor may "leav[e] something to the skill of persons applying the invention," *id.*, because a specification can enable a skilled artisan to make and use the invention when they are able to do it based on the disclosure's guidance *and* their existing knowledge. In contrast to such "routine experimentation," a specification fails to guide skilled artisans to make and use the invention when it requires them to engage in undue independent experimentation to practice the claims.

The Federal Circuit has replaced the statutory enablement standard with a special, atextual rule for certain types of patent claims—called "genus" claims—that encompass more than just the specific examples described in the patent. The Court should correct three flaws in the Federal Circuit's approach to enablement.

First, to "reach the full scope of claimed embodiments," the Federal Circuit asks whether making and using all of the claimed embodiments would take "substantial time and effort." But that turns the enablement inquiry into a counting exercise and fails to account for the perspective of the skilled artisan. The enablement provision does not force innovators to perform routine make-work that any skilled artisan could do and that is, by definition, not inventive.

Second, the Federal Circuit prejudges the enablement inquiry for claims employing functional language in any manner, declaring that such claims raise "special problems" warranting a special test. But the statute makes no distinction between claims that include or omit functional language—its inquiry compares what the claims encompass to what the patent disclosure (in conjunction with the prior art and the state of the art at the time of invention) enables. Moreover, for certain types of inventions, functional language can best delineate the features of the invention that warrant patent protection. Claims should not start with a handicap simply because they contain functional language.

Third, the Federal Circuit's rule upends the burden of proof in challenging issued patents. It forces patentees to prove that hypothetical embodiments ginned up by their opponent in litigation *are* enabled, rather than requiring that challenger to prove that embodiments encompassed within the issued claims are *not* enabled. That is wrong—it is the patent challenger's burden to

prove[2] there is a concrete gap between what the claims cover and what the patent disclosure, the prior art, and the skilled artisan's knowledge together can fill.

II. The patent system is built on a bargain. Inventors get a time-limited right to exclude others from practicing their inventions in exchange for promptly and adequately disclosing those inventions to the public. When the proper balance is struck, the patent system incentivizes investments in innovation *and* early dissemination of technological advances to the public, thereby advancing progress in science and the useful arts.

The Federal Circuit's "reach the full scope" standard skews the balance of incentives for continued innovation. For inventors seeking broader and potentially more commercially valuable rights, it demands that they make and test additional examples beyond what is necessary to enable others to make and use the invention, and to cram their patent applications with information already known to skilled artisans. The alternative is to pursue narrower patent rights that may fail to adequately protect the invention.

The public loses out in both of these scenarios. In one, fewer inventions will be made or reach the market, because exhausting a genus's "full scope" takes time and resources. In the other, the patent system will prompt narrower disclosures that limit innovation-adjacent insights that might otherwise benefit the public but are unnecessary to enable narrow patent

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[2] The challenger's burden of proving lack of enablement varies based on where the challenge is made. In a district court or before the International Trade Commission, it is by clear and convincing evidence, while in administrative proceedings before the Patent and Trademark Office, it is by a preponderance of the evidence.

claims. Potential breakthrough technologies risk wasting away on the shelf—and taking with them potential licensing revenues that could be reinvested in further research.

The Federal Circuit's standard also harms innovation in other ways. For example, in the fast-paced fields of research that *amici* are in, producing redundant examples will divert limited resources and delay filing patents and risk loss of rights. In the midst of litigation, moreover, no amount of rote work may be enough to combat an alleged infringer's list of hypothetical embodiments. When innovators making fully enabling disclosures are stripped of exclusivity rights commensurate with their inventions—as the Federal Circuit's standard does—consumers, patients, and the public at large all lose.

ARGUMENT

I. THE FEDERAL CIRCUIT'S ENABLEMENT STANDARD FOR GENUS CLAIMS IS WRONG.

A. The Enablement Requirement's Role in Patent Law.

The patent system serves its constitutional mandate—to "promote the Progress of Science and useful Arts," U.S. Const. art. I, § 8, cl. 8—when it incentivizes both groundbreaking advances and the plethora of subsequent innovations that follow. The system is designed to encourage patent grants that strike this balance: claims that are too broad can stifle subsequent innovation, while claims that are too narrow fail to provide necessary incentives to spur innovation and commercialization.

