No. 21-757

In the Supreme Court of the United States

AMGEN INC., ET AL.,

Petitioners,

v.

SANOFI, ET AL.,

Respondents.

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

BRIEF OF *AMICUS CURIAE* GSK PLC IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

GSK plc ("GSK") spends billions of dollars annually—including more than $6.5 billion in 2021 alone—developing innovative medicines, vaccines, and therapies. Those efforts have yielded breakthroughs in the fight against COVID-19, HIV, cancer, shingles, meningitis, asthma, diabetes, malaria, and other diseases. During fiscal year 2021, GSK had three major product approvals, eight phase III starts, and twenty-two vaccines and medicines in pivotal trials. In total, GSK had more than sixty new medicines and vaccines under development, many of which offer first-in-class medicines for patients.[2]

Genus claims are critical to protecting the innovations of companies like GSK, as well as those of smaller entities and academic institutions, and encourage discovery and investment in the chemical, pharmaceutical, and biotechnological arts. They often reflect major scientific breakthroughs, establish first-in-class medicines, and encourage downstream improvements that can themselves be patented. But the Federal Circuit's newly minted enablement standard has called the validity of genus claims into question and undermines the incentives to innovation that the patent system was designed to foster.[3] GSK respectfully submits this brief to the Court to underscore the importance of genus claims to innovation.

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[1] Pursuant to Sup. Ct. R. 37.6, counsel for *amicus* certifies that no counsel for any party authored this brief in whole or in part, and that no entity or person other than *amicus* and its counsel made any monetary contribution toward this brief.

[2] *See* GSK, *Annual Report 2021* at 2, https://www.gsk.com/media/7462/annual-report-2021.pdf.

[3] *Amicus* takes no position on the validity of the particular claims at issue and submits this brief solely to encourage the Court to correct the legal framework that the Federal Circuit applied.

SUMMARY OF THE ARGUMENT

Genus claiming is critical to protecting ground-breaking discoveries in the life sciences. *See* Section I. Such discoveries often manifest as an entirely new genus containing many individual compound "species." Without the ability to secure patent protection over a genus, competitors could make closely related species or modifications to a patented compound to avoid infringement while still appropriating the heart of the invention. Faced with that reality, a pioneer might be less likely to invest in discovery because disclosure of her full discovery would unfairly enrich mere copyists, and instead would be motivated, to mitigate that risk, to maintain secrecy over the breadth of her breakthrough for as long as possible to maintain her lead over the copyists. The public's ability to build on the collective knowledge of discoveries and inventions would suffer and, most importantly, patients would have access to fewer vital medicines.

Furthermore, genus claiming encourages downstream innovation. *See* Section II. Pioneers' disclosures in their patents allow others to learn from, and build upon, their inventions. Other innovators can themselves obtain patent protection for discovering improved species within a patented genus, such as species with non-obvious benefits or unexpected properties.[4] Such non-obvious improvements are—and deserve to be—independently patentable under United States patent law, and, depending on the improved properties, may provide the public with significantly better medicines. In such a scenario, the pioneer and improver have a strong incentive to enter

[4] The same is true for the discovery of an improved subgenus within the original genus. For simplicity, this brief refers to subgenera and species collectively as "species" within a pioneering genus.

into a contractual arrangement and to distribute the improved medicine to patients. Moreover, even where patent protection is unavailable, downstream parties can avail themselves of other legal protections and incentives to build upon a pioneer's invention, such as the 35 U.S.C. § 271(e) "safe harbor" and regulatory data exclusivity. Accordingly, genus claiming does not preempt the continuing progress of science. Rather, genus claiming allows downstream innovators to receive the benefits of their later discoveries.

The rationale behind enablement supports the "undue experimentation" test, not the "full scope" test. *See* Section III. The Patent Act relies on a *quid pro quo* where a time-limited, exclusive right is exchanged for public disclosure of an invention. The rationale of the "enablement" requirement, in particular, is to protect that *quid pro quo* and ensure that once a patentee's exclusivity has ended, others can "make and use" the invention and reap the benefits of that advancement. However, a patent does not need to literally teach every variation of an invention to satisfy the enablement requirement nor is a claim's breadth dispositive—even if the variations included in the scope are numerous or infinite. Instead, the traditional "undue experimentation" test for enablement is flexible: it allows the factfinder to synthesize a variety of considerations relevant to whether an artisan is sufficiently able to "make and use" the invention based on the patent disclosure. Inflexible tests, like the Federal Circuit's "full scope" test, by contrast, deny recourse to common sense.

