No. 20-___

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Patent Act provides that patents must "contain a written description of the invention" in "such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a).

The law has long recognized that patents including "genus" claims—*i.e.*, claims that identify a class of substances—can satisfy § 112(a). In the field of pharmaceuticals, inventing a genus of compounds is often the key to lifesaving medical innovation, and spelling out each potential embodiment—that is, every chemical variant with the same property—can be practically impossible.

This petition presents two related questions:

1. Whether, as the Federal Circuit has held, a genus claim is not enabled "as a matter of law" if it encompasses a large number of compounds—or whether, as this Court has recognized, enablement is a context-specific jury question; and

2. Whether, as the Federal Circuit has held, § 112(a) contains a separate "possession" requirement—or whether, as the statute provides, § 112(a) sets forth a single substantive requirement of "a written description of the invention" sufficient "to enable any person skilled in the art … to make and use the same."

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioner Idenix Pharmaceuticals LLC is a wholly owned subsidiary of Merck & Co., Inc., which is a publicly traded company.

Petitioner Universita Degli Studi di Cagliari has no parent corporation, and no publicly held company owns more than 10% of its stock.

Respondent is Gilead Sciences, Inc.

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INTRODUCTION

Every day, scientists work around the clock, at great expense, to find lifesaving cures. That has never been more true than now, as the world anxiously awaits the development of some form of protection against COVID-19.

Biotech and pharmaceutical breakthroughs often look different than other inventions. The true innovation frequently consists of discovering a family of related compounds that produce a desired effect. Once that foundational discovery is made, making and testing any individual chemical variant in the family for that desired effect can be routine.

To obtain patent protection commensurate with such a discovery, innovators must rely on "genus" claims—ones that "deal[] 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). Often, a genus claim will identify the "structural requirements" that define the genus and the "function" that covered compounds can perform. *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 n.2 (Fed. Cir. 2020).

Genus claims are "[t]he central feature of patent law in the chemical, biotechnology, and pharmaceutical industries." Dmitry Karshtedt, Mark A. Lemley, and Sean B. Seymore, *The Death of the Genus Claim*, at 1 (Aug. 5, 2020) ("KLS"), *available at* https://ssrn.com/abstract=3668014. With them, scientists have appropriate incentives to innovate and share their discoveries with the world. Without them, scientists—if they would even have

incentives to proceed with this kind of research in the first place—would have to keep structural breakthroughs secret, and could claim protection only for individual compounds they later develop. Even then, others could profit from the inventor's core insight, without making a scientific contribution of their own, by commercializing a substantively similar compound.

The plain terms of 35 U.S.C. § 112(a) encompass genus claims. That provision says that a claim's "written description" must include "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." Given the fact-intensive nature of that inquiry, "[i]t [is] the right of the jury to determine … whether the specifications … were so precise as to enable any person skilled in the [art] … to make the [invention] described." *Battin v. Taggert*, 58 U.S. (17 How.) 74, 85 (1854). If a jury finds a skilled artisan would understand the relevant structural characteristics and could easily identify effective compounds, a genus claim satisfies § 112(a).

The Federal Circuit, however, has replaced this case-specific jury determination with two judicially invented bright-line rules that make it nearly impossible for genus claims to satisfy § 112(a). *First*, it has adopted a numbers-based enablement rule for genus claims based on the assumption that an artisan must be able to identify every covered compound—what that court calls the patent's "full scope"—for the invention to be enabled. Pet.App.23a–26a. Specifically, the Federal Circuit has held that, where identifying every species of a

claimed genus "would require synthesizing and screening" thousands of compounds for the desired effects, the claim fails "as a matter of law." *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1385–86 (Fed. Cir. 2013); Pet.App.23a–26a. That is true even if the evidence shows, and a jury finds, that making and screening thousands of compounds is "largely routine." Pet.App.18a. *Second*, the Federal Circuit has developed a separate "written description" requirement—distinct from the statutory "enablement" touchstone—under which a claim passes muster only if the inventor "had possession of the claimed subject matter," including the infringing embodiment, "as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Those rules lack any basis in statutory text. They conflict with this Court's treatment of § 112(a) generally and of genus claims specifically. And they threaten serious disruption to innovation in this important field by putting biotech and pharmaceutical innovators in an impossible position. If they claim the full scope of their discovery, they run afoul of the Federal Circuit's genus-specific enablement rule. If they claim something narrower, they invite competitors to free-ride on their breakthrough by making minor variations to create similar compounds that achieve the same effect. Either way, the separate "possession" requirement threatens to invalidate the claim if the specification includes too few representative examples to show possession—or so many that the exclusion of any particular compound is deemed intentional. The

result has led prominent commentators to declare "[t]he death of the genus claim." KLS, *supra*, at 1.

This is a case in point. Idenix's scientists found that a particular set of compounds—which share the same basic chemical structure—are effective against the deadly Hepatitis C virus ("HCV"). To protect that discovery, Idenix patented the use of that genus to treat HCV. Gilead took Idenix's patent (quite literally) in hand, used it to identify an effective compound within the claimed genus, and developed an HCV treatment that has yielded it billions in sales. After hearing from 27 witnesses over nine days, the jury rejected Gilead's challenges to the validity of Idenix's patent and awarded Idenix damages. In so doing, the jury weighed the evidence and found that Idenix's description enabled "any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). After all, that is exactly what Gilead's own scientist had done—he used Idenix's patent to make and use an effective compound within the claims.

That should have been the end of this story. Instead, the Federal Circuit applied its two erroneous legal rules and overturned the jury's verdict. According to the Federal Circuit, Idenix's patent was not enabled "as a matter of law" because identifying every covered compound "would require synthesizing and screening tens of thousands of candidate compounds for the claimed efficacy." Pet.App.25a. And Idenix lacked "possession" of the claimed genus as a matter of law, given the infringing embodiment's "conspicuous absence" from the patent's examples. Pet.App.30a.

