No. 20-380

In The

Supreme Court of the United States

IDENIX PHARMACEUTICALS LLC AND
UNIVERSITA DEGLI STUDI DI CAGLIARI,

Petitioners,

v.

GILEAD SCIENCES, INC.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF INTELLECTUAL PROPERTY PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

Amici curiae are intellectual property law professors throughout the United States.[1] We have considerable experience with both patent practice and patent doctrine. *Amici* have no personal interest in the outcome of this litigation, but we share a professional interest in seeing that the patent laws are applied in such a way as to provide adequate incentives for innovation.[2] All parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

The central feature of patent law in the chemical, biotechnology, and pharmaceutical industries is the genus claim—a patent that covers not just one specific chemical but a group of related chemicals. Genus claims are everywhere, and any patent lawyer will tell you they are critical to effective patent protection. This Court has long recognized the legality and desirability of genus claims. Without them, a competitor could make a minor change to the chemical the patentee

[1] Appendix A includes a list of the *amici*.

[2] *Amici* certify that no party or party's counsel authored this brief in whole or in part, no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief, and no person or entity—other than *amici* or their counsel—authored the brief or made a monetary contribution to its preparation or submission.

invented and avoid liability while capturing the heart of the invention.

This Court, the Patent and Trademark Office ("PTO"), and the regional circuit courts have long upheld genus claims, finding that they were compliant with the enablement requirement of 35 U.S.C. § 112(a) provided they taught the person having ordinary skill in the art ("PHOSITA") enough that the PHOSITA could make and use a chemical within the genus without undue experimentation. Early cases from the Court of Appeals for the Federal Circuit and one of its predecessor courts, the Court of Customs and Patent Appeals ("CCPA"), were also in accord.

But the Federal Circuit has changed the law dramatically in recent years, to the point where it is no longer possible to have a valid genus claim in the chemical and biotechnology industries. Federal Circuit opinions confronting those claims almost always hold them invalid. They do so because the Federal Circuit has, without acknowledging it, fundamentally changed this important area of law. Under that new interpretation, it no longer suffices that the patent gives enough information that the PHOSITA can "make and use" the invention, as § 112(a) requires. Rather, the Federal Circuit now rejects claims as invalid because the genus contains thousands or millions of possible chemicals, unless the patent itself identifies exactly which of those myriad species will work. That is an impossible burden, and it is not one the law imposed until recently.

This case presents a strong vehicle for reviewing the Federal Circuit's new rule and returning the law to its traditional moorings. The Federal Circuit's decision "cemented . . . a categorical shift in thinking away from teaching the PHOSITA and towards a precise delineation of the boundaries of the claim." Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. (forthcoming 2021), at 43 ("KLS"), available at https://ssrn.com/abstract=3668014. As the authors note, the Federal Circuit opinion in this case "turns the law of genus claims on its head." *Id.* at 66.

ARGUMENT

I. Genus Claims Have Traditionally Been Understood to Be Critical for Meaningful Patent Protection in the Chemical Industry

This Court has long recognized that, in order to achieve meaningful patent protection, the patentee must be allowed to claim more than merely a specific embodiment in the invention. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950) (warning that failure to prohibit minor variants on an invention would turn a patent into a "hollow and useless thing").

In the chemical and biochemical sciences, patent claims that capture a group, or "genus," of related molecular structures that may be used for a particular purpose achieve these aims. *See In re Kalm*, 378 F.2d

959, 963 (C.C.P.A. 1967) ("When one speaks of a 'genus' in the chemical arts, one ordinarily speaks of a group of compounds closely related both in structure and properties."). Until recently, genus claims have routinely been held to comply with the Patent Act's enablement requirement. The traditional patentability of such claims is reflected not only in a long line of decisions of this Court and other courts, but also in the numerous patent treatises and handbooks reflecting the assumption that such claims are available. This Court should change the law "back to the way it was" before the Federal Circuit's departure from precedent, KLS, *supra*, at 4, to restore adequate patent protection for chemical, pharmaceutical, and biotechnological inventions.