The Federal Circuit's atextual "full scope" enablement test punishes innovators in the life sciences and usurps Congress's role. *See* Section IV. While nearly all patent claims encompass a large number of embodiments, inventions in the life sciences have recently encountered

focused, unfavorable treatment under the Federal Circuit's "full scope" test. But it is not the role of courts to devise domain-specific patentability rules to address issues that arise in particular arts. That is Congress's role: a role that it has exercised a number of times with appropriate legislation after balancing the diverse interests between innovators, imitators, and the public.

In sum, this Court should declare that the traditional, fact-bound enablement test applies to genus claims in the life sciences, just like any other type of utility claim in any other art, and reject the circuit court's atextual "full scope" enablement test.

ARGUMENT

I. Genus Claims Are Critically Important To Meaningful Patent Protection For Life Sciences Inventions.

In granting certiorari on Question 2, this Court recognized its significance. As *amici* have explained, genus claims are "critical to protecting and advancing innovation," especially in the chemical, pharmaceutical, and biotechnological industries. *E.g.*, GSK Cert. Amicus Br. 2, 6; IP Profs. Cert. Amicus Br. 4. Although inventors in all arts depend on patent claims broader than a specific embodiment—to protect a class of apparatuses or methods sharing the common advancement of the invention against unscrupulous competitors seeking to evade the literal scope of the claims—genus claims are especially important for inventions in the life sciences. They have been called "[t]he ***central feature*** of patent law in the chemical, biotechnology, and pharmaceutical industries." Karshtedt, Lemley & Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1 (2021) (emphasis added).

Virtually all patents to a novel machine, composition, or process are drafted to claim a class (*i.e.*, genus) of structurally related or similar things. Consider Thomas Edison's patent on a lightbulb using a carbon filament. U.S. Patent No. 223,898 (issued Jan. 27, 1880). He claims an electric lamp that contains a carbon filament, secured to metallic wires, to produce light by incandescence. *See id.*, Claim 1. By defining his invention in such broad and general terms, Edison's claim covers copycat lightbulbs—even if his competitors varied the shape of the filament, the composition of the wires, the voltage used, the shape of the glass, and so on. Thousands, if not millions, of species of the invention could exist within the scope of

Edison's patent claim. This is what all patent applicants are taught to do: define the invention not by the specifics of a commercial product, but by the attributes that define the novel advancement of one's invention over the prior art (in Edison's case, a carbon filament). Of course, Edison could have drafted his claim narrowly, specific to the precise measurements and compositions of his particular prototype—but then the claim would not have been commensurate in scope with Edison's invention and it would have been trivial for a copyist to evade Edison's patent by the slightest of alterations.

This principle applies with equal, if not greater, force in the life sciences. A scientist who discovers that a particular chemical compound works to treat some disease may easily obtain a "species" claim over that precise medicine, defined by its exact structure. But such a narrow claim would not reflect the full scope of her inventive contribution to the art nor offer commercially meaningful protection against competitors. She would appreciate that thousands of close analogues have similar desired properties and utility (*e.g.*, efficacy for treating a disease). Indeed, known techniques permit competitors to circumvent the literal scope of such a narrow claim by making and testing slight variants of the patentee's product to produce a copycat, without themselves doing the work to advance science. But the genus claim provides a solution: The inventor may write her patent application to claim a ***genus*** of many related species that together represent the true extent of her discovery. This is why genus claims are "ubiquitous" in the life sciences. Sean B. Seymore, *Patenting the Unexplained*, 96 WASH. U.L. REV. 707, 729 (2019).

