No. 21-1566

IN THE

Supreme Court of the United States

JUNO THERAPEUTICS, INC., *ET AL.*,

Petitioners,

v.

KITE PHARMA, INC.,

Respondent.

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

BRIEF OF AMGEN INC., ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS (AUTM), INSTIL BIO, INC., CORNING INCORPORATED, BAVARIAN NORDIC A/S, AND GLAXOSMITHKLINE PLC AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

STUART L. WATT
WENDY A. WHITEFORD
STEVEN D. TANG
EMILY C. JOHNSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Counsel for Amgen Inc.

JEFFREY A. LAMKEN
Counsel of Record
MICHAEL G. PATTILLO, JR.
SARAH J. NEWMAN
WALTER H. HAWES IV
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Ave. N.W.
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

Counsel for Amici Curiae

(Additional Counsel Listed on Inside Cover)

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D.C. 20002

JOHN M. DESMARAIS
DESMARAIS LLP
230 Park Ave., 26th Floor
New York, NY 10169
(212) 351-3400
jdesmarais@desmaraisllp.com

Counsel for GlaxoSmithKline plc

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

IN THE

Supreme Court of the United States

JUNO THERAPEUTICS, INC., *ET AL.*,
Petitioners,

v.

KITE PHARMA, INC.,
Respondent.

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

BRIEF OF AMGEN INC., ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS (AUTM), INSTIL BIO, INC., CORNING INCORPORATED, BAVARIAN NORDIC A/S, AND GLAXOSMITHKLINE PLC, AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF *AMICI CURIAE*[1]

Amgen Inc. is one of the world's largest independent biotechnology companies. Amgen discovers, develops, manufactures, and delivers innovative therapeutics to treat patients suffering from cancer, kidney disease, heart

[1] All parties received timely notice of this brief, and all parties have consented to its filing. No counsel for a party authored this brief in whole or in part; no such counsel or party made a monetary contribution intended to fund the preparation or submission of the brief; and no person other than *amici*, their members, or their counsel made such a contribution.

disease, rheumatoid arthritis, and other serious illnesses. To develop these therapies, Amgen annually invests billions of dollars on research and development. Amgen relies on dependable patent protection to ensure a return on its investment.

AUTM is a non-profit organization dedicated to bringing research to life by supporting and enhancing the global academic technology transfer profession through education, professional development, partnerships, and advocacy. Instil Bio, Inc., is a biotechnology start-up focused on developing innovative cell and gene therapies for cancer patients.

Corning Incorporated is one of the world's leading innovators in materials science. For over 170 years, Corning has applied its unparalleled expertise in glass science, ceramic science, and optical physics to develop products that transform industries and enhance people's lives. Corning is home to one of the longest operating research laboratories in the United States. It invests in research, development, and engineering at a much higher rate than its peers and relies on patents to protect that investment.

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

GlaxoSmithKline plc is one of the largest and most innovative pharmaceutical companies in the world. GSK spends billions of dollars annually developing groundbreaking drugs, vaccines, and therapies. Those efforts have yielded breakthroughs in the fight against HIV, can-

cer, shingles, meningitis, asthma, diabetes, malaria, and other diseases.

Given their significant participation in and reliance upon the patent system, *amici* have a strong interest in ensuring that the Nation's patent laws are interpreted in an accurate and predictable manner consistent with the statutory text and this Court's precedent.

SUMMARY OF ARGUMENT

The U.S. patent system presents a bargain: In exchange for publicly disclosing their inventions, as well as how to make and use them, inventors receive the exclusive right to their inventions for a limited time. The Federal Circuit's interpretation of "written description" under 35 U.S.C. § 112 rewrites that bargain. The Federal Circuit's "possession" standard for written description strays far from the statutory standard and this Court's precedent. It imposes extra-statutory barriers to patent protection, and results in a shifting array of uncertain subtests that destabilize the incentives and certainty needed to drive the development of breakthrough inventions. This Court's review is warranted.

I. A. Section 112(a) of the Patent Act requires a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same * * * ." The statute thus requires a written description covering two topics—the invention, and how to make and use it. The statute also sets forth a single standard for the written description: It must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use" the invention.

