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 *AMICUS CURIAE* AMGEN INC. IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICUS CURIAE*[1]

Amgen Inc. is the world's largest independent biotechnology company. Amgen discovers, develops, manufactures, and delivers innovative human therapeutics to treat patients suffering from cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses. To develop these therapies, Amgen spends billions of dollars on research and development.

Amgen has a significant interest in ensuring that rules governing patent validity are predictable and in line with congressional intent as reflected in statutory text. Amgen has a particular interest in urging the Court to supervise the Federal Circuit's shifting and non-textually-grounded interpretation of 35 U.S.C. § 112(a). Novel interpretations of that statute have been used to overturn jury verdicts in Amgen's favor in a case involving a competitor's copy of Amgen's pathbreaking (and expensively researched) discovery of antibodies that dramatically lower levels of LDL cholesterol linked to heart disease. *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017); *Amgen Inc. v. Sanofi*, 2019 WL 494620 (D. Del. Feb. 8, 2019), *appeal pending*, No. 20-1074 (Fed. Cir.).

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[1] All parties have consented to the filing of this brief. No counsel for a party has written this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than *amicus curiae* or its counsel, has made a monetary contribution to this brief's preparation or submission.

SUMMARY OF ARGUMENT

I. A. The text of 35 U.S.C. § 112(a) creates one standard for evaluating a patent's "written description": Both "the invention" and the "manner and process of making and using it" must be described "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same."

Rather than follow the text, the Federal Circuit has added a requirement. Although Section 112(a) requires only a written description that enables, the Circuit has imposed a judge-made "possession" requirement.

B. Section 112(a) poses a factual inquiry, and proper appellate review is deferential. Federal Circuit case law, however, holds that the "enablement" question is a legal one, based on underlying facts. Mislabeling the inquiry as a legal one has led the Federal Circuit to devise increasingly stringent tests without statutory basis as it non-deferentially reviews factfinders' choices between competing expert testimony. The proper approach is simpler: asking the factfinder directly whether, in the words of the statute, the patentholder has described "the invention" and the "manner and process of making and using it" "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same."

II. A. The "possession" standard has taken on a life of its own. The standard initially had a narrow remit—policing priority disputes. Since the late 1990s, however, this atextual test has grown into a freestanding barrier to patent validity.

B. The Federal Circuit has not administered its "possession" standard in an orderly fashion. Instead,

it has cycled through various sub-tests at a dizzying pace.

C. Simultaneously, the court has, of late, interpreted the enablement inquiry so stringently as to distract from the textually grounded inquiry. Instead of focusing on whether the patent's disclosure enables a person skilled in the art to make and use the invention, the Circuit has fixated on the metes and bounds of the invention—even when discovering those boundaries has no practical effect on the skilled artisan's ability to achieve operable embodiments.

III. A. The protean nature of the Federal Circuit's Section 112(a) jurisprudence puts a damper on innovation. The Circuit's Section 112(a) standards inappropriately "disrupt the settled expectations of the inventing community" and "destroy[] the legitimate expectations of inventors in their property." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

B. The Federal Circuit's Section 112(a) jurisprudence is particularly destabilizing to the biopharmaceutical industry—whose molecular products are a poor fit with the Circuit's ill-explained sub-tests.

C. Worse, the Circuit's jurisprudence discourages the most innovative work on the most intractable medical problems. With the barriers to broad protection extending ever higher, companies will leave the high-risk business of true innovation in favor of far less economically risky "fast follower" drugs that target known biological pathways.

ARGUMENT

Patent law rests on a straightforward bargain: The inventor discloses her invention to the public, so that others can make and use it, and in return gets

the exclusive right to her invention for a limited period. Section 112(a) codifies the inventor's obligation to teach the public. But the Federal Circuit has shunned that statutory text, upsetting the patent bargain in the process.

It has strained to read two standards into that provision, when the text states just one. It has supplied a second, judge-made standard—"possession"—that is as unclear as it is unwarranted. Attempting to implement that rudderless standard, the Circuit has created, revised, and eliminated an ever-changing series of poorly developed sub-tests. At the same time, the Circuit has expanded Section 112(a)'s enablement requirement well beyond what the text demands.