A. This Court's Precedents Recognize the Critical Role of Genus Claims

This Court has repeatedly held that patentees are entitled to claim their inventions generically if they demonstrate, in the patent's specification, some feasible way of making and using the invention. Upholding the claims to Alexander Graham Bell's patent on the telephone, this Court observed that "a patent for such a discovery is not to be confined to the mere means he improvised to prove the reality of his conception." *The Telephone Cases*, 126 U.S. 1, 539 (1888). The Court held that "[i]t is enough if [the patentee] describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out *some* practicable way of

putting it into operation." *Id.* at 536 (emphasis added). Quoting from a leading patent law treatise, this Court explained in another opinion that "the principle of the invention is a unit, and invariably the modes of its embodiment in a concrete invention may be numerous and in appearance very different from each other." *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419-20 (1908) (quoting 2 WILLIAM CALLYHAN ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 485 (Boston, Little, Brown & Co. 1890)). This rule has a venerable pedigree, and this Court expounded upon it in the seminal case of *Tilghman v. Proctor*:

> Perhaps the process is susceptible of being applied in many modes and by the use of many forms of apparatus. The inventor is not bound to describe them all in order to secure to himself the exclusive right to the process, if he is really its inventor of discoverer. But he must describe some particular mode, or some apparatus, by which the process can be applied with at least some beneficial result, in order to show that it is capable of being exhibited and performed in actual experience.

102 U.S. 707, 728-29 (1880).

This Court's approach to enablement is critical for meaningful patent protection. As this Court put it in *Continental Paper Bag*, "[i]f this were not so most patents would be of little worth." 210 U.S. at 418. Indeed, a contrary rule creates "the risk of an infringement being avoided" by a minor modification of the particular embodiments disclosed in the patent's specification.

Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 437 (1902). Applying these principles to a patent on a process of concentrating crushed or powdered ores containing various "metal and metallic compounds," this Court held that the claims at issue "satisf[y] the law" even though "the process is one for dealing with a large class of substances and the range of treatment within the terms of the claims." *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916). This Court explained that a contrary result would lead to a patentability standard that cannot be met for any chemical patent claim covering a significant number of species: "[T]he composition of ores varies infinitely, each one presenting its special problem, and it is obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case." *Id.*

To be sure, this Court has found patent claims nonenabled when the characteristic around which the genus was organized was irrelevant or even harmful for the invention's purpose. *See*, *e.g.*, *Consol. Elec. Light Co. v. McKeesport Light Co.* (*Incandescent Lamp Patent*), 159 U.S. 465, 468 (1895) (invalidating a claim for a light bulb filament made of fibrous or textile materials because these materials were generally bad as filaments); *cf.* KLS, *supra*, at 86-87 (explaining that claims are correctly invalidated for this kind of "improper generalization"). In addition, this Court has rightly frowned upon claims drafted in purely functional terms, since such claims tend to have immense breadth and, as a result, require an impermissible amount of

experimentation to practice. *See*, *e.g.*, *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 256-58 (1928). Finally, this Court has invalidated claims if the patentee failed to provide any guidance on how to practice the claimed invention. *Tyler v. Boston*, 74 U.S. (7 Wall.) 327, 330 (1868); *Wood v. Underhill*, 46 U.S. (5 How.) 1, 4-5 (1846); *see also Grasselli Chem. Co. v. Nat'l Aniline & Chem. Co.*, 26 F.2d 305, 308 (2d Cir. 1928) (L. Hand, J.) (invalidating claim where patent "furnishes no guidance to the art"). But this Court has never endorsed a rule, relied upon by the Court of Appeals in this case, that a structurally well-defined genus is not enabled unless the patent's specification provides a way for rapidly making and testing numerous species that potentially fall into that genus.