This case is thus the ideal vehicle for this Court to take up the two questions presented, which are two sides of the same coin. Together, they ask this Court to ensure the vitality of genus claims by reinstating the singular, case-specific enablement standard that Congress and this Court endorsed and entrusted to the jury. Review is warranted.

OPINIONS BELOW

The district court's opinion granting judgment notwithstanding the verdict to respondent with regard to enablement but denying it with respect to written description (Pet.App.53a–116a) is unreported. The Federal Circuit's decision affirming in part and reversing in part (Pet.App.3a–48a) is reported at 941 F.3d 1149.

JURISDICTION

The Federal Circuit entered judgment on October 30, 2019, and denied petitioner's timely rehearing petition on April 24, 2020. Pet.App.2a–3a. This Court extended the time to file a petition for a writ of certiorari until September 21, 2020. *See* Order of March 19, 2020. This Court has jurisdiction under 28 U.S.C. § 1254(1).

PROVISIONS INVOLVED

35 U.S.C. § 112(a) provides:

> (a) In General.—The 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, or with which it is most nearly connected, to make and use the same,

and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

STATEMENT

A. Idenix's Breakthrough Invention

HCV was a terrible virus. Most of the millions who contracted it faced a "chronic," "lifelong infection" that led to "liver damage," "cirrhosis," "liver cancer," and "even death."[1] The "cures," such as they were, often felt worse than the disease. They required regular injections that gave many patients perpetual flulike symptoms; even then, only 40% to 50% of patients experienced significant viral reduction.[2] By 2016, HCV had "kill[ed] more Americans than any other infectious disease."[3]

This was the state of affairs when Idenix's founder had a flash of insight. He saw that the NS5B polymerase—an enzyme that HCV uses to reproduce itself—resembled enzymes that he had previously encountered in his cancer research. C.A.App.37081–82. He hypothesized that certain *modified* ribonucleosides could bind to the active

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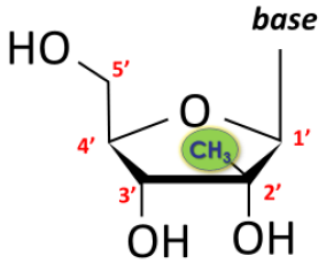
[1] CDC, *Hepatitis C Questions & Answers for the Public*, https://www.cdc.gov/hepatitis/hcv/cfaq.htm#A3 (July 28, 2020).

[2] *See* FDA, *Hepatitis C Treatments Give Patients More Options*, https://www.fda.gov/consumers/consumer-updates/hepatitis-c-treatments-give-patients-more-options (Mar. 4, 2017).

[3] CDC, Press Release, "Hepatitis C Kills More Americans than Any Other Infectious Disease," https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html (May 4, 2016).

sites of those enzymes and stop HCV from replicating. *Id.*

Idenix's scientists began testing modified ribonucleosides that they had "on the shelf" against HCV. *Id.* They found the key structure that worked: a ribonucleoside modified to substitute a methyl group (-CH_3) at the 2′-up position on the molecule's sugar ring, as depicted, that blocked HCV replication. *Id.*



Further screening confirmed the breadth of the discovery, as other 2′-methyl-up ribonucleosides were "active against HCV." C.A.App.37084. For the "very first time," scientists "knew" of a "new class of compounds that were demonstrated to be active … against HCV." *Id.* So they filed a patent application, disclosing their invention to the world.

Idenix developed three compounds—all 2′-methyl-up, all effective against HCV—and began to seek FDA approval. C.A.App.37658–60. Idenix also continued to seek patent protection for its discovery. The patent's specification disclosed how 2′-methyl-up compounds target NS5B polymerase, and included numerous examples of covered compounds. U.S. Patent No. 7,608,597; C.A.App.57–141. In keeping with Idenix's invention, the relevant claims (contained in the '597 patent) cover modified

ribonucleosides that are effective against HCV, have methyl at 2′-up, and something other than hydrogen at 2′-down. Pet.App.78a. Claim 1, for example, reads:

> A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β-D-*2′-methyl*-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.

C.A.App.140 (emphasis added). This is a classic genus claim. *See* KLS, *supra* at 16–17 (using Idenix's claims as illustrative of genus claims).

B. Gilead's Willful Infringement

Idenix's "pioneering discovery" was hailed as a "breakthrough." C.A.App.37752–53. Before the publication of the '597 patent, no one had reported using 2′-methyl-up nucleosides to treat HCV. *Id.* Afterward, "many companies started focusing their effort" on that "class of compounds." *Id.*

Pharmasset, Gilead's predecessor in interest, was one of them. Its founder had consulted for Idenix and learned of its work on 2′-methyl-up ribonucleosides. He shared that confidential information with scientists at Pharmasset, which started producing its own 2′-methyl compounds. C.A.App.37162, 37167, 37168, 37169. Pharmasset knew there was a "patent conflict with Idenix over [those] compounds." C.A.App.37200. But it pressed ahead anyway. In November 2002, a Pharmasset chemist met with Pharmasset's Chief Scientific Officer to discuss anti-HCV ribonucleosides. C.A.App.37195, 37310, 37320. That chemist had

only a master's degree, unusual in this highly specialized field. But he brought more to the meeting than his education: *In his hand*, he held Idenix's patent. C.A.App.37196, 37321. He proposed making a 2′-methyl-up compound that used fluorine at the 2′-down position—a compound now known as PSI-6130. *Id.*

Soon after the meeting, he did just that. Using a process culminating in "a 15-minute [fluorination] reaction" he described as "pretty much self-explanatory," Pharmasset's chemist synthesized PSI-6130. C.A.App. 37314–15, 37318. PSI-6130 led to sofosbuvir, the active ingredient in Gilead's drug Sovaldi® and other anti-HCV products. C.A.App.37215, 37332, 37425.

These direct-acting antivirals come in pill form, have few serious side effects, and "cure over 90%" of HCV infected persons within eight to twelve weeks.[4] Sovaldi® and its related products—all of which infringe—have been a runaway commercial success. By August 2016, they netted Gilead more than $25.4 *billion* in sales. C.A.App.145.