Without the robust protection offered by genus claims, innovator companies will be reluctant to invest the substantial time and money necessary to make significant

discoveries. The second a patent is published, a competitor can begin to look for a way to evade the literal scope of the claims. Under the "full scope" enablement test that is "impossible" to meet for a genus of nontrivial size, *see* Karshtedt et al. at 4, 56–57, today's inventor is caught in a trap: Either she discloses her secrets for a narrow claim, bearing the risk that the literal scope of her claim can be easily circumvented; or she must redirect resources into impractical, wasteful experiments just to shore up her patent disclosure to teach how to ***cumulatively*** produce ***all*** the variants of her invention, to obtain a meaningful genus claim. *But see In re Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976) (recognizing that it would be futile and wasteful to force an inventor to do so to obtain a patent). Even then, she cannot assume that the genus will not be invalidated by a court simply because somewhere in the far corners of the genus, the court discerns embodiments that cannot be easily made using the disclosures of the patent. Against that backdrop of uncertainty in the patent system, a pioneer would be motivated not to disclose the whole genus—instead relying on trade secrecy to protect the full scope of her discovery, delaying disclosure of the information relied on by the mere copyists in order to maintain her competitive edge. The result undermines the purposes of the Patent Act for contributing to public knowledge so that others may learn from and build on the invention. *See infra* Section III.

As for the inventions that were already disclosed and patented under then-existing law, the Federal Circuit's judicial rewriting of the enablement standard is destroying their value and undermining the robust protections that those patents were thought to provide. The resulting breakdown undermines confidence in the patent system and incentives for research-oriented companies, like GSK, to invest in the discovery of new medicines.

II. Genus Claims Do Not Preempt The Progress Of Science And The Useful Arts—They Encourage Downstream Innovation.

This Court has long recognized the patent system's role in encouraging innovation. *See, e.g.*, *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) ("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."). Genus claims are no different in this respect from any other patent claims. The bargained-for disclosure in the form of genus claims both promotes the progress of science and human health and also provides the public with a head start to future discoveries that build upon the genus claims.[5]

Genus claims can inspire downstream parties to discover species within a claimed genus that have beneficial properties or make inventive modifications to species within the genus. Indeed, downstream parties may obtain patent protection for non-obvious improvements to past discoveries, including for species with unexpected properties that fall within the genus claims of a preexisting patent. *See, e.g.*, *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1379 (Fed. Cir. 2014) ("It is well-settled that a narrow species

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[5] *See generally* Whitney E. Frasier Tiedemann, *First-to-File: Promoting the Goals of the United States Patent System Through the Biotechnology Industry*, 41 U.S.F.L. REV. 477, 477 (2007).

can be non-obvious and patent eligible despite a patent on its genus.").[6]

Thus, a pioneer can hold patent rights over an entire genus, and, at the same time, an improver can hold patent rights to species that provide unexpected benefits within that genus. Consequently, genus claims encourage downstream innovators to build upon pioneering discoveries and discover even better compounds, with unexpectedly beneficial properties, that they can patent and commercialize themselves. Genus claims neither foreclose innovation nor preempt others from obtaining patents on downstream discoveries.

Market forces then encourage cooperation. While the pioneer and the improver could potentially exclude each other from commercializing the improved species in such a scenario,[7] there are strong incentives against their doing so. If an improved invention is better than other known species in the genus, it could command greater market demand—*e.g.*, by providing greater benefit to patients. Reaching an agreement, the innovator and improver could offset their significant investments and split the economic recovery commensurate with their respective contributions and expenditures.[8] The parties therefore have

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[6] *See also Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1098 (Fed. Cir. 2015); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1321–22 (Fed. Cir. 2004); *Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1270 (Fed. Cir. 2003); *In re Petering*, 301 F.2d 676, 683 (C.C.P.A. 1962).

[7] Each would have the right to exclude the other by virtue of their concurrent patent rights over the species. *See generally* 35 U.S.C. § 154(a)(1).

[8] Where the improved invention presents substantial marketable benefits over the rest of the genus, one would expect the parties to try to reach agreement to get the benefit of the improvement. *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1008–10 (1997).

a strong market incentive to reach an agreement and sell the improved invention together, rather than hold out and refuse to enter into a license agreement. Since they can potentially reach an agreement with the pioneer, downstream parties also have incentives to invest in improving upon past inventions in the first place, even in "the shadow" of a patent over the genus.[9]

Reputational and legal protections also encourage licensing. Attempting to enjoin the commercialization of an important medicine could be untenable from a public relations perspective—and courts are generally unwilling to enjoin health-related products, such as medicines and antibodies, in which there is a strong public interest. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (requiring a plaintiff seeking a permanent injunction to satisfy a four-factor test including "that the public interest would not be disserved by a permanent injunction.").[10] Accordingly, the parties have incentives to negotiate an agreement to bring the improved product to

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[9] *Id.* at 1052 ("Improvers have an incentive to invest in research even in the shadow of an original invention, since they can obtain a patent on their improvement. And the fact that that improvement patent gives them some real bargaining power gives them an incentive to come to the bargaining table, and indirectly, an incentive to invest in improvement in the first place.").