B. Decisions of Other Tribunals and Secondary Sources Confirm the Historical Viability of Genus Claims

Until the Federal Circuit's jurisprudence took its recent turn, the decisions of other tribunals were consistent with this Court's case law. For example, upholding a claim requiring a particular use of a genus of acids against an overbreadth challenge, the Ninth Circuit observed that "[o]bviously [the patentee] was not required to experiment with all kinds of acids, and to state in his specifications what acids would and what would not be suitable for the purpose." *Fullerton Walnut Growers' Ass'n v. Anderson-Barngrover Mfg. Co.*, 166 F. 443, 450 (9th Cir. 1908). It was enough that some acids "may . . . be successfully used in the process." *Id.*;

see also, *e.g.*, *Malignani v. Hill-Wright Elec. Co.*, 177 F. 430, 433 (C.C.S.D.N.Y. 1910) ("The specification referring [sic] to the use of substances adapted under certain conditions to generate gases or vapors mentions arsenic, sulphuric, or iodine. The patentee, however, did not limit himself to the use only of such substances, and he was not required to specify all the known substances which might be advantageously used in the process."). These precedents confirm that it was permissible for a patentee to validly claim a class of chemicals so long as the specification made a showing that there was some way to put the invention into practice.

To a similar effect are the decisions of the PTO and the CCPA. Applying this Court's precedents, the Patent Office Board of Appeals explained in *Ex parte Sloane* that

> While the number of specific substances mentioned is doubtless important, especially in a case where the generic nature of a case must be inferred from the mention of specific substances, we do not think that a proper determination of the breadth of disclosure can be made solely from a consideration of the specific examples given. If the disclosure, taken as a whole, is generic, an applicant is entitled to generic claims if they are otherwise allowable.

22 U.S.P.Q. 222, 1934 WL 25325, at *2 (1934) (citing *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358 (1928) and *Incandescent Lamp Patent*, 159 U.S. 465).

The CCPA's decisions are in accord. *See*, *e.g.*, *In re Angstadt*, 537 F.2d 498, 503-04 (C.C.P.A. 1976) (citing *Minerals Separation*, 242 U.S. at 270-71) (relying on this Court's reasoning to uphold a broad chemical genus claim); *In re Grimme*, 274 F.2d 949, 952 (C.C.P.A. 1960) ("It is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species. It is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it.").

Finally, secondary sources routinely assume that chemical genus claims can be patented without the inventor's having to test all or most of the species to see if they work. *See*, *e.g.*, CHRIS P. MILLER & MARK J. EVANS, THE CHEMIST'S COMPANION TO PATENT LAW 7-8 (2010); ROBERT C. FABER, LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING § 6.9 (5th ed. 2003 & Supp. July 2008); *see also* 2 ROBINSON, THE LAW OF PATENTS, *supra*, at § 535; *cf.* GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS § 224 (Boston, Little, Brown & Co., 4th ed. 1873) (explaining that "[t]he rule of our law [is] that the specification may control the generality of the terms of the patent" provided there is adequate teaching of a general invention).

C. Enablement is Not a Numbers Game

The basic "bargain" or "quid pro quo" of patent law is that in exchange for the limited period of exclusivity, the patentee must "reveal to the public the substance

of his discovery" so that, once exclusivity expires, the public is "enabled without restriction to practice it and profit by its use." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). Section 112(a) ensures that the public gets its end of the bargain by requiring that the patent's description of the invention "enable any person skilled in the art to which it pertains . . . to make and use the same."

An invention is enabled if the PHOSITA, armed with the patent's specification, can practice the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). What constitutes undue experimentation is a case-specific, fact-intensive inquiry that depends on the breadth of the claims; the nature of the underlying technological field; the amount of guidance provided in the specification, including the presence or absence of working examples; the quantity of experimentation required to practice the invention; and the PHOSITA's knowledge, abilities, routine activities, and tools. *Id.*

The basic premise and practical advantage of genus claims in the chemical and life sciences is that providing a detailed teaching about several covered compounds in the form of examples can sufficiently enable the entire claimed genus. This means that the PHOSITA is permitted to engage in a reasonable amount of routine experimentation to figure out compounds that can achieve the claimed result. *See id.* at 736-37. Experimentation is a common part of the PHOSITA's work and "does not preclude enablement." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750

F.2d 1569, 1576-77 (Fed. Cir. 1984). So as long as the specification provides some working examples, that disclosure can give the PHOSITA sufficient guidance to enable the full scope of a genus claim. This is what the law has generally required. *See* 2 ROBINSON, THE LAW OF PATENTS, *supra*, at § 485 ("The applicant is not required to describe all possible forms" of his invention; "[t]hese belong to the skill of the mechanic, not the inventor; and having one embodiment before them, the public are presumed to be able to construct such others as they desire.").