C. Idenix Prevails Before the Jury

After Gilead rejected Idenix's licensing offers, Idenix sued for patent infringement. The district court construed the patent to cover every modified ribonucleoside that has methyl at 2′-up, something other than hydrogen at 2′-down, and is active against

[4] CDC, *Hepatitis C Questions & Answers for the Public*, https://www.cdc.gov/hepatitis/hcv/cfaq.htm#d3 (July 28, 2020).

HCV. *See* C.A.App.12845–58. Gilead conceded infringement. C.A.App.37799.

As an affirmative defense, Gilead asserted that Idenix's patent failed the separate "enablement" and "written description" requirements the Federal Circuit has interpreted 35 U.S.C. § 112 to contain. On the Federal Circuit's view, the first (enablement) asks whether the patent's specification instructs skilled artisans how to "practice [the claim's] full scope without undue experimentation." *Wyeth*, 720 F.3d at 1384. The second (written description) asks whether the patent's disclosure demonstrates that the patent owner "had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351.

Regarding enablement, all agreed that artisans could make and use the examples in Idenix's patents. Gilead instead argued that identifying *all* of the covered compounds would require undue experimentation. Gilead's evidence focused on the number of 2′-methyl-up compounds potentially covered by Idenix's patent and on the supposed difficulty of making them and screening them for anti-HCV activity. Like many pharmaceutical patents, Idenix's "theoretical[ly]" covered "a lot" of compounds, given the many conceivable chemical variations. C.A.App.37734. But researchers in this field routinely work "from baseline classes containing potentially billions of compound variations." Pet.App.85a. And those reading Idenix's disclosure would understand that the "key structures" are those 2′-methyl-up compounds that "inhibit[ ] … the NS5B polymerase." C.A.App.37734. Because those structures work by "mimic[ing]" the naturally

occurring nucleoside, C.A.App.37397, a researcher would understand the actual number of claimed compounds to be dramatically smaller—"many, many thousands," not "billions." Pet.App.12a.

The evidence also showed that "synthesis of an individual compound was largely routine." Pet.App.18a. Indeed, Gilead's chemist—who lacked the ordinary level of skill in the art—had produced PSI-6130 "in relatively short order." Pet.App.19a. The evidence similarly demonstrated that screening compounds for effectiveness was "routine"; experienced labs could test tens or hundreds of thousands of compounds in weeks or months. Pet.App.18a; *see, e.g.*, C.A.App.37496 (214,000 in one year).

Regarding written description, Idenix's experts explained how the patent describes the common structural features linking the covered compounds—the methyl at 2′-up and the NS5B polymerase that 2′-methyl-up compounds target. C.A.App.37670–75, 37732–34, 37755–56. The patent also provides representative compounds; Formula XI, for instance, lists methyl at 2′-up, non-hydrogen substituents at 2′-down, and a defined universe of chemicals at other positions. And it includes synthesis routes, formulas, and a host of other relevant data. *See* C.A.App.37731–32.

The trial court instructed the jury on the enablement standard and the Federal Circuit's "possession" test for written description. C.A.App.37802. After hearing from 27 witnesses (including several experts) and reviewing countless exhibits during the 9-day trial, the jury concluded that Gilead had not shown—by clear and convincing

evidence—that Idenix's patent was insufficiently enabled or inadequately described. C.A.App.142–45. The jury awarded Idenix a 10% royalty on Gilead's adjusted net sales and found that Gilead had willfully infringed. *Id.*

D. The District Court and the Federal Circuit Disregard the Jury's Verdict

1. Gilead sought judgment notwithstanding the jury's verdict. The district court upheld the verdict with respect to written description. It reasoned that the jury could have properly credited evidence demonstrating that Idenix "had possession" of the full range of covered compounds. Pet.App.76a.

But the district court set aside the jury's decision on enablement. It held that any reasonable jury would have had to conclude that synthesizing new candidate compounds was neither "routine nor simple," but instead would require "substantial time and effort." Pet.App.89a, 92a. As a result, the court believed the case bore a "striking" resemblance to *Wyeth & Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013). Pet.App.112a. In *Wyeth*, the Federal Circuit had invalidated a patent that covered a large number of compounds that had to be synthesized and screened for effectiveness. The district court thus believed itself bound to hold that the jury had "legally err[ed]" in finding enablement despite the number of compounds covered by the patent. Pet.App.113a.

2. The Federal Circuit affirmed in part and reversed in part.

The court began by walking through the factors it has deemed relevant to the jury's context-specific

enablement inquiry (such as amount of experimentation required, level of skill in the art, and nature of the invention). Pet.App.11a–23a (discussing *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)). It held, however, that the ultimate result under those factors was "compel[led]"—"as a matter of law"—by the rule in *Wyeth*. Pet.App.23a–24a. As in *Wyeth*, identifying *every* covered compound "would require synthesizing and screening tens of thousands of candidate compounds." Pet.App.25a. That "constitute[d] undue experimentation" as a matter of law, despite the jury's contrary finding. *Id.*

The court reached this conclusion despite agreeing with Idenix—and disagreeing with the district court—about the ease of synthesis and screening. "[A] jury could have found that the synthesis of an individual compound was largely routine." Pet.App.18a. It could also have found that "screening an individual compound" was routine. Pet.App.25a. But those facts made no difference: Enablement, the Federal Circuit held, requires that artisans be able to "practice the[ ] full scope" of the claim "without undue experimentation." Pet.App.6a (quoting *Wyeth*, 720 F.3d at 1384). On the Federal Circuit's view, "full scope" means identifying each and every embodiment. *See* Pet.App.24a. Under that standard, the need to make and screen tens of thousands of candidate compounds to find every embodiment defeated enablement, even "'putting the challenges of synthesis aside,' and accepting as true that screening was 'routine[ ].'" Pet.App.26a (quoting *Wyeth*, 720 F.3d at 1384, 1386).