To achieve that goal, the Patent Act imposes three independent requirements that, together, regulate the

proper scope of patent rights granted to innovators. Each helps to police patent grants against over-breadth.

First, the invention must be more than an abstract idea or at the conceptual stage—it must be a new and useful process, machine, manufacture, or composition of matter. This is the territory of section 101, which "defines the subject matter eligible for patent protection." *Alice Corp. Pty. Ltd.* v. *CLS Bank Int'l*, 573 U.S. 208, 216 (2014). "[F]or more than 150 years," the Court has recognized that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Id.* The "concern that drives this exclusionary principle [i]s one of pre-emption," such that "the basic tools of scientific and technological work" are not preempted by a patent monopoly. *Id.*

Second, the invention must be novel, distinct, and not obvious from the knowledge already available to those working in the field of the invention. This is the territory of 35 U.S.C. §§ 102 and 103. These requirements "express a congressional determination that the purposes behind the Patent Clause are best served by free competition and exploitation of either that which is already available to the public" (§ 102), "or that which may be readily discerned from publicly available material" "by a person of ordinary skill in the pertinent field of endeavor" (§ 103). *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 149–50 (1989). A claim "will not qualify for federal patent protection if its contours are so traced by the existing technology in the field that the 'improvement is the work of the skillful mechanic, not that of the inventor.'" *Id.*

Third, the patent must both sufficiently define the invention in patent claims and provide a disclosure that describes that invention and enables the skilled artisan to practice it as the invention has been defined

in the patent claims. These requirements are the territory of § 112. The first subsection requires that "[t]he specification shall 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).[3] The second demands that the claims "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention." *Id.* § 112(b). These requirements apply explicitly to "the invention" and, therefore, to the range of compounds, compositions, machines, or methods that the claims encompass.

This Court has long recognized the purpose behind section 112's disclosure requirements: "[t]he object … is to apprise the public of what the patentee claims as his own, the courts of what they are called upon to construe, and competing manufacturers and dealers of exactly what they are bound to avoid." *Consol. Elec. Light Co.* v. *McKeesport Light Co.*, 159 U.S. 465, 474 (1895). Two hundred years ago, the Court similarly identified "two objects" of the specification, including "to make known the manner of constructing [the invention] so as to enable artizans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent." *Evans* v. *Eaton*, 20 U.S. 356, 433–34 (1822); see also, *e.g.*, *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 480–81

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[3] The Federal Circuit has construed § 112(a) as containing two requirements, known as "enablement" and "written description." *Ariad Pharms., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (*en banc*). No language in § 112 requires that a specification describe and disclose what skilled artisans already know or provide endless examples in order to "reach the full scope" of claimed embodiments.

(1974) (enablement provision ensures that, "upon the expiration of the 17-year period 'the knowledge of the invention enures to the people, who are thus enabled without restriction to practice it and profit by its use'"). If skilled artisans cannot reproduce the invention by following the guidance in the patent, the public is not receiving its end of the bargain.

Overbroad claims, including overbroad genus claims, risk running afoul of any or all of these requirements. Indeed, the broader the claim, the more exposed it will be to challenges: a broad claim is more likely to capture territory already disclosed in prior art, more likely to bump up against limits on patentable subject matter, and more likely to come up short of sufficiently defining the claims and sufficiently describing the invention and the manner and process of making and using it. Enablement is just one of many overbreadth checks that Congress has incorporated into the patent system.