Enablement has not traditionally turned on whether there are a lot of compounds in the claimed genus or whether routine screening takes considerable time. *Wands*, 858 F.2d at 736-37. An enabled patent may "deal[] with a large class of substances" and "leav[e] something to the skill of persons applying the invention." *Minerals Separation*, 242 U.S. at 271; *see also id*. (upholding patent with "infinite[]" embodiments as "clearly sufficiently definite to guide those skilled in the art to its successful application"); *In re Angstadt*, 537 F.2d at 502-03 (rejecting an enablement challenge despite "thousands" of possible embodiments within the scope of the genus because the needed experimentation "to determine which catalysts will produce hydroperoxides would not be undue and certainly would not 'require ingenuity beyond that to be expected of one of ordinary skill in the art'" (quoting *Fields v. Conover*, 443 F.2d 1386, 1390-91 (C.C.P.A. 1971))).

II. The Federal Circuit Has Changed the Law of Enablement

A. The Federal Circuit Has Made Enablement a Numbers Game

Despite the case-specific, fact-intensive nature of the enablement inquiry, the Federal Circuit has more recently adopted a numbers-based standard to evaluate enablement. This standard gauges enablement not by whether the experimentation needed to make and test particular species is undue, but by how long it would take the PHOSITA to make and screen *every species within the claimed genus*—even if that work would be routine. This heightened enablement standard is inconsistent with the purposes of the enablement doctrine, is impossible to meet for large genus claims, and threatens patent protection for many inventions in the chemical and life sciences where large genus claims are ubiquitous. Unfortunately, that new standard has become the norm in Federal Circuit enablement cases.

In *Wyeth & Cordis Corp. v. Abbott Laboratories*, for example, the claims were directed to methods of treating or preventing restenosis, a re-narrowing of an artery following procedures such as balloon angioplasty, by treatment with a therapeutically effective amount of a chemical belonging to the class of compounds called "rapamycin." 720 F.3d 1380, 1382 (Fed. Cir. 2013). The specification demonstrated that at least one of the species within the rapamycin genus was effective in treating restenosis, and it taught how to determine through routine experimentation if other

rapamycin compounds have the requisite therapeutic property. *See id.* at 1385. But this was not enough for the Federal Circuit. The court concluded that the need to synthesize "tens of thousands of candidate[]" compounds doomed the claims. *Id.* By focusing on the size of the genus, *Wyeth* found a claim nonenabled even though the PHOSITA could make and test each claimed compound with routine experimentation.

The Federal Circuit cemented its heightened enablement standard in the case under review. The inventors discovered that a certain group of compounds sharing the same basic chemical structure are effective against the Hepatitis C Virus ("HCV"). Pet. App. 7a–9a. They then obtained a patent for a method of treating HCV, claiming a genus of compounds with a core cyclic ring structure with a certain methyl group in a 2'-up position with multiple independent options for other chemical moieties on the ring. While members of the claimed genus numbered in the thousands, PHOSITAs could rely on their knowledge to exclude some species that were unlikely to work. *Id.* at 16a. Some candidate species could be bought commercially, *id.* at 18a, while others could be synthesized using routine methodologies, *id.* at 18a–19a. Finally, the patent disclosed several working examples. *Id.* at 19a–21a.

Nevertheless, applying *Wyeth*, the panel held that the PHOSITA would have too many compounds to obtain and screen because it was not possible to tell in advance for many candidates whether their structures would have the desired HCV efficacy. As the panel framed it, "[t]he key enablement question is whether a

[PHOSITA] would *know*, without undue experimentation, which 2'-methyl-up nucleosides would be effective for treating HCV," and the answer was "no." Pet. App. 10a. (emphasis added). Even accepting that the disclosed screening process allowed for straightforward identification of compounds that worked, the panel determined the work involved to be excessive for enablement purposes. While any particular compound falling within the scope of the genus and is effective against HCV might be readily found, the overall sorting process was held to require undue experimentation. It is effectively impossible for a genus claim of any non-trivial size to comply with this enablement standard.