Departing from that text, the Federal Circuit requires a different standard for the written description of the invention. The Federal Circuit holds that, to provide the required "written description of the invention," the patent must establish that the inventor had "possession of the claimed subject matter as of the filing date." That standard lacks any basis in the statutory text. And it imposes heightened burdens found nowhere within § 112.

B. The Federal Circuit's "inventor had possession" standard defies history and precedent. The language of what is now § 112 has not substantially changed in the last 200 years. Never in that history did the Nation's Patent Acts impose a "possession" requirement. Nor have the decisions of this Court.

II. A. The issue is exceptionally important. In an ongoing effort to give its "inventor had possession" test meaning, the Federal Circuit has over time developed a shifting array of subtests—*e.g.*, the "representative-species" test, "structure-function" test, and "common-structural features" test. The Federal Circuit provides little guidance on how to satisfy its subtests.

Innovation often requires substantial investment into research and development, in terms of both money and time. The promise of robust, predictable patent protection is vital to providing parties with the incentive to make those investments. The Patent Act cannot foster progress if the standard for the written description of the invention required by § 112 is a constantly moving and unknowable target.

B. The harmful effects of the Federal Circuit's atextual standard for written description are particularly acute in the biotechnology industry. Because biotechnology inventions can often be modified in countless minor ways without affecting their function, they face special challenges in

meeting the Federal Circuit's written-description standard. To even try to show that they have full "possession" of their invention, innovators may have to expend tremendous resources producing an exhaustive catalogue of every variation of the inventive product. And when one considers the cumulative effort required for *every* inventor to perform that work for *every* patent application, the costs imposed on the industry are truly staggering. That wastes resources that could be spent on further innovation. And it adds nothing to the store of scientific knowledge. The Federal Circuit's standard poses significant risks to the continued development of breakthrough drugs and therapies in this vitally important sector.

ARGUMENT

I. THE FEDERAL CIRCUIT'S "POSSESSION" STANDARD FOR THE WRITTEN DESCRIPTION OF THE INVENTION DEFIES TEXT, HISTORY, AND PRECEDENT

This Nation's patent laws reflect "a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). In exchange for disclosing their inventions, as well as how to make and use them, inventors are granted the exclusive right to those inventions for a limited time. *Ibid.* Section 112 of the Patent Act of 1952 spells out inventors' side of the bargain:

> 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 * * * to make and use the same * * * .

35 U.S.C. § 112(a).

This Court has repeatedly emphasized that the Patent Act is a statute and must be read as such. *Bilski* v. *Kappos*, 561 U.S. 593, 602-603 (2010). The Federal Circuit, however, has departed from § 112's text and this Court's precedent by creating its own *sui generis* standard for written description: whether the specification "reasonably conveys to those skilled in the art that the inventor had *possession* of the claimed subject matter as of the filing date." Pet. App. 7a (emphasis added) (quoting *Ariad Pharms., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). In an effort to give content to that abstract and amorphous concept, moreover, the Federal Circuit has adopted a shifting array of subtests. The uncertain and ever-changing nature of the Federal Circuit's approach to written description destabilizes patent law and, in the process, erodes the incentives needed to drive the development of breakthrough inventions. This Court's review is warranted.

A. The Federal Circuit's Standard for Written Description Strays from Statutory Text

1. Statutory construction must "[s]tart where the statute does." *SAS Inst. Inc.* v. *Iancu*, 138 S. Ct. 1348, 1355 (2018). Section 112(a) requires 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" skilled artisans "to make and use" the invention. 35 U.S.C. § 112(a). Those requirements are straightforward.

Section 112(a) begins by mandating a disclosure: The "specification *shall* contain a *written description*." It then identifies two subjects that must be included in the written description. First, the description must be "*of* the invention." Second, the description must be "*of* the manner and process of making and using" that invention. Finally, the

statute sets out the standard for evaluating the sufficiency of the written description: It must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the" invention. That standard applies whether the written description is addressing "the invention" or "the manner and process of making and using it."