B. Section 112 and Longstanding Precedent Establish the Appropriate Enablement Standard.

Section 112 requires that a patent's specification "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 proper enablement standard follows directly from that statutory text. The key term—from which the doctrine gets its name—is "enable." And the plain meaning of that term is that the disclosure must equip a skilled artisan with *the ability* to "make and use" the invention. That is exactly what the word meant when

first U.S. patent statute was enacted, when the Patent Act of 1952 was enacted, and still today. See, *e.g.*, Samuel Johnson's A Dictionary of the English Language 689 (6th ed. 1785)[4] ("To make able; to empower; to supply with strength or ability"); Webster's New International Dictionary 841 (2d ed. 1951) ("To make able; to give (one) power, strength, or competency sufficient for the purpose"); The Concise Oxford Dictionary of Current English 391 (4th ed. 1951) ("Authorize, empower, (person *to* do); supply (person etc.) with means *to* do"). As these authorities all make clear, *enabling* someone to do something does not require that the enabling party (here, the patentee) actually *do* it herself.

Equally important is what the patent's specification need not disclose. The statute specifies that the adequacy of the disclosure is assessed from the perspective of "any person skilled in the art to which [the invention] pertains." 35 U.S.C. § 112(a). Indeed, "patents are 'not addressed to lawyers, or even to the public generally,' but rather to those skilled in the relevant art." *Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 572 U.S. 898, 909 (2014). More than that, the description should be focused on the invention, not what is already known: the disclosure must be in "full, clear, *concise*, and exact terms." 35 U.S.C. § 112(a) (emphasis added). As a result, a patent "specification need not disclose what is well known in the art." *Lindemann Maschinenfabrik* v. *Am. Hoist & Derrick Co.,* 730 F.2d 1452, 1463 (Fed. Cir. 1984).

The perspective of the skilled artisan is thus a critical aspect of the enablement inquiry. It brings a practical lens to the analysis that accounts for a particular

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[4] Available at https://archive.org/details/dictionaryofengl01johnuoft/page/n689/mode/2up.

discipline's evolving knowledge, training, and experience. It requires assessing not only the relevant skills, education, and training the artisan would possess, but also a measure of that person's capacity for insights, judgment, and awareness of practicalities of working in the field. Put another way, the skilled artisan understands not only what to do and how to do it but also what *not* to bother doing. Consequently, "the specification need not necessarily describe how to make and use every embodiment of the invention 'because the artisan's knowledge of the prior art and routine experimentation can often fill in the gaps.'" *Liebel-Flarsheim Co.* v. *Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007). Because enablement is assessed at the time of the invention, and because innovation often progresses quickly, a proper enablement analysis must accurately reflect the state of the art and the skilled artisan's knowledge at the time of the invention.

This Court has recognized these parameters for centuries, and *Mineral Separations* articulates them particularly well. The substantive standard is flexible: as the Court put it, the specification must be "***sufficiently definite to guide*** those skilled in the art to [the invention's] successful application." *Minerals Separation*, 242 U.S. at 271 (emphasis added). Providing such a "guide" is precisely what it means to "enable." The Court also explained the importance of the skilled artisan's perspective: "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject matter." *Id.* at 270. It is perfectly appropriate to "leav[e] something to the skill of persons applying the invention." *Id.* at 271.

To analyze a patent's compliance with the enablement requirement, courts often consider the amount of "experimentation" that a skilled artisan would have to undertake in order to "make and use" the invention.

Some amount of experimentation is acceptable (and sometimes necessary), but "undue" independent experimentation is not. The skilled artisan, however, understands that uncertainty exists in many fields of endeavor and accounts for it, recognizing that some degree of experimentation is often required and expected to put the invention into practice.

Cases upholding or invalidating patent claims illustrate how this Court has enforced the standard. On one side, inventors need not "specify in a patent" the "impossible," like which "precise treatment … would be most successful and economical in each case." *Minerals Separation*, 242 U.S. at 271. There was no enablement problem in that case even though, "when different ores [we]re treated[,] preliminary tests must be made to determine the amount of oil and the extent of agitation necessary in order to obtain the best results." *Id.* at 270. In a similar vein, a patent satisfied section 112 when the "patent and its specifications were manifested to readers who were skilled in the art of paper making" such that skilled artisans "had no difficulty" recreating the invention. *Eibel Process Co.* v. *Minn. & Ont. Paper Co.*, 261 U.S. 45, 65–66 (1923).