The Federal Circuit further held that Idenix's patent failed the separate written-description

requirement. The patent, the court reasoned, listed "tens or hundreds of thousands of possible nucleosides, substituent-by-substituent, with dozens of distinct stereo-chemical structures." Pet.App.29a. It did not, however, list Gilead's infringing variant. Pet.App.26a–30a. Given that "conspicuous absence," no reasonable juror could have concluded that Idenix "had possession of that embodiment." Pet.App.30a.[5]

REASONS FOR GRANTING THE WRIT

This petition presents two related questions about the scope of § 112(a). Combined, the Federal Circuit's rules impose barriers to patentability—particularly in the essential fields of biotechnology and pharmaceuticals—found nowhere in the statutory text. This case is the ideal vehicle for course-correcting the Federal Circuit's § 112(a) jurisprudence and ensuring the viability of genus claims.

I. THE FEDERAL CIRCUIT HAS REPLACED § 112(a)'S FACT-INTENSIVE JURY INQUIRY WITH TWO ERRONEOUS BRIGHT-LINE RULES.

Section 112(a) presents a case-specific jury question: Does the patent's description of the invention "enable any person skilled in the art to which it pertains … to make and use the same." 35 U.S.C. § 112(a). The Federal Circuit, however, has devised two atextual legal rules that usurp the jury's

[5] Judge Newman dissented. She would have construed the patent's claims more narrowly and would have held that, so construed, the patent was valid but not literally infringed. Pet.App.32a–48a.

role and make it nearly impossible to protect important advancements in biotechnology or pharmaceutical sciences. *First*, the Federal Circuit has adopted a bright-line rule whereby genus claims are not enabled if they cover "too many" compounds. *Second*, the Federal Circuit has adopted a separate "written description" requirement, which, in the context of genus claims, demands a showing that the inventor actually "possessed" each covered compound. Both rules are wrong.

A. Section 112(a) Calls for a Fact-Intensive Jury Inquiry—Including for Genus Claims.

The basic "bargain" of patent law is well known: In return for a temporary period of exclusivity, the inventor 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 sets out the patentee's side of the deal: The specification must "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 make and use the same." 35 U.S.C. § 112(a); *see also, e.g.*, Patent Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321–22.

On its face, § 112(a) calls for a flexible inquiry into what a skilled artisan could do with the patent's disclosures. The test is straightforward: A written description is adequate "if [the inventor] 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." *The Telephone Cases*, 126 U.S. 1, 536 (1888). But answering that question requires case-specific consideration of the nature of the invention and the state of the art. That fundamentally factual undertaking falls well within the province of the jury. *See Battin*, 58 U.S. (17 How.) at 85.

Genus claims are no exception. In *Minerals Separation*, for example, the inventors claimed a method for separating "metalliferous" matter by beating a large amount of air into a mixture containing an ore and a small amount of oil. 242 U.S. at 265. Their competitors complained—accurately—that the patent failed to specify "the amount of oil and the extent of agitation necessary in order to obtain the best results" for each of the vast array of ores to which the claimed method could be applied. *Id.* at 270. This Court upheld the patent nevertheless. "The composition of ores varies infinitely," "and it is obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case." *Id.* at 271. Although the "large class of substances" and the "range of treatment within the terms of the claims … le[ft] something to the skill of persons applying the invention," "the evidence abundantly show[ed]" that the description was "sufficiently definite to guide those skilled in the art to its successful application." *Id.* That factual showing was enough to satisfy the patent laws.

What it takes for a genus claim to satisfy § 112(a), accordingly, is nothing more and nothing less than is required of any other patent: a written

description that is sufficient "to enable any person skilled in the art … to make and use the same." 35 U.S.C. § 112(a). Where a properly instructed jury reasonably so finds, that should end the matter.

B. The Federal Circuit Has Deviated from § 112(a)'s Flexible Approach in Two Critical Respects.

1. *The Federal Circuit's Genus-Claim-Specific Enablement Rule Is Wrong.*

According to the Federal Circuit, a genus claim fails *as a matter of law* if it covers too many compounds—even if a jury finds that it would be routine for a skilled artisan to make and screen them. That illogical rule has no basis in § 112's text or this Court's precedent, and implicates a longstanding circuit split about the role of the jury in enablement decisions.

a. The Federal Circuit first endorsed its genus-specific enablement rule in *Wyeth*. The patent there claimed certain compounds that had "immunosuppressive and antirestenotic effects." 720 F.3d at 1384. Identifying all covered compounds—what the Federal Circuit refers to as practicing the patent's "full scope"—"would require synthesizing and screening *each* of at least tens of thousands of compounds" for the desired effects. *Id.* at 1385. As a matter of law, the court held that such activity "constitute[d] undue experimentation." *Id.*

The decision below "cemented" that categorical, numbers-based approach to enablement. KLS, *supra*, at 43. The court acknowledged that a rational jury could have found that synthesizing any compound "was largely routine." Pet.App.18a. It

also acknowledged that a rational jury could have found that "screening an individual compound" for anti-HCV effect was routine. Pet.App.25a. Yet the panel overturned the jury's verdict. The enablement inquiry, it explained, was "control[led]" by *Wyeth*: If there are "many, many thousands of candidate compounds, many of which would require synthesis and each of which would require screening" to practice the patent's "full scope," then the claims are not enabled, no matter how routine synthesis and screening are in the field. *Id.*

The result of these cases has been "a fundamental … change in patent doctrine." KLS, *supra*, at 31. Under this new regime, "[a] chemical genus with any decently large number of species will never be able to satisfy" the Federal Circuit's enablement standard. *Id.* at 91. Indeed, "there are virtually no significant examples of genus claims in the life science fields upheld on appeal as compliant with § 112(a)." *Id.* at 31.

b. The Federal Circuit's bar on genus claims that cover some undefined-but-too-large number of compounds lacks any basis in text or precedent.