B. The Federal Circuit's Approach to § 112(a) Frustrates Patenting and Innovation in the Chemical and Life Sciences

The Federal Circuit's approach is problematic because it focuses on knowing exactly which species of a claimed genus will work instead of knowing how to make and use the invention, which is what the text of § 112(a) actually requires. This Court and the Federal Circuit's predecessors have never required "reasonable certainty" that a particular chemical structure would work for its intended purpose. *In re Angstadt*, 537 F.2d 498, 503 (C.C.P.A. 1976) (emphasis omitted). As the CCPA astutely noted, if this were so "then *all* 'experimentation' is 'undue,' since the term 'experimentation' implies that the success of the particular activity is *uncertain*." *Id.* (emphases in original).

The decision below confirms the massive shift in the Federal Circuit's enablement doctrine. Asking the PHOSITA to sort operative from inoperative species, whether routine or not, is emerging as a critical challenge for patentees facing enablement attacks. When the number of operative species in a chemical genus seems too time-consuming to identify, this proves fatal to enablement. Under this new regime, "[a] chemical genus with any decently large number of species will never be able to satisfy" the Federal Circuit's new enablement standard. KLS, *supra*, at 1. Worse yet, the "routine but undue" theory makes it much easier for defendants in patent infringement suits to argue that genus claims are overbroad on their face. Any genus claim covering a significant number of species in the chemical and life sciences fields, which typically come with built-in unpredictability even if the claimed technology is mature, is now in question. Accordingly, few patent claims in this industry survive enablement challenges today. *See id.* at 31.

III. This Court Should Grant Certiorari to Restore the Traditional Law of Genus Claims

The Federal Circuit's move to invalidate large genus claims on enablement grounds reflects a puzzling and troubling doctrinal shift. The Federal Circuit has changed what it means to "enable the full scope of the claim" in ways that make many genus claims unsustainable. In doing so, it has conflated different legal theories and justifications for restricting the scope of genus claims. And it has broken the symmetry that has

traditionally existed between nonobviousness analysis under 35 U.S.C. § 103 and the disclosure rules of § 112.

A. The Federal Circuit's New Rule Ignores the Knowledge of the PHOSITA

Both sections 103 and 112 set standards based on the knowledge and experience of the PHOSITA. The PHOSITA is rather like the "reasonable expert" in patent law. When we test whether a patentee has done something obvious under § 103, we ask whether the PHOSITA would have been motivated to make the new invention and had a reasonable expectation of success. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366-69 (Fed. Cir. 2016). And when we decide how much information the patentee must disclose, we turn again to the PHOSITA, making sure the patent discloses enough that the PHOSITA can make and use the invention without undue experimentation. The enablement and obviousness PHOSITAs are not always exactly the same, but in general, there is symmetry between obviousness and disclosure that turns on the level of skill in the art. If PHOSITAs in a field know a lot, they are more likely to find an invention obvious, but they also do not need as much detail to educate them about how to make and use that invention. If they know very little, by contrast, it is easier to show nonobviousness (because they were less likely to figure it out), but the patentee must teach more to make sure the PHOSITAs understand the invention for enablement purposes.

That symmetry held for decades in the chemical arts. Courts have regularly told us that chemistry is an unpredictable art, so the PHOSITA cannot know what effects a small change in chemical structure would have. *Brenner v. Manson*, 383 U.S. 519, 532 (1966) (recognizing the unpredictability of chemical compounds). But chemical compounds have a regular and well-understood structure, so courts confronting obviousness challenges have long held that variants on a known chemical are likely obvious unless they embody unexpected results. *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc); *see also Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1364 (Fed. Cir. 2007) (Dyk, J., concurring) (noting the validity of subject matter involving unexpected results relative to a known compound was "not in question" on obviousness grounds).

But a parallel assumption is strikingly absent from the Federal Circuit's recent enablement cases. To the contrary, the recent cases generally start from the premise that the chemical arts are unpredictable and then apply the opposite of the *Dillon*-type analysis. They assume that PHOSITAs would not be able to figure out what works in a genus unless the patent specification teaches them which variants of the chemical compounds disclosed in the specification will have the same effects and which ones will not. The result for chemical patentees is the worst of both worlds—the Federal Circuit will presume the new species you claim is not patentable because PHOSITAs could figure out how to make it if it is just a variant on an existing one,

but it will not presume they understand the very same thing when they try to practice your genus claim.