On the other side, a patent should not require the skilled artisan to perform undue independent experimentation in order to make and use the invention. The disclosure cannot "be so vague and uncertain that no one can tell, except by *independent* experiments, how to construct the patented device," and "except by the most careful and painstaking experimentation." *Consol. Elec. Light Co.*, 159 U.S. at 474–75 (emphasis added). Likewise, when the skilled artisan had to "resort to experiments *of his own to discover*" certain ingredients for a hair treatment product, the disclosure was "not full and clear enough to give one skilled in chemistry such an idea of the particular kinds and

character of the chemicals, or combination of chemicals, with the relative proportions of each, as would enable him to use the invention." *Bene* v. *Jeantet*, 129 U.S. 683, 686 (1889) (emphasis added).

More recently, the Federal Circuit articulated several factors to consider "in determining whether a disclosure would require undue experimentation." *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988). They are: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 737. As explained further below, this non-exhaustive list of factual inquiries has proven useful in framing the ultimate question—does the patent's disclosure enable the skilled artisan to make and use the claimed invention?

C. The Federal Circuit's Enablement Standard for Genus Claims is Flawed.

At bottom, the Federal Circuit found Amgen's patent claims not enabled because they covered more examples of antibodies than had been disclosed in the patent specification. The court faulted the patent specification because a skilled artisan would need to perform experiments: screening newly made antibodies or modified forms of the exemplified antibodies using "the patent's 'roadmap' [that] provided guidance for making antibodies with binding properties similar to those of the working examples." Pet. App. 14a. But the patent challenger never proved there was a deficiency with Amgen's roadmap—the district court and the Federal Circuit instead found the claims deficient because "'substantial time and effort' would be required to reach the full scope of claimed embodiments." *Id.*

Finding that a skilled artisan must spend "substantial time and effort" following a "roadmap" to make additional examples of an invention is a troubling standard for enablement and cannot be reconciled with the Court's long-standing precedent. Most patent claims encompass more than the specific work done by the inventor, and for good reason—they provide inventors exclusive rights to not just a particular example of the invention they have made but to related variations that share the invention's attributes. In the chemical arts, for example, genus claims[5] have been described as "a group of compounds closely related both in structure and in properties." *In re Kalm*, 378 F.2d 959, 963 (C.C.P.A. 1967).

This *amicus* group reflects diverse interests and perspectives on the question of enablement, but *amici* all agree that the Federal Circuit's decision on the enablement standard for genus claims suffers from three flaws that should be remedied.

1. The Federal Circuit Erroneously Requires Routine or Predictable Testing.

First, the Federal Circuit requires, particularly when there is general uncertainty or unpredictability in the field of the invention, that the inventor must actually make and test most (if not all) of the genus's embodiments and disclose them in the specification. But the enablement standard has never compelled an inventor to perform work that is within the known capabilities of the ordinarily skilled artisan, following the guidance and procedures in the patent disclosure. On

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[5] The members of a claimed genus—particular compounds, compositions, machines, or processes—are called "species."

the contrary, although "the quantity of experimentation" is *one* of many *Wands* factors, 858 F.2d at 737, it did not ask about "the quantity of grunt work" and was in no way decisive on its own.

The decision below enshrines a rigid standard for genus claims that fixates on how many members of the genus have actually been made and tested and how much a skilled artisan may theoretically need to do—irrespective of whether that testing would be routine or predictable to the skilled artisan. According to the Federal Circuit, for example, "it is important to consider *the quantity* of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also *the full scope of the claim*." Pet. App. 11a (emphasis added). And that was dispositive here: the patent was not enabled because it supposedly "would take a substantial amount of time and effort … to exhaust [the] genus" and "to obtain embodiments outside the scope of the disclosed examples and guidance." *Id.* at 14a; see also *id.* at 63a (articulating vague and circular special test for "[b]iological compositions not actually prepared"). The "quantity of experimentation" simply meant the "quantity of work," and "a substantial amount of time and effort" was too much work.