[10] *See also* Lance Wyatt, *Rebuttable Presumption of Public Interest in Protecting the Public Health—The Necessity for Denying Injunctive Relief in Medically-Related Patent Infringement Cases After eBay v. MercExchange*, 13 CHI.-KENT J. INTELL. PROP. 298, 320 (2013); *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. CV-03-0597-PHX-MHM, 2009 WL 920300, at *8 (D. Ariz. Mar. 31, 2009) (declining to enjoin sale of infringing medical device because "the values of the Patent Act and the protections that it offers to the patentee are sometimes outweighed by the Court's equitable

patients.[11]

If, however, downstream researchers fail to discover non-obvious improvements that qualify for independent patent protection, the pioneer retains the right to practice the entire genus unencumbered by the rights of others. But that is a fair outcome. The pioneer invested the time and resources to discover the genus and disclosed that discovery to the public. Accordingly, where others had neither discovered the genus first, nor invented non-obvious improvements afterwards, the pioneer, *ipso facto*, deserves the broad genus claim. *See also infra* Section III (discussing obviousness and novelty as mechanisms for guarding against overbroad claims).

A downstream improver has protections and incentives aside from the opportunity to secure a patent on her own work. For example, they can avail themselves of the 35 U.S.C. § 271(e) "safe harbor," which insulates acts of patent infringement "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . ." 35 U.S.C. § 271(e)(1). As this Court has explained, "the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process" and the safe harbor "necessarily includes," for example, "preclinical studies of patented compounds that are appropriate for

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concern for the greater public good, particularly in the realm of vascular surgery and other potentially life saving technologies."); *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 712 F. Supp. 2d 1285, 1293 (M.D. Fla. 2010) (declining to enjoin sale of infringing contact lens product because of public health concerns).

[11] *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1365 (Fed. Cir. 2010) (Rader, J. dissenting-in-part and concurring-in-part) (stating that such circumstances "serve the market well by pressuring both inventors to license their innovations to each other and beyond.").

submission to the FDA in the regulatory process." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). Thus, downstream researchers can conduct research to advance the progress of science by operating within the "wide berth" of the § 271(e)(1) safe harbor.

Similarly, downstream researchers can avail themselves of regulatory data exclusivity, which protects data submitted for regulatory approval for certain periods of time.[12] Thus, even if they do not qualify for independent patent protection, downstream parties can receive other protections and incentives for their research into new medicines that build upon the genus claim.

In short, a pioneer's disclosure of a genus claim can invite downstream innovation that builds upon it.

III. The Rationale Behind Enablement Supports The Traditional "Undue Experimentation" Test.

When an inventor devises something novel, be it an automobile, airplane, or antibody, the Patent Act allows her to secure a time-limited, exclusive right in exchange for public disclosure of how "to make and use" her invention. 35 U.S.C. §§ 112, 154. The moment her invention is disclosed, its teachings become immediately available to others who may learn from, and build upon, the invention

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[12] The Drug Price Competition and Patent Term Restoration Act (commonly known as the "Hatch-Waxman Act") of 1984, Pub. L. No. 98-417, 98 Stat. 1585, introduced regulatory exclusivity in the United States. The Hatch-Waxman Act provides up to five years of market exclusivity to pharmaceutical companies which introduce a new chemical entity to the market (NCE exclusivity), up to three years of market exclusivity for conducting new clinical investigations (other than bioavailability studies) to support changes to drug products already on the market (Clinical Investigation or CI Exclusivity). If the statutory requirements are satisfied, regulatory exclusivity attaches upon approval of the product. *See* 21 U.S.C. § 355(c)(3)(E)(ii).

with their own innovations—provided, of course, that they commercialize the invention only with the inventor's permission. *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974); *see also supra* Section II.

About twenty years later, when the patent expires and the patentee's rights are extinguished, the invention enters the public domain, merging into the corpus of shared knowledge that all may draw upon freely. *Kellogg Co. v. Nat'l Biscuit Co.*, 305 U.S. 111, 120 (1938). The disclosures extracted by the patent system "are of such importance to the public weal that the Federal Government is willing to pay the high price of [up to 20 years] of exclusive use" so that they "will stimulate ideas and the eventual development of further significant advances in the art." *Kewanee Oil*, 416 U.S. at 481. This *quid pro quo* is how the patent system "promote[s] the Progress of Science and useful Arts," art. I, § 8, cl.8, driving the engine of American innovation as it has since 1790 when the First Congress enacted the Patent Act, 1 Stat. 109. *See Graham v. John Deere Co.*, 383 U.S. 1, 6, 9 (1966).