Investors in the biopharmaceutical space can ill afford doctrinal uncertainty, given the cost and risk of failure that come with elucidating biological pathways of disease and development and approval of novel medicines to prevent and treat disease. And the Circuit's jurisprudence makes it extremely difficult to defend justifiably broad patents on pathbreaking innovations, discouraging industry players from trying to solve our biggest health problems.

I. SECTION 112(a)'S PLAIN TEXT SETS FORTH A SINGLE, FACT-DEPENDENT STANDARD.

The text of Section 112(a) is clear. An inventor must provide one written description—a description that enables a person of ordinary skill in the art to "make and use" her invention. This Court's cases track that reading. The Federal Circuit, by contrast, has held that a component of the written description is not governed by the written description's standard and has imposed its own "possession" standard.

As it does in other areas of patent law, the Federal Circuit reviews enablement *de novo*, substituting its judgment for the factfinder's. But the correct Section 112(a) standard—a "written description that enables"—is highly fact bound, and factfinders' application should be reviewed deferentially.

A. Text and Precedent Point to a Single Section 112(a) Standard—A Written Description that Enables.

Section 112(a)'s text measures the "written description"—all of it—by a single standard. Specifically, it 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 which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). The phrase "written description" is modified by three prepositional phrases: "of the invention"; "of the manner and process of making and using it"; and "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same." Section

112(a) tells the reader what the inventor must disclose (a "written description"); what that disclosure must describe ("the invention" and "the manner and process of making and using it"); and how detailed that description must be ("in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use [the invention]").

But the Federal Circuit has held that Section 112(a) "contains two separate description requirements: a 'written description [i] of the invention, *and* [ii] of the manner and process of making and using [the invention']." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc). According to the Circuit, "the prepositional phrase 'in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same' modifies only 'the written description … of the manner and process of making and using [the invention].'" *Id.*

That interpretation defies basic principles of statutory interpretation. It ignores Section 112(a)'s ordinary meaning. *See Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 137 S. Ct. 1002, 1010 (2017). If Congress intended two different standards to govern the written description "of the invention" and "of the manner and process of making and using it," it would have set down two standards. Instead, Congress demanded one written description, which must meet two requirements, governed by one standard.

Splitting Section 112(a) into two written descriptions governed by two tests also flouts that provision's grammatical structure. *See United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241-42 (1989). On the Federal Circuit's reading, the comma following

the phrase "of making and using it" is "meaningless." *Ariad*, 598 F.3d at 1363 (Rader, J., dissenting in part).

And the Circuit's interpretation creates the bizarre result that *no* statutory standard governs the "written description" of "the invention." That would be an inexplicable omission from the provision that codifies "the very purpose and quid pro quo of the patent system." *In re Barker*, 559 F.2d 588, 594 (C.C.P.A. 1977) (Markey, J., dissenting).

The Federal Circuit has filled the void by supplying its own tests. The invention's description must show "possession." *Ariad*, 598 F.3d at 1352. But the text says nothing of "possession." And "courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Bilski v. Kappos*, 561 U.S. 593, 602 (2010).

This Court's precedents, by contrast, accord with Section 112(a)'s unitary standard: a written description that enables. Indeed, this Court has often suggested that the "only" purpose of that provision is enablement. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012); *see, e.g.*, *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) ("a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires"); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974) ("the patent application shall include a full and clear description of the invention and 'of the manner and process of making and using it' so that any person skilled in the art may make and use the invention"); *The Telephone Cases*, 126 U.S. 1, 536 (1888).

What is more, Section 112(a)'s single standard is universal—it applies to all "invention[s]." The text is technology neutral. *Cf. Diamond v. Chakrabarty*, 447

U.S. 303, 309 (1980). The Patent Act should not be applied in a technology-specific manner because "times change," and "[t]echnology and other innovations progress in unexpected ways." *Bilski*, 561 U.S. at 605 (plurality opinion). Yet the Circuit's judge-made possession test is applied very differently to some inventions (such as biopharmaceuticals) than to others (such as software and the mechanical arts). *See infra* Part III.B; *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1325-26 (Fed. Cir. 2003) (Rader, J., concurring).