Nothing in Section 112 suggests that genus claims should be subject to an arbitrary numerical threshold. It simply requires that the specification describe the invention (and the manner of making and using it) so as to "enable [artisans] … to make and use the same." 35 U.S.C. § 112(a). The text does not distinguish among different kinds of patent claims for enablement purposes. Nor does it mention numbers. Assuming the criteria for patentability are satisfied, the statute sets no limit on the number of variants any particular claim can enable. Rather,

where a jury finds that the genus's description "enable[s] [artisans] to make and use" the invention, the statutory language is satisfied. *Id.*

That is how this Court treated genus claims in *Minerals Separation*. Nothing in that decision suggests that genus claims are subject to some numerical threshold. Instead, the Court held that the description sufficiently "guide[d] those skilled in the art to its successful application" even though it covered a "large class of substances." 242 U.S. at 271. "The composition of ores varies infinitely," the Court reasoned, "and it is obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case." *Id.* This Court held that was no barrier to enablement, and upheld the patent. *Id.* But a genus claim that covers embodiments that "var[y] infinitely" would plainly fail under the Federal Circuit's current numbers-based rule.

c. The Federal Circuit's rule also makes no sense as a matter of logic and science. The ability to make and screen many possible embodiments—even "many, many thousands" of them, Pet.App.25a—does not prove that the patent fails to provide adequate guidance to skilled artisans. As an initial matter, the patent "bargain," *Bonito Boats*, 489 U.S. at 150–51, merely requires that the patent teach artisans to "make and use" the patented invention. 35 U.S.C. § 112. It makes no sense to conclude—as the Federal Circuit now holds—that a patent that does just that is invalid simply because additional effort would be required to make and identify every conceivable variation. "[I]f [a skilled artisan] can figure out how to make a working embodiment without too much

effort—there is no reason to require more." KLS, *supra*, at 84.

Skilled artisans simply want to find a version that works, not collect them all. If, for example, "half of the species in the genus don't work," a scientist "working at random" "might have to try two before finding one that works." *Id.* at 41. If "90% are inoperable, [she] might have to try ten species, or maybe twenty if [she is] very unlucky." *Id.* at 41–42. Even in the unlucky scenario, so long as an artisan "can figure out how to make a working embodiment without too much effort—there is no reason to require more in most cases." *Id.* at 84. On no account would anyone have reason to make and test every covered compound, as the Federal Circuit's numbers-rule presumes. Indeed, the only reason to "make that effort" is that, now, "Federal Circuit cases seem to require it." *Id.*

Moreover, in specialized fields, scientists frequently handle "baseline classes containing potentially billions of compound variations." Pet.App.85a. When a patent's disclosure of a breakthrough discovery is combined with rapid-fire synthesis and high-throughput screening, it becomes possible—sometimes even "routine," Pet.App.19a—for follow-on scientists to rapidly generate other compounds with the requisite structure and function. *See, e.g.,* Br. of REGENXBIO Inc. in Support of Reh'g En Banc, C.A.Dkt. 73, at 9. In those circumstances, a jury may properly find that the specification "enable[s] [an artisan] to make and use" the claimed invention—regardless the number of compounds theoretically covered. 35 U.S.C. § 112(a). After all, patents "need not teach, and preferably omit[], what

is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

This case is a good example. The patent itself disclosed numerous active compounds, making it easy for skilled artisans to make them. To identify additional covered compounds, a scientist could pull existing modified nucleosides "off the shelf," purchase them, or synthesize them. Given that the most complicated synthesis step took a lesser-credentialed Gilead scientist only fifteen minutes, C.A.App.37314–15, 37318, a team of five researchers could easily synthesize thousands of compounds in a single year. And given that labs can test hundreds of thousands of compounds in even less time, *see* C.A.App.37496, those same compounds could be screened roughly simultaneously. While that year of labor might sound like a lot of work to those in other fields, it is par for the course in pharmaceuticals and biotechnology—as the world is, unfortunately, now coming to understand all too well. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016) ($1.861 billion in average out-of-pocket costs and $2.870 billion in capitalized R&D costs per approved drug). After all, developing *just one* into an FDA-approved treatment would generate tremendous profits.

That is exactly why—after spending nine days hearing from 27 witnesses—the jury concluded that Gilead had not met its clear-and-convincing burden of proof. Unlike appellate courts, juries are well suited to take each case on its own facts, rather than rely on one-size-fits-all rules. Sometimes, a jury

might reasonably conclude—given the skill an ordinary artisan possesses, the state of the art for testing compounds, or other case-specific considerations—that a genus claim covering "many, many thousands" of compounds is insufficiently enabled. Pet.App.25a. Here, however, the evidence supported the jury's finding that Idenix's claim satisfied § 112(a).

That the Federal Circuit *agreed* with the jury about many of the relevant enablement factors, *see* Pet.App.19a (synthesis not difficult), 24a (level of skill in the art is high)—and nevertheless rejected its ultimate conclusion "as a matter of law," Pet.App.23a—highlights the illogic of the Federal Circuit's rule. As the jury's finding demonstrates, a patent that covers many variants *can* sufficiently describe the class so as to enable a person "skilled in the art to which it pertains … to make and use the same." 35 U.S.C. § 112(a).

d. The Federal Circuit's bright-line legal rule also improperly empowers courts and subjugates juries.

For centuries, this Court—like founding-era English courts—has understood it to be "the right of the jury to determine, from the facts in the case, whether the specifications … enable any person skilled in the [art]" to make and use the claimed invention." *Battin*, 58 U.S. (17 How.) at 85 (collecting English cases); *Wood v. Underhill*, 46 U.S. (5 How.) 1, 5–6 (1847). Before the Federal Circuit's creation, most circuits followed *Battin* and considered enablement a question of fact for the jury. *See, e.g.*, *A.B. Dick Co. v. Barnett*, 288 F. 799, 800 (2d Cir. 1923) ("Whether the description … is clear

enough to enable a person of ordinary skill to construct or make it is a question for the jury[.]"); *Research Prod. Co. v. Tretolite Co.*, 106 F.2d 530, 533 (9th Cir. 1939) (similar). A few did not. *See, e.g.*, *Minn. Mining & Mfg. Co. v. Carborundum Co.*, 155 F.2d 746, 749 (3d Cir. 1946) (enablement "is a question of law, open to this court").