The rationale of the "enablement" requirement for patentability is to protect that essential *quid pro quo*—to ensure that, once the patentee's exclusivity has ended, others may practice the invention and reap the benefits of that advancement. *See Universal Oil Co. v. Globe Co.*, 322 U.S. 471, 484 (1944); *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 418 (1822) ("The object is to put the public in complete possession of the invention . . . so that . . . its benefits may be fully enjoyed by the public, after the patent expires.").[13] If a patent were so devoid of teachings that another artisan would practically have to re-discover the

[13] Moreover, by giving accused infringers a validity defense based on the adequacy of enablement, *see* 35 U.S.C. § 282(b)(3)(A), the Patent Act ensures that those with a personal stake may hold patentees to the statutory requirements of patentability.

invention anew to make and use it, the patentee has not fulfilled her part of the bargain.

On the other hand, artisans are not automatons; they are also persons of "ordinary creativity." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). A patent should not need to literally teach every variation of the invention for an artisan to reconstruct it. For instance, a patent claim to the first typewriter may literally encompass millions of variations of key layouts for the letters A–Z and other symbols, the composition of materials used, and the colors or sizes of the device. No one would expect that broad patent claim to a "genus" of typewriters to be judicially invalidated—for failing to enable the "full scope" of the invention—simply because it did not guide an artisan to each and every species in the far corners of its broad scope.

Until recently, courts have recognized the folly of counting the number of species included within the scope of a claim for determining its validity. *See, e.g.*, *In re Cavallito*, 282 F.2d 357, 361 (C.C.P.A. 1960) ("The mere fact that a claim covers a large, or even an unlimited number of products, does not necessarily establish that it is too broad. Claims are commonly allowed for alloys or mixtures which permit substantial variations in the proportions of two or more ingredients. Theoretically an infinite number of products may be produced falling within the scope of such a claim.").

Instead of making claim breadth dispositive, the traditional "undue experimentation" test for enablement has always allowed the factfinder to synthesize all the considerations—like the predictability of the art, preexisting knowledge in the art, existence of working examples, guidance in the patent disclosure, and the level of skill that a person of ordinary skill in the art possesses—relevant to whether an artisan is sufficiently able to "make

and use" the invention based on the patent disclosure. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These common-sense considerations are probative of whether the *quid pro quo* of disclosure has been fulfilled: whether others may follow the patent's teachings to make use of the invention.

Rigid and inelastic tests like the Federal Circuit's "full scope" enablement test, by contrast, leave no room for nuance and deny factfinders recourse to common sense. *Cf. KSR*, 550 U.S. at 415, 421. Something has gone awry when the aims of a "full scope" test, which polices the ***breadth*** of the exclusive rights claimed in a patent, is untethered to why the enablement requirement exists (*i.e.*, to ensure that the patent's contribution to the public domain allows others to use the invention when the exclusive term ends). *See* Karshtedt et al. at 58.

Moreover, there is no reason to burden enablement with an artificial breadth requirement when other rules that apply to all inventions equally, like novelty and obviousness (35 U.S.C. §§ 102–103), ensure genus claims are not inequitably broad. Those usual questions—*Has someone else already discovered this? Has there been a leap forward beyond routine combinations?*—ensure that a claim is not so broad that it ensnares what was known. *See O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 135 (1853) ("What is meant by a claim being to[o] broad? The patent law and judicial decisions may be searched in vain for a provision or decision that a patent may be impugned for claiming no more than the patentee invented or discovered. It is only when he claims something before known and used, something as new which is not new, either by mistake or intentionally, that his patent is affected.").

This Court should restore enablement to the sensible, traditional test that has always governed this area of law.

IV. Courts Should Not Devise Domain-Specific Patentability Rules—That Is Congress's Role.

The burdens of the Federal Circuit's "full scope" enablement test have largely fallen upon the life sciences. *Wyeth*, for example, invalidated patent claims on a class of chemical compounds used to treat the narrowing of arteries. *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1382 (Fed. Cir. 2013). *Idenix* involved a class of small chemicals used to treat the hepatitis C virus. *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1153–54 (Fed. Cir. 2019). And this case involves a class of antibodies used to reduce bad cholesterol. Pet. App. 3a–4a.