B. The Unitary Section 112(a) Inquiry Is a Question of Fact.

Just as Section 112(a) clearly sets forth its single standard—a written description that enables—it is also clear about the written description's audience: "any person skilled in the art to which [the invention] pertains or with which it is most nearly connected." Deciding whether a person skilled in the art could "make and use" an invention based on a patent's written description necessarily depends on expert testimony from persons skilled in the art. This fact-intensive inquiry is well within the traditional ken of the jury. *See Battin v. Taggert*, 58 U.S. (17 How.) 74, 85 (1854) ("It was the right of the jury to determine, from the facts in the case, whether the specifications, including the claim, were so precise as to enable any person skilled in the structure of machines, to make the one described.").

Functionally, too, "as a matter of the sound administration of justice," a jury "is better positioned than [a judge] to decide" issues of enablement—such as which expert is more credible. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996)

(instructing courts to consider history, precedent, and functional considerations when deciding whether a question of patent law is for judge or jury). It is thus unsurprising that, before the Federal Circuit was created, the weight of appellate authority was to review enablement as a fact question. *See* Pet. 22-23 (collecting cases).

The Federal Circuit does review its atextual "possession" requirement as a question of fact. *Ariad*, 598 F.3d at 1351. But the same is not true for the Circuit's version of the statutory standard—enablement. Even though the "legal criteria" of possession and enablement are "related and are often met by the same disclosure," *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005), the Circuit holds that whether the written description "enable[s] any person skilled in the art * * * to make and use the [invention]" is a "question of law based on underlying facts." *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013).

This disparate treatment is "inexplicable," *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1342 (Fed. Cir. 2010) (Gajarsa, J., concurring), especially given "the importance of uniformity" in allocating patent-law tasks between judge and jury. *Markman*, 517 U.S. at 390.

And, although the Federal Circuit's enablement law nods to "underlying facts," in practice the Circuit often treats the question as purely legal, failing to heed this Court's instruction that "'[a]n issue does not lose its factual character merely because its resolution is dispositive of the ultimate' legal question." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 333 (2015) (quoting *Miller v. Fenton*, 474 U.S. 104, 113 (1985)); *see* Pet. 23. Although the legal rubric is

different, the genus of error is the same as that in *Teva*, namely setting aside the factfinder's acceptance of one expert's testimony in favor of the opposing expert's testimony without considering whether the factfinder's determination met the high standard of clear error. *See* 574 U.S. at 335-36. *See also* Alan B. Parker, *Examining Distinctive Jurisprudence in the Federal Circuit: Consequences of a Specialized Court*, 3 Akron Intell. Prop. J. 269, 276 (2009) (citing pre-Federal Circuit concerns that a specialized court would "attempt[ ] to retry cases at the appellate level and * * * substitute its judgment for that of the trial court"). This Court should make clear that the sole question posed by Section 112(a) is one of fact.

II. THE FEDERAL CIRCUIT HAS CREATED AN ATEXTUAL AND UNWORKABLE FRAMEWORK.

The "possession" test was once constrained to a limited context—adjudicating claim priority. But in *Lilly* the Federal Circuit turned "possession" loose as a freestanding requirement for initial claim applications. The Circuit reaffirmed the possession standard in *Ariad*, creating uncertainty and confusion.

Recent years have also seen a shift in the Federal Circuit's enablement standard away from the textual anchor of a written description that enables. By holding that even "routine" experimentation can be too much to ask of a person skilled in the art, and that the specification must teach that person to distinguish operative embodiments from even the rarest inoperative embodiments, the Circuit has gone well beyond what Section 112(a) requires.

In both doctrinal areas, the Federal Circuit's departure from the text has put into question countless important patents. Worse, these doctrines have begun to approach mutual inconsistency in some circumstances—demanding the disclosure of many examples but punishing the inventor for disclosing *too many* if the infringer's product happens not to be listed. *See* Pet. 33.

A. The Federal Circuit Vastly Expanded Possession's Domain in *Lilly*.

After more than a century applying a single standard in accordance with the text, in 1967 the Federal Circuit's predecessor introduced a separate "possession" standard as a tool to police the priority of claims. *See In re Ruschig*, 379 F.2d 990, 991, 995-96 (C.C.P.A. 1967); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (the "purpose of the 'written description' requirement" is for an applicant to convey "that, as of the filing date sought, he or she was in possession of the invention"). In essence, that early version of "possession" guarded against patent applicants' revising or augmenting pending patent applications while claiming the benefit of an earlier filing date. When used to evaluate disputes over claims *added* to a patent after the invention received protection, the court's "possession" doctrine, though atextual, had a clear and limited function to "prevent[] new matter from creeping into claim amendments." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 978 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing en banc).