B. The Federal Circuit's New Requirement of "Full Scope" Enablement Is Not Consistent with the Purposes of that Doctrine

There is a second, and more fundamental, shift in the Federal Circuit's § 112 case law. The Federal Circuit has changed the focus of the § 112(a) inquiry from "what information would be required to permit the PHOSITA to make and use species that make up the invention" to "what information is required to teach the PHOSITA which species in the genus work and which ones do not." Put another way, before the Federal Circuit's recent approach took hold, § 112(a) was about use and practice of the invention, while today it is primarily about understanding the boundaries of the invention. That shift has profound implications for large genus claims. It is frequently impossible to test all or even a significant fraction of the species of a genus that may contain millions of different species. Even a patentee who tests a considerable number of species may be unable to predict which species will work. The question is whether that inability should matter, and why.

If the goal is to enable the PHOSITA to make and use the invention, the inability to predict in advance which species will work does not matter much except at the extremes. The patentee in *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, mentioned in Part I.C,

did not know which of its claimed dynamite compounds would work and which would not, but with a 40% failure rate, a user would likely only have to try two or maybe three compounds to find one that would work. 750 F.2d 1569, 1577 (Fed. Cir. 1984). That required some experimentation, but the law has traditionally allowed claims that require experimentation as long as it is not "undue." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986); *see also* Sean B. Seymore, *Patenting Around Failure*, 166 U. PA. L. REV. 1139, 1165-73 (2018) (explaining that longstanding law has allowed claims to encompass inoperative species without defeating patentability). There may be some genus claims that give so little information that trying to find a species that works takes too much effort, but that is likely to be rare if the genus is proper and well-defined.

The case under review and its immediate antecedents, like *Wyeth*, ignore this focus on how much experimentation is required. Rather, those cases reflect the Federal Circuit's new and different goal for § 112(a)—explaining to the PHOSITA what subset of the genus claims will work. The goal of those cases seems to be knowledge of the precise boundaries of the genus. That may be desirable in some cases (*e.g.*, for purely functional claims). But it is not normally required for the PHOSITA to make and use the invention without undue experimentation. And it has proven in practice to be an impossible burden.

We think that this move, from undue experimentation to a search for a clear definition of which species

work and which do not, misunderstands the basic purpose of the § 112(a) inquiry. If the patentee defines a clear genus, so people will know whether or not the chemicals they make fall within that genus, PHOSITAs will be able to make and use the full scope of that genus so long as they can figure out how to make chemicals within it and determine whether they work for the intended purpose without having to engage in undue experimentation. True, they will not be able to make *every* working species. But why would they want to? And true, they might have to experiment to figure out whether the species they made works for the intended purpose, but that has never been a problem so long as they do not have to do too much experimentation.

To be sure, there will be cases where the patent does not give enough information to allow the PHOSITA to do even that much without undue experimentation, as discussed in Part I.A. And those claims are properly invalid under the enablement doctrine. But that problem is not limited to broad genus claims. The claims may well be narrow, even directed to one species, but they are invalid if the patent's specification fails to give enough information and the PHOSITA would not be able to figure out how to make the invention work at all.

If the PHOSITA can figure out how to make a working embodiment without too much effort, there is no reason to require more in most cases. Cases like *Wyeth* and *Idenix*, which focus on the breadth of the genus claim as the reason to reject it, miss the point.

The genus is very large and it would take an impossible effort to identify all the species within its scope that work. But there is no reason anyone needs to do that. Anyone who wants to know if their chemical is within the scope of the claim can figure that out: the boundaries of the chemical genus are well-specified, and it does not take much effort to determine whether or not any particular chemical works for its intended purpose.[3]

C. The Federal Circuit's New Requirement Makes Effective Patent Protection Nearly Impossible in the Chemical Industry

The Federal Circuit's heightened enablement standard frustrates patenting and innovation. It "force[s] an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments" and ultimately "discourage[s] inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to