The disproportionate impact of the "full scope" test on the life sciences is no accident. As discussed above, pharmaceutical and biotechnology innovators, more than those in other industries, depend on genus claims. While all claims cover a class of embodiments, and some, like composition-of-matter and alloy claims, often encompass ***infinite*** embodiments, *see In re Cavallito*, 282 F.2d at 361, it is easier to recognize a genus and count up the finite number of species for life sciences inventions. Chemical nomenclature provides known ways to estimate the total number of species included within a chemical genus. And the limits of biology dictate that, to claim a genus of antibodies rather than one species, such a claim necessarily includes up to "millions" of countable embodiments, Pet. App. 15a; *see also* Pet. App. 33a (district court opinion, noting that up to 97,000 variants of one embodiment could be obtained just by applying the substitutions taught in Table 1 of the patent to one disclosed example in the patent). So it is no surprise that the court of appeals applied its recent precedent invalidating other broad life science inventions on enablement grounds, in this case. *See* Pet. App. 15a.

But courts should not devise domain-specific patentability rules to address issues that arise in particular arts. That is not what Congress envisioned when it enacted one Patent Act with the same enablement test—35 U.S.C. § 112—for all utility patents. Homogeneous utility patent law does not favor or disfavor any particular science or art. *See Graham*, 383 U.S. at 5–6. Beyond the threshold issue of whether subject matter is patentable at all, there is no statutory mandate to "raise" the patentability bar for certain kinds of inventions. *But see* Pet. App. 13a (using functional limitations "raises the bar for enablement").

Where Congress saw fit to fine-tune intellectual property law and incentives for particular industries, it has done so by appropriate legislation. For instance, Congress enacted the Drug Price Competition and Patent Term Restoration Act (commonly known as the "Hatch-Waxman Act") of 1984, Pub. L. No. 98-417, 98 Stat. 1585, to manage the interplay between FDA's process for generic drugs and innovators' patent rights. In response to the advent of using biological products for medical treatment (such as antibodies), Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) of 2009, Pub. L. No. 111-148, tit. VII, 124 Stat. 804 (2010) and, in the process, created an abbreviated process for biosimilar drugs while preserving a way to resolve patent disputes. *See Sandoz Inc. v. Amgen Inc.*, 137 S.Ct. 1664, 1669–70 (2017). To incentivize the development of novel plant varieties that may advance the nation's agricultural interests, while counterbalancing farmers' practices and the needs of the food supply, Congress enacted the Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970), to create an intellectual property regime outside of utility patents to address the unique issues in those arts. *See, e.g.*, *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 181, 185–86 (1995). To incentivize the development of integrated circuits in the electronic age, Congress enacted the

Semiconductor Chip Protection Act of 1984, Pub. L. No. 98-620, tit. III, 98 Stat. 3347, to create a unique intellectual property scheme, with attributes of patents and attributes of copyright, for "mask works" representing semiconductor chip designs.

Each of these examples shows Congress appropriately exercising its constitutional powers, art. I, § 8, cl.8, to weigh and balance the diverse interests between innovators, imitators, and the public. That delicate balance requires a deliberative process with careful weighing of the consequences. Yet when the Federal Circuit announced a heightened enablement test for genus claims that uniquely affects pharmaceutical and antibody inventions, *see* Pet. App. 13a ("the use of broad functional claim limitations raises the bar for enablement"), it took the issue on without similarly balancing the diverse interests and without the institutional capability to foresee the consequences.

This Court should restore the uniform rules that Congress enacted in § 112. And it should do so by declaring that the traditional, fact-bound enablement test applies to this case, and to genus claims, just like it does to any other invention.

A traditional "undue experimentation" test that measures what it takes for an artisan to make and exploit the invention for its utility, rather than a formalistic test that asks what it would take for an artisan to make ***every*** embodiment of the claim (or ***every*** candidate that might lead to a claimed species), would better respect the mandate of § 112. And it would reaffirm the viability of genus claims commensurate with a patentee's contribution to the art, of vital importance to the chemical, pharmaceutical, and biotechnology arts.

CONCLUSION

The judgment of the court of appeals should be reversed.

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