The Court should correct the Federal Circuit's "actually-make-the-full-scope" requirement. The enablement inquiry instead must focus on whether the specification *enables* a skilled artisan to make and use the invention—in other words, whether the skilled artisan *can do it* by following the guidance in the patent disclosure and what the skilled artisan knows. It is not anchored on how long it will take and does not require extinguishing the possibility that one of the species within the genus might not work. It depends on the

field and state of the art. In short, it is qualitative, not quantitative.

The Federal Circuit's specialized test also overemphasizes and misapplies the *Wands* factor pertaining to "the predictability or unpredictability of the art."[6] 858 F.2d at 737. In the decision below, the Federal Circuit highlighted the supposedly "unpredictable field of science with respect to satisfying the full scope of the functional limitations" and found it persuasive that "only … a small subset of examples of antibodies can *predictably* be generated." Pet. App. 14a (emphasis added). But that (again) ignores the skilled artisan's perspective. Skilled artisans in many fields are aware of and comfortable navigating scientific uncertainty—it often is simply part of the landscape.

For example, scientists working in the field of antibody development may not be able to predict, *a priori*, the amino acid sequences within a particular antibody responsible for particular functional characteristics associated with the antibody that make it inventive. However, once that particular antibody is made and fully characterized, the following of a detailed protocol that reliably identifies additional antibodies with the same functional characteristics would not be considered undue experimentation by scientists skilled in that art. That is true even if skilled artisans have to repeat multiple steps, tweak protocols and devote weeks or months to the project.

Enablement also does not mandate absolute certainty. Rather, the question is whether, combined with preexisting knowledge at the time of the invention, the

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[6] *Wands* was a 1988 case that also involved monoclonal antibodies, 858 F.2d at 733, a field that has advanced dramatically in the intervening 30+ years.

patent is sufficiently definite to guide the skilled artisan to make and use the invention and to navigate any identified gaps in the disclosure. The Federal Circuit's apparent concern over unpredictability in the chemical arts in particular has led to an impossible-to-meet standard divorced from what is actually claimed. Unpredictability, by itself, reveals nothing about whether there is an enablement problem specific to the patent disclosure at issue.

2. The Federal Circuit Erroneously Imposes a Special and Higher Standard on Claims with Functional Language.

Second, the enablement standard does not forbid use of functional language in patent claims, nor does it ascribe any kind of special test for evaluating claims that include such language. On the contrary, in certain fields, functional properties (*e.g.*, stability in solution or binding characteristics) or functional effects (*e.g.*, anti-infective properties) of a compound may be the most informative way of describing the invention.

The Federal Circuit, however, professes an overt hostility toward the use of functional language in claims that has distorted the enablement inquiry. According to the Federal Circuit, such claims "pose high hurdles," "raise[] the bar for enablement," and "raise special problems." Pet. App. 12a, 13a, 66a. For those supposedly "special problems," the Federal Circuit has devised a special test: "the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements" and "the quantity of experimentation that would be required to make and use … the full scope of the claim." *Id.* at 11a.

There is no sound basis for the Federal Circuit's special standard. To be sure, claims to compounds, compositions or devices identified *solely* by reference to what they do, but which impose *no* requirements as to *any* structural characteristics of those compounds, compositions or devices (so-called "single means" claims), are unlikely to pass scrutiny. That has always been the case: "[t]he 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." Pet. App. 66a.

But many patent claims employ functional language in a far more limited and appropriate way—using it *in conjunction with* other language anchoring the functional attributes to members of a genus sharing certain structural attributes. For example, a claim may define a genus of bioactive molecules that each possess a characteristic chemical structure that causes it to exhibit a particular behavior or effect recited in the claim. Similarly, if the patent describes a set of antibodies as being useful because each binds to a structure (*i.e.*, an epitope) within a particular region of the target antigen, there should be no inherent problem in defining that genus using the term "antibody" in combination with functional language requiring each antibody to bind to its epitope in that region of the antigen. Such claims should be treated like any others—by determining whether a skilled artisan can make and use the invention with the patent's guidance and without undue experimentation. *Supra* § I.B. In other words, the enablement inquiry for a claim containing functional language should be performed without additional labels or requirements, which only serve to prejudge the outcome.