In 1997, the Federal Circuit began applying its possession requirement as a freestanding, *general* requirement for initial patent applications. *See*

Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997). The atextual standard thus expanded dramatically from a "clear and limited" context into patent validity writ large. *See* Dmitry Karshtedt, Mark A. Lemley, and Sean B. Seymore, *The Death of the Genus Claim*, at 56 (Aug. 5, 2020) ("KLS"), https://bit.ly/3nXeD7z. Then, in *Ariad*, the court doubled down on its error. *Ariad*'s "lack of clarity" has "created openings for multiple distinct lines of written description attacks, which have been pursued with great success." *Id.* at 61.

B. The Federal Circuit's Attempts at Implementing "Possession" Have Failed.

Endeavoring to ground its "possession" requirement, the Federal Circuit has crafted several protean and ill-defined sub-tests. For example, it has created tests requiring the disclosure of "a representative number of species falling within the scope of the genus," or "structural features common to the members of the genus." *Ariad*, 598 F.3d at 1350. The latter sub-test can also be met by satisfying a sub-sub-test: a functional description coupled with a known relationship between structure and function. *See Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1378 (Fed. Cir. 2017). Without any textual North Star, these ill-defined standards are in constant flux.

Take the "common structural features" test. The Federal Circuit had, at first, required structural disclosure. *See Lilly*, 119 F.3d at 1568-69. But in *Gen-Probe* the court clarified that functional disclosure (*i.e.*, describing the invention's intended effect) suffices when "coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." 323 F.3d at 964. As an

example, the court endorsed the functional description of an antibody when coupled with a structural description of the antigen to which it binds. *See id.*

The Circuit has never provided meaningfully clear guidance on what degree of "correlation" qualifies. What the court *has* demonstrated, though, is that a patentee cannot safely rely even on the Circuit's express exemplars. *Compare Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004) (reaffirming "fully characterized antigen" test), *with Amgen*, 872 F.3d at 1377-79 (rejecting that test).

Or consider the "representative number of species" sub-test. How many is "representative"? The Federal Circuit has provided no clear guidance. *Compare AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014) (large catalog of embodiments did not suffice because they did not "qualitatively represent other types of antibodies encompassed by the genus"), *with Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1347 (Fed. Cir. 2013) ("in some cases, broad or generic disclosures can adequately describe particular constituent species."), *and* Pet. App. 29a-30a (effectively punishing disclosure of many embodiments because infringing embodiment was "conspicuously absent").

These doctrinal lurches have taken the Federal Circuit ever further from the textually express purpose of Section 112(a): sharing the information necessary for a person skilled in the art to make and use the invention.

C. The Federal Circuit's "Full Scope" Enablement Doctrine Goes Beyond the Text of Section 112(a).

It is bad enough that the Federal Circuit's decision to cleave Section 112(a) in two has led to instability and unpredictability in implementing "possession." But those distortions have also reverberated in the Circuit's enablement jurisprudence.

The Circuit has long held that, "[a]lthough not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). That "full scope" standard traditionally permitted reliance on the knowledge of a person skilled in the art to distinguish acceptable experimentation inherent in "making and using" the invention from experimentation that was undue. *See In re Angstadt*, 537 F.2d 498, 502-04 (C.C.P.A. 1976). It also looked to the disclosure necessary to describe the claim in a "sufficiently definite" manner, which would include disclosure necessary to enable the creation of embodiments without needing to list every embodiment in the patent. *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916); *see* Pet. 18-19; *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984).

In recent years, however, the Federal Circuit has ratcheted up the enablement standard to the point that it can be nearly impossible to meet for certain inventions. First, the court held that even "routine" experimentation can be "undue." *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (citing *Enzo Biochem, Inc. v. Calgene, Inc.*, 188

F.3d 1362, 1371 (Fed. Cir. 1999)). That development contradicts the fact-dependent nature of the test and has "been used to great effect in recent enablement cases," KLS at 36-37.

Then, in *Wyeth*, the court held that a patent disclosure must enable a person of ordinary skill in the art to know *which* embodiments would be operative. 720 F.3d at 1385. The case below reinforced those shifts. *See* Pet. App. 10a-11a, 16a.