The Federal Circuit joined the short side of that split. Although it has "long held" that the supposedly separate "written description" requirement presents "a question of fact," *Ariad*, 598 F.3d at 1351, it views enablement as "a question of law." Pet.App.6a. In the context of genus claims, that means a court may disregard a properly instructed jury's weighing of the relevant factors relevant to enablement whenever it decides, after the fact, that a genus claim covers too many compounds. That is exactly what district courts are doing. *See, e.g.,* Pet.App.115a–16a; *Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, 2019 WL 4058927, at *13 (D. Del. Aug. 28, 2019).

2. *The Federal Circuit's Separate "Possession" Requirement Is Wrong.*

The Federal Circuit's separate written-description requirement—which deems the description of a genus claim adequate only if it proves that the inventor was in "possession" of the specific infringing compound—suffers from similar flaws: It has no basis in § 112(a)'s text, contravenes this Court's and others' precedents, and has been the subject of consistent criticism.

a. Section 112(a) provides 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 make and use the same." That text does not mention "possession." To the contrary, it makes clear that enablement is the measure of—rather than distinct from—an invention's description.

In *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) ("*Eli Lilly*"), however, the Federal Circuit imported a "separate written description" doctrine into § 112(a). *See, e.g.*, Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 834 (1999) (*Eli Lilly* "broke new ground by applying the written description requirement … to claims filed in the *original* patent"). Instead of asking whether a "written description" "enable[s]" a skilled artisan to "make and use" the claimed invention, *Eli Lilly* held that § 112(a) *also* requires that the patentee "convey with reasonable clarity … that, as of the filing date sought, he or she was in possession of the invention." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008).

In *Ariad*, the Federal Circuit addressed the intra-circuit split *Eli Lilly* had created. The en banc court considered the argument "that the written description requirement exists, not for its own sake as an independent statutory requirement, but only to identify the invention that must comply with the enablement requirement." 598 F.3d at 1344. But—over a strong dissent—the court rejected it, "reaffirm[ing]" the court's post-1997 holdings that

§ 112 "contains a written description requirement separate from enablement." *Id.* at 1340.

The Federal Circuit has applied that "separate" written-description requirement ever since. According to the Federal Circuit, that "separate" requirement is satisfied if "the disclosure … reasonably conveys to those skilled in the art that the inventor had *possession* of the claimed subject matter as of the filing date." *Id.* at 1351 (emphasis added); *see also* Pet.App.26a–30a (applying that "possession" standard). The Federal Circuit has in turn held that, to establish "possession," the description must include a "precise definition" of the claimed invention "such as by structure, formula, chemical name, or physical properties." *Eli Lilly*, 119 F.3d at 1566. For genus claims, the Federal Circuit adds yet more judicial gloss: The "precise definition" must include "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus"—though the court has not specified how many examples is sufficient. Pet.App.27a (quoting *Ariad*, 598 F.3d at 1350). And here, the Federal Circuit went a step further and appeared to hold that a failure to disclose the *specific infringing compound* at issue is dispositive. Pet.App.28a–30a.

b. This "possession"-based "written description" requirement has no basis in text.

Section 112(a) states that a patent specification "shall contain a" single "written description." That provision then identifies *what* must be described: "the invention," "the manner and process of making

and using it," and "the best mode contemplated by the inventor … of carrying [it] out." *Id.* And it further specifies the *standard* for determining whether such a description is adequate: it must be delivered "*in such full, clear, concise, and exact terms as to enable any person skilled in the art* … to make and use the same." *Id.* (emphasis added).

Section 112(a) thus makes clear that enabling artisans to make and use the invention is the measure by which a written description must be judged. Its language offers no basis for imposing some other "written description" requirement; the word "possession" does not appear in § 112(a) at all, nor can it be inferred from Congress's chosen words. And the Federal Circuit's genus-specific subtest has no grounding in the text either.

c. The Federal Circuit's atextual "possession" rule conflicts with this Court's treatment of § 112(a) and with decisions from other circuit courts.

This Court has long understood § 112(a) and its forbears to demand a single inquiry: Whether an inventor "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." *The Telephone Cases*, 126 U.S. 1, 535–36 (1888); *see also, e.g.*, *United States v. Dubilier Condenser Corp.,* 289 U.S. 178, 187 (1933) (similar); *Schriber-Schroth Co. v. Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938) (similar); *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944) (similar). The Court's focus has consistently been on what an ordinary artisan could do with the specification's disclosures. It has never separately

asked what an inventor "possessed." If a jury finds that a written description enables a skilled artisan to make and use an invention, § 112(a) is satisfied.

Before the Federal Circuit was established, other Courts of Appeals adhered to the text of § 112(a) and its precursors—none of which mentioned "possession." Those courts just asked whether "the patentee [had made] a written description of his invention or discovery, 'in such full, clear … and exact terms as to enable any person skilled in the art … to make, construct … and use the same.'" *Donner v. Am. Sheet & Tin Plate Co.*, 165 F.199, 206 (3d Cir. 1908); *see also Philip A. Hunt Co. v. Mallinckrodt Chem. Works*, 177 F.2d 583, 585 (2d Cir. 1949); *Ill. Tool Works, Inc. v. Foster Grant Co.*, 547 F.2d 1300, 1309 (7th Cir. 1976). They did *not* require patents to satisfy some independent "written description" standard, framed as "possession" or otherwise.

d. The Federal Circuit's separate "written description" rule has faced consistent judicial and academic criticism. Since *Eli Lilly*, Federal Circuit judges have repeatedly assailed that jurisprudential misstep.[6] Academics have noticed too. *See Univ. of*

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[6] *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 976 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing en banc, joined by Gajarsa, Linn, JJ.); *id.* at 987 (Linn, J., dissenting from denial of rehearing en banc, joined by Rader, Gajarsa, JJ.); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1322 (Fed. Cir. 2003) (Rader, J., concurring); *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1307 (Fed. Cir 2004) (Rader, J., dissenting from denial of rehearing en banc, joined by Gajarsa, Linn, JJ.); *id.* at 1325 (Linn, J., dissenting from denial of rehearing en banc, joined by Rader, Gajarsa, JJ.); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 433

Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1314–25 (Fed. Cir. 2004) (Rader, J., dissenting from denial of rehearing en banc) (listing more than 20 articles disagreeing with the Federal Circuit's approach); *see also generally, e.g.*, Allen K. Yu, *The En Banc Federal Circuit's Written Description Requirement: Time for the Supreme Court to Reverse Again?*, 33 CARDOZO L. REV. 895 (2012).