3. The Federal Circuit Erroneously Flipped the Burden of Proof for Challenging Issued Patents.

Third, the Court should reestablish the proper burden of proof in enablement challenges to issued patents. The Federal Circuit's prevailing enablement authority, *Wands*, 858 F.2d 731, is based on an appeal from the denial of a patent application. Once a patent issues, however, it gets a presumption of validity that requires the challenger to prove, by clear and convincing evidence, that the guidance in the patent disclosure is insufficient. *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. 91 (2011).

The Federal Circuit's rule inverts the burden of proof and requires *the patentee* to carry the affirmative burden of showing that something less than "'substantial time and effort' would be required to reach the full scope of claimed embodiments," no matter how routine or predictable the process of making and using such embodiments might be. Pet. App. 14a. This puts the patent owner in the impossible situation of disproving the relevance of hypothetical scenarios invented by its opponent in the context of litigation—explaining why the patent disclosure enables skilled artisans to make and use the invention notwithstanding the hypothetical existence of hypothetical embodiments. Worse still, these made-for-litigation embodiments can be very different from the accused infringer's *own* embodiments, which are the subject of the lawsuit and often track the patent's disclosure.

The Court should reaffirm that the burden of proof for issued patents lies with the patent challenger and reject the Federal Circuit's unwarranted demand that the patentee "prove enablement." Rather than forcing patentees to prove that hypothetical embodiments *are*

enabled, therefore, the challenger should have to provide "concrete identification" of embodiments that are *not* enabled by following the specification's guidance. See *McRO, Inc.* v. *Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020); Pet'r Br. 41–48. Stated differently, if the challenger contends that there is a non-enabled gap between what is disclosed and what is claimed, and the challenger contends that the disclosure combined with the skilled artisan's knowledge cannot bridge that gap, then *the challenger* has to concretely identify and explain the alleged disconnect. The Federal Circuit's approach is backwards.

II. THE FEDERAL CIRCUIT'S "REACH THE FULL SCOPE" REQUIREMENT UNDERMINES THE PATENT SYSTEM'S BARGAIN AND DISRUPTS INNOVATION.

A. The Patent System Is Built on a Bargain that Drives Innovation.

The U.S. patent system frames a bargain: inventors are granted the exclusive right to their inventions in exchange for disclosing those inventions to the world. *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). That bargain has generated "the greatest innovation engine the world has ever known."[7]

Section 112 concerns the inventor's end of that bargain. It is "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 right." *Festo Corp.* v. *Shoketsu Kinzoku*

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[7] *Innovation Act: Hearing on H.R. 3309 Before the H. Comm. on the Judiciary*, 113th Cong. 40 (2013) (statement of David J. Kappos, former Director of the U.S. Patent & Trademark Office).

Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002). The same bargain has been described as a *quid pro quo*: in exchange for a limited period of exclusive rights in the invention, inventors must make a "disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted." *Universal Oil Prods. Co.* v. *Globe Oil & Refin. Co.*, 322 U.S. 471, 484 (1944).

The tradeoffs built into that system yield a proportionality principle. What a patentee discloses must be commensurate with the scope of the claims, and a patentee should be entitled to receive claims of a scope that is commensurate with what the patentee has given to the public through the disclosure. The enablement requirement thus "ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Nat'l Recovery Techs., Inc.* v. *Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999). To that end, when innovators make a significant advancement in the field and hold up their end of the patent bargain by providing an enabling disclosure of their invention, they are entitled by statute to patent protection commensurate with the scope of their contribution.

Extremes in either direction undermine the patent system's design. On the one hand, a disclosure that is nothing more than a research plan is unlikely to enable a yet-to-be identified species with desired properties, let alone a broad genus claim. Such patents improperly put the burden of inventive research and experimentation on other skilled artisans, particularly

when it requires solving undisclosed challenges, developing new materials or methods, or engaging in significant experimental work whose results cannot be reasonably predicted.