These changes echo the Federal Circuit's atextual "possession" turn. There, rather than simply demand that the written description teach a skilled artisan to "make and use" the invention, the Circuit demands a showing of "possession," distilled into sub-tests that emphasize the enumeration of variants. In assessing enablement, too, the Federal Circuit eschews functionality in favor of exhaustive description. It insists that a disclosure must enable a person skilled in the art to know in advance which embodiments will be operable—without too much experimentation (whether or not routine) and without relying on the artisan's knowledge. *See* Pet. App. 10a-11a, 16a, 18a-19a. This misunderstands what it means to enable an artisan to "make and use" an invention.

Enablement does not require that a person skilled in the art perform every possible substitution and test each to exclude hypothetical outliers that do not work. *Atlas Powder*, 750 F.2d at 1576. It is only when "the number of inoperative combinations becomes significant" that the disclosure "in effect forces" artisans "to experiment unduly in order to practice the claimed invention." *Id.*; *see* KLS at 90-91 (describing possession-infused "category error" of requiring "enough information to figure out the full list of what works and what doesn't"). As Judge Bryson, sitting

by designation, put it, "[a] patent must enable a skilled artisan to practice the full scope of the invention; it does not need to ensure that a skilled artisan can practice the entire scope of the invention within a short period of time." *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 661 (E.D. Tex. 2017).

With these changes to its enablement doctrine, the Federal Circuit drifted still further from the statutory standard. The Circuit now "focuses on 'knowing' instead of 'making and using,' which is what the text of § 112(a) actually requires." KLS at 46. And, rather than look to skilled artisans to determine how much experimentation is due, it substitutes judge-made tests. This train has run off the rails.

* * *

The Federal Circuit's recent possession and enablement precedents have increasingly placed a higher priority on perfect knowledge (*e.g.*, through the collation of many embodiments) than on the express purpose of Section 112(a)—enabling other persons of skill to make and use the invention. *See* KLS at 3 ("The Federal Circuit has abandoned a practical focus on whether others could make use of the claimed invention in favor of a fruitless search for the exact boundaries of that invention."). Besides its other defects discussed above, that new focus on collecting variants is in tension with Section 112(a)'s mandate that the written description be "concise," *see In re Knowlton*, 481 F.2d 1357, 1367 (C.C.P.A. 1973). And the Circuit's shift in emphasis also imports into Section 112(a) a quasi-"definitiveness" requirement—even though it is Section 112(b)'s claims requirement,

not Section 112(a), that requires that the specification "particularly point[ ] out and distinctly claim[ ] the [invention's] subject matter." 35 U.S.C. § 112(b). Unlike the Circuit's exacting Section 112(a) standards, Section 112(b) requires only that a "patent's claims * * * inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).

The Federal Circuit's meandering tests and sub-tests demonstrate the wisdom of the proper approach to Section 112(a): letting the jury decide whether a patent enables a person skilled in the art to "make and use" the invention on the facts of each case. That approach would accommodate evolving and emerging technologies—juries can be trusted to determine when an innovator should be rewarded for a broad claim versus when a researcher has merely made an inchoate discovery and attempted to "preempt the future before it has arrived," *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

This Court has not provided guidance on the meaning of Section 112(a) in many years. Without that direction, the Federal Circuit has drifted away from the text of Section 112(a). And there is no relief on the horizon. This Court should grant review and reorient Section 112(a) doctrine to the statutory text. "Only the written word is the law." *Bostock v. Clayton County*, 140 S. Ct. 1731, 1737 (2020).

III. THE FEDERAL CIRCUIT'S APPROACH CHILLS LIFESAVING INNOVATION.

This Court has warned time and again in patent law against crafting atextual standards that undermine reliance interests. And yet the Federal

Circuit has minted a possession standard that, by itself and in combination with augmented enablement requirements, calls into question countless patents. Worse, it has done so without even settling on a set of rules on which inventors could rely prospectively.

The Circuit's Section 112(a) jurisprudence is a threat to innovation of all stripes but perhaps especially troublesome in the biotechnology sector, within which *amicus* operates. Indeed, one recent study suggests that "pharmaceutical patents litigated outside of the [generic drug] ANDA context * * * are, by far, the worst performers on written description of any industry." Jacob S. Sherkow, *Describing Drugs: A Response to Professors Allison and Ouellette*, 65 Duke L.J. Online 127, 127-28 (2016). The court has moved the goalposts, focusing more on embodiment-collecting than on a specification's practical value to a person of skill in the art.