Commentators have homed in on the particularly problematic consequences of the "possession" standard—as applied in this case—for genus claims. *See* KLS, *supra*, at 49–67. "No matter how much testing the patentee does, there will always be untested"—and thus undescribed—"species." *Id.* at 91. Any genus claim is thus all but destined to fail the Federal Circuit's separate "written description" test. That cannot be right.

II. THE QUESTIONS PRESENTED ARE EXCEPTIONALLY IMPORTANT.

While the Federal Circuit's atextual rules are generally bad for innovation, they are devastating for life sciences innovation. By itself, each presents a nearly insurmountable obstacle to genus claims, which are the life-blood of the field and "critical to effective patent protection." KLS, *supra*, at 1. Together, they put innovators in an impossible position, eviscerating incentives to develop life-saving cures.

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F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting from denial of rehearing en banc, joined by Gajarsa, J.).

A. The Federal Circuit's numbers-based enablement rule leaves biotech and pharmaceutical inventors without viable patent protection for their discoveries. And the uncertainty inherent in that rule will only further stymie innovation in the field.

1. Most important pharmaceuticals and biologics have numerous possible chemical variants, many of which share the same basic properties. It is often "impossible" to identify each one that will share that property in advance; "trial and error experiments" cannot be "[a]void[ed]." Matthew D. Kellam, Comment, *Making Sense Out of Antisense: The Enablement Requirement in Biotechnology After* Enzo Biochem v. Calgene, 76 IND. L.J. 221, 227 (2001). Those who discover these important biochemical families now face a difficult choice. If the inventor claims the class that shares a specific structure and exhibits a particular property, she runs headlong into the Federal Circuit's numerosity prohibition: Her patent may cover too many possible embodiments to be enabled. *See* Pet.App.25a; *see also* KLS, *supra*, at 49 ("Any genus claim covering a significant number of species in the life sciences and chemical fields … is now in question."). But if she claims only specific compounds, competitors can free-ride on her key insight by creating a slightly different variant. "A potential infringer could readily avoid 'literal' infringement … by merely finding another analogous [compound] which could be used" the same way. *Application of Angstadt*, 537 F.2d 498, 503 (C.C.P.A. 1976); *see also* Jason Mast, *Merck's last crack at salvaging a $2.5B jury verdict in hep C patent showdown is shot down by appeals court*, EndPoints News (Oct. 31, 2019) *available at*

https://bit.ly/2ZAe49G (decision below "call[s] into question an innovator's ability to prevent others from marketing a drug that is only modestly different").

Left standing, the Federal Circuit's rule thus leaves biotech innovators with no viable means of claiming adequate protection for their often life-saving discoveries. It "potentially exposes existing patents to new challenges from competitors in the field." Valerie Bauman, *Merck's Patent Loss to Gilead May Have Big Impact on Drugmakers*, Bloomberg Law (Oct. 31, 2019), *available at* https://bit.ly/3eGBuOY; *see also* Matthew Bultman, *Drug Cos. May Rethink Patent Strategy After Fed. Circ. Ruling*, Law360 (Nov. 13, 2019), *available at* https://bit.ly/3fBzp7Y (opining that the decision below will "[ ]invigorate certain types of challenges to pharmaceutical patents"). And it creates incentives for innovators to "suppress[] disclosure" of their discoveries in the first instance by "[d]epriving [them] of claims which adequately protect them and limiting them to claims which practically invite appropriation … while avoiding infringement." *Angstadt*, 537 F.2d at 504.

2. The uncertainty created by the Federal Circuit's rule exacerbates these problems. A claim covering "many, many thousands" of compounds is insufficiently enabled. Pet.App.25a. But *how* "many, many" is *too* "many, many"?

"I know it when I see it" is rarely a workable rule. It is intolerable in patent law, where doctrine must "remain stable and clear." *Bilski v. Kappos*, 561 U.S. 593, 613 (2010) (Stevens, J., concurring in the judgment). The unpredictability the Federal Circuit's enablement rule invites is bad enough for

established drug manufacturers, who spend small fortunes on each new medicine. *See supra* at 21. It will likely prove fatal for startups or non-profits hunting for cures. *See* Br. of REGENXBIO Inc. in Support of Reh'g En Banc, C.A.Dkt. 73, at 11.

B. The Federal Circuit's separate written-description requirement—and its atextual "possession" standard—likewise sows confusion and impedes innovation.

1. The Federal Circuit's separate "written description requirement is at worst indecipherable, and at best unruly." Mark D. Janis, *On Courts Herding Cats: Contending With the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 106 (2000). Even the en banc Federal Circuit acknowledged that the standard "has never been very enlightening." *Ariad*, 598 F.3d at 1351. Its meaning is "quixotic." *Id.* at 1362 (Rader, J., dissenting in part and concurring in part). And it "provides no conclusive answers." *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1342 (Fed. Cir. 2010) (Gajarsa, J., concurring); *see also Rochester*, 375 F.3d at 1327 (Dyk, J., concurring) (explaining that the court has "yet to articulate satisfactory standards [for its written-description doctrine] that can be applied to all technologies").

The indeterminacy of the "possession" standard has "'created confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude,' causing uncertainty 'in how inventions are protected, in how the Patent & Trademark Office discharges its responsibilities, and in how business is conducted in emerging fields of

law.'" *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1381 (Fed. Cir. 2009) (Linn, J., concurring). That additional "zone of uncertainty" further "discourage[s] invention." *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

One thing about the separate written-description requirement *is* for certain: It invalidates inventions that satisfy the statutory enablement standard. "*[I]t is not enough*," the Federal Circuit has said, "for the specification to show how to make and use the invention, *i.e.*, to enable it." *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017) (emphasis added). The separate "possession" standard must *also* be satisfied.