On the other hand, it is equally improper to "limit[]" claims "to the 'concise and exact terms' in which the specifications ordinarily describe a single example of the invention" when the patent discloses a broader inventive contribution. *Philip A. Hunt Co.* v. *Mallinckrodt Chem. Works*, 177 F.2d 583, 585 (2d Cir. 1949). Doing the latter allows others to easily bypass the investments and efforts of the innovator through routine and non-inventive work, and "few, if any, patents[] would have value." *Id.*

The system is set up to establish a balance in which both ends of the bargain must be respected. The bargain "only works if the patent's specification … provides sufficient technical information about the invention to enrich the public storehouse of knowledge." Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 7–8 (2021) ("KLS"). At the same time, innovators must be granted commercially meaningful exclusivity commensurate with their innovations or else the incentive to share their inventions with the public will evaporate.

B. The Federal Circuit's Erroneous Standard for Genus Claims Threatens to Upend the Bargain that Drives Continued Innovation.

Amici are innovators. Some are small startups, and some are established pioneers. Some are for-profits and others not-for-profits. Some come from different industries, and some are fierce competitors in the same industry. Despite these divergent perspectives,

amici all depend on the patent system to protect their inventions. And they all share deep concerns about the consequences that the Federal Circuit's "reach the full scope" standard will have on that patent system's fundamental bargain between inventors and the public—whatever the technological field.

1. Several *amici* operate in the pharmaceutical, biotechnology, and chemical sectors. "When one speaks of a 'genus' in the chemical arts, one ordinarily speaks of a group of compounds closely related both in structure and in properties." *Kalm*, 378 F.2d at 963. Within that historical understanding, innovation has thrived. Through properly enabled genus claims, "biotechnology patents helped to spur research and development … and to bring forth groundbreaking, commercially significant inventions." KLS, *supra*, at 22. Not only that, but such genus claims can "drive certain classes of innovation, pushing pharmaceutical research away from 'me-too' drugs towards new classes of treatments." *Id.* at 68–69.

Modern therapeutics face similar risks and rewards. They derive from the discovery and targeted manipulation of cellular mechanisms that cause disease. Therapeutic monoclonal antibodies, for example, stimulate or inhibit a cell's behavior due to their precisely defined functional properties. Their discoveries have revolutionized modern medicine and led to unprecedented success in treating diseases, including cancers, autoimmune diseases, and other conditions, many of which previously had no treatment.

But successfully delivering a new antibody-based therapy to patients is complex and expensive—and comes with a high risk of failure. Current figures show that it can take 10 to 15 years to bring a new therapeutic to market. See PhRMA, *Biopharmaceuticals in*

Perspective 27 (Fall 2020).[8] Taking into account the "many potential medicines" that fail, the average cost to bring a single new drug to market is more than $2.6 billion. *Id.* These costs have increased tenfold from the 1980s. See Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 1 (Apr. 2021).[9] But the innovations have been literally lifechanging, elucidating cellular pathways that can be exploited to treat previously untreatable diseases and developing compounds to address unmet medical needs.

The same general path of innovation—including an analogous role for appropriate genus claims—occurs in other industries where *amici* operate. *Amici* Corning and 3M, for example, are materials science innovators. The former's inventions are manifested in products ranging from Pyrex® cookware to optical fiber to the crack resistant glass used on billions of smartphones, while the latter's are found in a wide range of consumer products ranging from adhesives to components of popular consumer electronics. For example, Corning inventors discovered that a unique combination of a polymer coating on glass imparted certain highly-valuable benefits like superior touchscreen surfaces for mobile phones. A species of that invention might cover one particular polymer mixture with traits that confer that desired set of inventive features, while a genus claim would cover a range of mixtures of polymers that share those traits reflecting the invention. Similarly, 3M inventors discovered that particular mixtures of

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[8] This publication is available online at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/ChartPack_Biopharmaceuticals_in_Perspective_Fall2020.pdf.