Perhaps most critically, within the biotech industry the Federal Circuit's Section 112(a) doctrines punish innovation and reward imitation. If inventors cannot obtain appropriately broad patent protection for foundational inventions, they will focus their energies elsewhere. Established biological targets will receive more attention than necessary, while the stock of new targets dries up.

A. The Federal Circuit's Rules Engender Uncertainty, Chilling Innovation.

This Court has cautioned against "disrupt[ing] the settled expectations of the inventing community" and "destroying the legitimate expectations of inventors in their property." *Festo*, 535 U.S. at 739. The Federal Circuit's ever-shifting Section 112(a) jurisprudence does exactly that.

An inventor might rely on *Noelle*'s "fully characterized antigen" test, only to learn—a decade later—that the rule was never "legally sound." *See Amgen*, 872 F.3d at 1376. Or an inventor might hew to Circuit precedent by disclosing hundreds of "species that accomplish the [claimed] result," *Ariad*, 598 F.3d at 1350, only to learn that her disclosure was not "qualitatively represent[ative]" enough. *See AbbVie*, 759 F.3d at 1300. That inventor might even be ambushed by brand new evidence of a species not contained in a voluminous disclosure, *see* Pet. App. 29a-30a—a species created by an infringer using the inventor's own disclosure. And, even if an inventor could guess what sort of disclosure would satisfy the Federal Circuit's latest preference, she still could not amend her existing patent disclosures to track the Circuit's doctrine. *Moba*, 325 F.3d at 1325 (Rader, J., concurring).

This is no way to run a railroad. Innovation is expensive; inventors and their funders can hardly be blamed for cutting their bets if the ground rules might fall out from beneath them at any moment. That doctrinal instability is the natural result of attempts to implement an atextual principle that itself "has never been very enlightening," *Ariad*, 598 F.3d at 1351. Review is warranted to eliminate this innovation-squelching "zone of uncertainty," *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

B. The Federal Circuit's Rules Disproportionately Harm Innovation in Biotechnology.

Despite the Patent Act's technology-neutrality, the Federal Circuit's byzantine and rigid Section 112(a)

jurisprudence places special burdens on the biotechnology sector. *See* Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 Case W. Res. L. Rev. 691, 706 (2004) ("Even a casual juxtaposition of the biotechnology and software cases * * * shows dramatic differences in applying what are nominally the same legal rules."); *id.* at 692 ("the special rules the Federal Circuit has constructed for biotech cases are rather poorly matched to the specific needs of the industry. Indeed, in some ways the Federal Circuit cases have it exactly backwards.").

For instance, there are often many permutations of a claimed antibody that have the same function and that differ only slightly in structure—but the Federal Circuit's possession and enablement jurisprudence requires inventors to exhaustively catalog variants that, as a practical matter, are no different one from the next. *See Moba*, 325 F.3d at 1325-26 (Rader, J., concurring). Those standards are not so rigorously applied in other areas, like software. *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 Berkeley Tech. L.J. 1155, 1184 (2002) ("application of the biotechnology rule to software would radically change the law.")

C. The Federal Circuit's Rules Discourage the Most Important Biopharmaceutical Research.

The Federal Circuit's jurisprudence deters research on the most intractable medical problems burdening patients and health systems. The Circuit's unsparingly rigorous "possession" and enablement standards make it near-impossible to defend claims that fairly reflect the scope of an innovator's contribution. And, if an innovator can claim only

specifically named and described molecules, it will be all too easy for "fast follower" companies to co-opt the innovator's invention by creating a slightly different embodiment to treat the same disease through the same modality. *See Angstadt*, 537 F.2d at 503 ("[a] potential infringer could readily avoid 'literal' infringement" by developing a close cousin of the innovation); Klaus J. Nickisch et al., *How can pharmaceutical and biotechnology companies maintain a high profitability?*, 15 J. Com. Biotech. 309, 310-11 (2009), https://bit.ly/359OhX9 ("The overall risk profiles of these [fast follower] projects [are] quite favourable because the scientific and clinical proof of concept ha[s] already been delivered by another company/molecule."); *Biotechnology's Uncertainty Principle*, *supra*, at 733 (the "risk of unforeseen functional problems is absent for second-comers, who enjoy the benefit of the innovator's experience"). These imitator products may provide incremental clinical value. But there is no guarantee even of that; a strong marketing campaign can substitute for "clinically significant" consumer advantages in a successful follow-on product. *See* Nickisch et al., *supra*, at 310.