Indeed, because the "possession" standard requires a "far more specific disclosure than enablement," the Federal Circuit regularly resolves § 112(a) on "written description" grounds, without reaching enablement. *Enzo*, 323 F.3d at 981–82 (Rader, J., dissenting from denial of rehearing en banc) (defendants will "have no need to invoke enablement, but will proceed directly to the more demanding … written description requirement"). The doctrine has thus become "a sort of 'super-enablement' requirement," floating on top of the statutory enablement standard. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1652–54 (2003).

2. The Federal Circuit's separate "written description" requirement is especially problematic for biotechnology. In the Federal Circuit's view, genus claims satisfy the "possession" standard only when the description discloses, according to that court's satisfaction, "either a representative number

of species falling within the scope of the genus or structural features common to the members of the genus." Pet.App.27a.

Because it is rarely possible to spell out every structural feature common to such chemicals, innovators seeking to satisfy the Federal Circuit's requirements have little choice but to make, test, and disclose "nearly every possible species." KLS, *supra*, at 66; Bultman, *supra* (same). "[T]he rote disclosure of additional embodiments does not promote the progress of science." Br. of Amgen Inc. in Support of Reh'g En Banc, C.A.Dkt. 85, at 9. Moreover, the time it takes to gather redundant examples delays disclosure of the inventor's *actual* discovery, keeping the benefits of that discovery from the public and inhibiting follow-on research. *See id.* at 7–8. After all, every hour spent identifying yet more examples is one *not* spent "discovering the next breakthrough medicine." *Id.* at 9; *see also* Br. of REGENXBIO Inc. in Support of Reh'g En Banc, C.A.Dkt. 73, at 11 (similar).

Even when inventors strive to meet the Federal Circuit's "possession" standard, there are no guarantees. The court has not said and cannot say how many examples constitutes a "representative number." Pet.App.27a. And if the inventor lists too many, she runs the risk of suggesting that embodiments *not* specifically mentioned in the specification were purposefully omitted. *See* Pet.App.29a. The only sure way to protect an invention is to disclose and claim *every* covered variant—which is, of course, to forgo a genus claim altogether.

C. This case itself proves that, combined, the Federal Circuit's rules provide a "powerful" "weapon[ ] against genus claims." KLS, *supra*, at 67. As the Federal Circuit recognized, Idenix *did* disclose many, many working examples. Pet.App.29a–30a. But even that was not enough to satisfy the Federal Circuit's numbers-based approach to enablement, and it cut *against* Idenix on written description. Because the specification identified "tens or hundreds of thousands of possible nucleosides, substituent-by-substituent, with dozens of distinct stereo-chemical structures," the Federal Circuit deemed the "absen[ce]" of "the compound in question"—Gilead's infringing product—"conspicuous." Pet.App.29a; *see* KLS, *supra*, at 64 ("[T]he [*Idenix*] court came close to punishing the patentee for providing too many representative examples.").

The Federal Circuit, accordingly, has put inventors between a rock and a hard place: Disclose too few examples, and the "written description" will be deemed insufficient to demonstrate enablement or possession; too many, and the absence of the infringing compound becomes "conspicuous." Innovators are left with no reliable means of protecting their discoveries. That spells the end of genus claims as we know them. *See generally*, KLS, *supra*, at 1 (under the Federal Circuit's new rules, "it is no longer possible to have a valid genus claim").

In the end, the public will suffer. It is far from clear that the U.S. biotech and pharmaceutical industries can function without viable patent protection for genus claims. *See id.* at 96 (worrying about "the continued success of the biochemical

industries despite the invalidity of genus claims"). And it is near certain that, without genus claims, lifesaving cures will go undetected, and breakthroughs unshared—a prospect more troubling now than ever.

III. THIS CASE IS A GOOD VEHICLE.

This case is the right vehicle for this Court to ensure the ongoing vitality of genus claims. The Federal Circuit's decision in this case turned on its numerosity-based enablement rule and its separate "possession" requirement. *See* Pet.App.23a–30a. Had the court applied § 112(a) as written—that is, had it simply asked whether the jury reasonably found that the invention's description was sufficient to enable a "person skilled in the art to which it pertains … to make and use the same," 35 U.S.C. § 112(a)—it would have reinstated the jury's verdict. That is exactly what Idenix asked it to do, including in a petition for rehearing en banc. This case, accordingly, is an ideal vehicle for addressing both questions presented.

The Court has declined to take up the "possession" question in the past, but the cases previously raising that question have not been up to the task. *See, e.g.*, BIO, *Amgen Inc. v. Sanofi*, No. 18-127, 2018 WL 6134234, at *12–*23 (U.S. Nov. 19, 2018) (highlighting the interlocutory posture and the possibility of mootness given the upcoming retrial); BIO, *Janssen Biotech Inc. v. Abbot Labs.*, No. 11-596, 2012 WL 30293, at *13–*19 (U.S. Jan. 3, 2012) (arguing that the case implicated the distinct "written description" requirement for later-added claims, not the freestanding one from *Ariad*). Moreover, the passage of time has only further

cemented the Federal Circuit's erroneous rule and made the need for this Court's intervention clearer.

The two questions presented are independently worthy of review, and they are deeply intertwined. The "genus claim" enablement question is of the utmost importance to the fields of pharmaceuticals and biotechnology, wherein the breakthrough often consists of a genus of compounds that share a particular property. And the "written description" question will allow the Court to consider the proper treatment of genus claims against the backdrop of the Federal Circuit's broader § 112(a) jurisprudence.

This Court has not spoken to § 112(a) in decades. Much hinges on its meaning—particularly as applied to genus claims, and particularly now, as researchers race for a cure. The Court should grant review and hold again that § 112(a) calls for a single, case-specific jury finding as to enablement. It should not allow the Federal Circuit's atextual rules to condemn biotech breakthroughs to failure.

CONCLUSION

The petition should be granted.

September 21, 2020

Respectfully submitted,

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