[9] This publication is available online at https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.

certain metal elements improve the lifespan of lithium-ion batteries. One species of that invention might be the particular mixture of metal elements that 3M developed, while the genus claim covered a range of mixtures of these metal elements that exhibit the attributes responsible for the battery's extended lifespan.[10]

For the genus claim, all that enablement requires is that the specification list *enough* attributes of the polymers (not all) to enable a skilled artisan to select those that practice the invention, coupled with guidance on how to make compositions that have those attributes. The skilled artisan can identify known but unnamed polymer candidates based on the inventive functional attributes and can make them through routine experimentation. The inventor thus need not test each and every polymer mixture that would work to achieve the claimed benefits.

Still other *amici* work in non-profit research settings, such as universities and research hospitals, and have discovered pioneering inventions in life sciences and beyond. Like everyone else, however, these institutions cannot afford to waste their time and precious resources. For these *amici* as much as anyone, "[r]equiring specific testing of the thousands of [relevant] analogs encompassed by [a particular] claim in order to satisfy the how-to-use requirement of § 112 would delay disclosure and frustrate, rather than further, the interests of the public." *In re Bundy*, 642 F.2d

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[10] Over the life of the patent covering this invention, 3M licensed numerous entities, reflecting the value of its patented inventive "genus." *See, e.g.*, Elaine Chow, Law360, *3M, Lenovo Settle Over Lithium Ion Battery Patents* (Sept. 5, 2007); Business Wire, *3M and LG Chem Complete NCM Patent License Agreement* (Aug. 4, 2015).

430, 434 (C.C.P.A. 1981). These entities also have a mission that prioritizes discovery research alongside good stewardship of their limited funds (especially when they derive from federal sources), neither of which align with performing experiments unnecessary to enable skilled artisans to practice their inventions.

2. The Federal Circuit's ratcheted-up enablement standard for genus claims unsettles the patent system's innovation-fueling incentives from all sides.

For innovators, the Federal Circuit's unequivocal message is that meaningful patent protection now requires inefficient and even irrational conduct. To satisfy the "reach the full scope" rule, for example, innovators are being told to make and exhaustively test additional examples of their inventions and describe those tests in detail—just to confirm what a skilled artisan would know and expect from reading the patent with their training and experience. That imperils all genus claims, not just those employing functional language.[11] And it forces innovators to choose between two undesirable alternatives: secure narrow claims that are not commercially viable or engage in routine and predictable experimental work before filing their patent applications.

The latter choice diverts resources away from more productive activities, like creating new inventions or commercializing the one that has been made. Also, time spent "perfecting" the innovator's patent application delays the filing of the patent application, which

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[11] The slippery slope is steep. In the small molecule field, for example, structural genus claims may encompass thousands or even millions of compounds. Making all such compounds would take plenty of work, even if rote and routine: do inventors now need to do so or risk losing their patent rights?

can deprive the innovator of an effective (or any) patent exclusivity and allow intervening patent filings from competitors. It also frustrates the patent system's objective of prompting *early* disclosure of inventions.

An enablement standard that limits valid claims to only those species made, tested, and described in a patent disincentivizes the more difficult task of innovation. More directly, it rewards companies who make insubstantial changes to existing products and then displace the innovator in the market, rather than independently discovering and developing meaningfully different products. And it keeps potential breakthrough technologies collecting dust on laboratory shelves.

That is not the patent system that the Framers or Congress set up. The promise of patent exclusivity should induce innovators to take risks, to make the necessary investments, and to publicly disclose their inventions. But that requires robust patent protection that prevents others from unfairly exploiting the path blazed by the innovator, effectively freeriding on the innovator's risks and investments.

Properly enabled genus claims provide that protection. The economic benefits and market advantages made possible using genus claims make them a powerful incentive. They prevent others who have not made the investments and undertaken the risks of innovation from following the inventor's blueprint to simply carry out routine and predictable experimentation without significant independent effort. Genus claims of appropriate scope incentivize competition based on true scientific progress and meaningful innovation, inducing competitors to make their own investments and to take risks to make their own groundbreaking inventions.

In the end, the public loses under the Federal Circuit's "reach the full scope" rule. Society risks losing out on innovative products and services that will never reach the market, paying higher prices for those that do, losing the benefit of broader patent disclosures, or a combination of all three.

CONCLUSION

The Federal Circuit's decision should be reversed.

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