A project's risk is of paramount importance in the resource-intensive and highly regulated biotech and pharmaceutical industries. A study of more than 100 pharmaceuticals and biologics found an average pre-approval capitalized cost of $2.56 billion per approved new product. Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 J. Health Econ. 20, 20 (2016), https://bit.ly/3jagNNe. These projects can take a decade or more from lab bench to pharmacy shelf (*see* Nickisch et al., *supra*, at 316-20)—if they make it at

all. "Only around 10 per cent of drugs entering development finally reach the market, and only 20 per cent of marketed drugs recover their investment." *Id.* at 310.

Investors are already fleeing to safer ground. Recent years have seen a "precipitous decline" in the relative share of funding for the patent-dependent pharmaceutical and biotech sectors. Mark F. Schultz, *The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies*, at 32-33 (2020), https://bit.ly/3o4HJlu (surveying venture-capital investment from 2004-2017). Within those industries, investment will likely further shift from foundational innovation—such as the discovery and validation of new biological pathways—to follow-on products. *See* Nickisch et al., *supra*, at 312 ("strategies using well-known and well-characterised drug substances and modifying them to create incremental value to patients are especially attractive."); Ulrich A.K. Betz, *How many genomics targets can a portfolio afford?*, 10 Drug Discovery Today 1057, 1062 (2005), https://bit.ly/31kUFd3.

The Federal Circuit's Section 112(a) jurisprudence is hastening investors' retreat from first-in-class innovation. Those who "invest[ ] in discovering a new molecule" are unlikely "to receive a patent broad enough to support the further costs of development." *Biotechnology's Uncertainty Principle*, *supra*, at 734-35. Facing those headwinds, the most innovative companies will increasingly abandon the expensive and uncertain work of true invention, instead stocking their R&D portfolios with marginally differentiated products that target pathways already validated by others.

To be sure, patent law should not provide overbroad protection to underdeveloped inventions. But enforcing the plain meaning of Section 112(a) would not do that. Factfinders have the common sense to decide, on a case-by-case basis, whether the scope of an inventor's claim is justified by the teaching she provides.

What is more, prompt disclosure is a social good. Early publication of patent applications adds to the body of knowledge that fuels further invention, including innovations that design around patented matter. *See In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977). If a follow-on inventor creates a product that improves on the innovation, patent protection is not foreclosed. *See* 35 U.S.C. § 101. If the public interest is better served by the imitator's product than it is by the enforcement of patent exclusivity, a district court can fashion a narrowly tailored injunction or refuse to grant an injunction under *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

Consistent with the Constitution's grant of power, "the patent laws 'promote the Progress of Science and useful Arts' by rewarding innovation with a temporary monopoly." *Festo*, 535 U.S. at 730 (quoting U.S. Const. art. I, § 8, cl. 8). There is no need to distort that innovation-driven system for fear that there will be insufficient price competition in the market for biopharmaceuticals. Congress has been active in devising mechanisms to increase access to lower-cost generics and biosimilars, without deeply disincentivizing innovation, by enacting the Hatch-Waxman Act, 21 U.S.C. § 355, in 1984, and the Biologics Price Competition and Innovation Act, 42 U.S.C. § 262, in 2009. These mechanisms themselves depend on a well-functioning patent system that spurs innovation;

without such a system, there would be fewer pioneering branded drugs from which to formulate cheaper generics and biosimilars. With companies increasingly eschewing higher-risk research in favor of chasing the same known biological targets, it is foundational innovation that is at risk.

The Federal Circuit has lost its way in interpreting Section 112(a). Getting it back on track would require only that this Court do what it usually does in patent law as in all areas of statutory interpretation: return to the text. The time to act is now—before additional investment and innovation in biopharmaceuticals is stymied, and while scientists in the field are on the cusp of making pathbreaking advances in treatment.

* * *

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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