[3] Kristina Caggiano Kelly and Paul Calvo offer an excellent illustration of this. They point to an artist named Martin Silfen who uses a combination of just sixteen geometric tiles to create paintings. Because the tiles can be rotated and can each be used in a different order, there are 89 sextillion different possible tile combinations. But no one needs to try all or even very many of those combinations to make the invention work; they just need to know to lay out 16 tiles in a 4x4 grid. Kristina Caggiano Kelly & Paul A. Calvo, *The Scope of a Sextillion—How Courts Misapply Law of Enablement to Life Sciences*, BNA IP LAW NEWS, May 1, 2020, available at https://news.bloomberglaw.com/ip-law/insight-the-scope-of-a-sextillion-how-courts-misapply-law-of-enablement-to-life-sciences.

those [working] embodiments which are expressly disclosed." *In re Angstadt*, 537 F.2d 498, 502-03 (C.C.P.A. 1976). Nothing in § 112(a) or this Court's precedent suggests that genus claims should be subject to any numerical threshold. *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916) (explaining that while "[t]he composition of ores varied infinitely" and that "it is obviously impossible to specify in a patent the precise treatment which would be most effective and economical in each case," the patent's description sufficiently "guide[d] those skilled in the art to its successful application" in spite of covering "a very large class of substances").

The Federal Circuit has converted the enablement inquiry from this sensible approach into one that seems to ask the patentee to determine in advance which species work and which ones do not. In other words, instead of "did I teach you enough that you can make use of the full scope of the invention?" (which allows a genus to include some inoperative species as long as the PHOSITA can figure out whether a particular species works without too much effort), the question now is, "did I give you enough information to figure out the full list of what works and what doesn't?"

The latter is an impossible requirement to meet, and it does not serve the purposes of § 112. This category error is at the heart of the demise of genus claims in the chemical arts today. And it is not something patentees can simply draft around. A chemical genus with any decently large number of species will never be able to satisfy the Federal Circuit's *Idenix* standard.

No matter how much testing the patentee does, there will always be untested species, and because those species are not tested we do not know whether they are properly included in the genus, so the claim will be invalid under the enablement and written description doctrines. Under traditional law, all we cared about was whether the PHOSITA could make a species and figure out whether it worked without undue experimentation. But the Federal Circuit's shift in that law is fatal to genus claims.

That change endangers innovation. Patent protection is important in the pharmaceutical and biotechnology industries, perhaps more than anywhere else. Certainly, the industries themselves seem to think so. Policy disputes in courts and Congress over the past two decades have time and again seen the chemical and biomedical industries line up behind strong protection, with the information technology industries on the opposite side. *See generally* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009); JOHN R. THOMAS, CONG. RES. SERV., R43264, TAILORING THE PATENT SYSTEM FOR SPECIFIC INDUSTRIES (2015); WENDY H. SCHACHT, CONG. RES. SERV., RL33367, PATENT REFORM: ISSUES IN BIOMEDICAL AND SOFTWARE INDUSTRIES (2006). As Dan Burk and Mark Lemley explain, those political differences reflect very real differences in how the industries use and experience the patent system. Patents really are more important to those industries than to others.

Further, the patent system seems to function more like it was designed in the chemical industries. The scope of claims is clearer, independent invention is rarer, "stacking" of multiple patents is less common, and the slower pace of change means that a company thinking of making a product could search for and find the relevant patents, something that is not true in many other industries. James Bessen and Michael Meurer have gone so far as to suggest that the patent system works well *only* in the biomedical and chemical industries. JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION AT RISK 89-93 (2008). But at a minimum, it has been working there.

Given the importance of strong patent protection in these industries, the unwillingness of courts to permit chemical genus claims seems quite troubling as a policy as well as a doctrinal matter. The Federal Circuit's new rule will not eliminate all patents or all innovation in the chemical arts. Pharmaceutical companies can enforce claims to a single species against competitors who want to make a generic version of that very drug. But the Federal Circuit's rule in this case makes it unreasonably difficult for a pharmaceutical company that comes up with an innovative new *class* of drugs to protect that class against imitation. That result threatens innovation.

CONCLUSION

This Court should grant the petition for writ of certiorari on the first question presented.[4]

Respectfully submitted,

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[4] Amici take no position on the second question presented.