The first requirement, a description "of the invention," demands that inventors provide a level of specificity regarding the claimed subject matter. The patentee must "describe his invention" sufficiently so that "others may construct and use it." *Schriber-Schroth Co.* v. *Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938). A specification does not reasonably "enable" skilled artisans "to make and use the invention" if it does not clearly explain to them, in the patent itself, what it is they are trying to make and use. The requirement of a description "of the invention" also ensures that the patentee has fully disclosed to the world the invention over which he seeks exclusivity. A patentee may not "claim[ ] more than he has sufficiently described" in the specification. *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 121 (1853).

The second requirement, a description "of the manner and process of making and using" the invention, is likewise pragmatic. The patent's disclosures must be "sufficiently definite to guide those skilled in the art to * * * successful application" of "the invention," *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 271 (1916), "point[ing] out some practicable way of putting [the invention] into operation," *The Telephone Cases*, 126 U.S. 1, 536 (1888).

2. The Federal Circuit has adopted a different interpretation of §112's written-description requirement. Insofar as the "written description" addresses "the invention," the Federal Circuit holds that the statutory "full,

clear, concise, and exact" standard does not apply. *Ariad*, 598 F.3d at 1344. Instead, the Federal Circuit has held, the "prepositional phrase 'in such full, clear, concise, and exact terms as to enable' * * * modifies *only* 'the written description . . . *of the manner and process of making and using* [the invention].'" *Ibid.* (second ellipsis and brackets in original) (emphasis added). Under that interpretation, however, § 112(a) itself provides *no standard* for evaluating "written description *of the invention*."

To fill the void it created, the Federal Circuit devised its own standard for evaluating the "written description of the invention": The "test for sufficiency," it declared, is "whether the disclosure of the application * * * reasonably conveys * * * that the *inventor had possession* of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351 (emphasis added); see Pet. App. 7a. That standard appears nowhere in § 112(a). "[M]ore than once," this Court has "cautioned" the Federal Circuit "that courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Bilski*, 561 U.S. at 602 (quotation marks omitted). Yet the Federal Circuit's construction does exactly that.

If Congress had intended the Federal Circuit's standard, § 112(a) would require two written descriptions: "a written description of the invention, in such terms as to show 'possession,'" *and* "a written description * * * of the manner and process of making and using" the invention "in such full, clear, concise, and exact terms as to enable" skilled artisans "to make and use" it. That is not the statute Congress wrote.

Attempting to give its "inventor had possession" test meaning, the Federal Circuit has over time developed an array of subtests—*e.g.*, the "representative-species" test, "structure-function" test, and "common-structural fea-

tures" test. See pp. 12-14, *infra*. As explained below, those subtests have no more basis in the text of § 112 than the "possession" standard. Nor are the subtests merely different verbal formulations of the statute's requirements. While the contours of those tests are ill-defined, it is clear that they demand patentees disclose additional and different information beyond a "description of the invention * * * in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use" it. 35 U.S.C. § 112(a); see pp. 12-14, *infra*. The Federal Circuit has "often applied" those subtests "to hold claims invalid." *Novozymes A/S* v. *DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

B. The Federal Circuit's Approach Defies History and This Court's Precedent

The Federal Circuit's standard defies § 112's history and this Court's precedent. The written-description requirement in § 112, and its predecessors dating back to the 1790 Act, share similar language.[2] But not one Patent Act in 230 years has required proof the "inventor had possession" as the standard for the specification's written description of the invention.

Nor have this Court's cases. They explain that, to constitute a sufficient written description "of the invention," the specification must "*describe [the] invention* so that others *may construct and use it* after the expiration of the patent." *Schriber-Schroth*, 305 U.S. at 57 (emphasis added). The Court has explained that, "[u]nder the modern American system," patents must "contain[ ] a specification *describing the invention* 'in such full, clear, concise, and

---

[2] See Act of Apr. 10, 1790, ch. 7, § 2, 1 Stat. 109, 110-111; Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321-322; Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119; Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198, 201.

exact terms as *to enable* any person skilled in the art . . . to make and use the same.'" *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (emphasis added). The Court has further clarified that a patentee "can lawfully claim only what he has * * * described" as the invention in the specification; "if he claims more his patent is void." *O'Reilly*, 56 U.S. (15 How.) at 121. Not once has this Court applied the "possession" standard as a metric for patent validity under § 112.

For example, in upholding Alexander Graham Bell's patent, this Court applied the statutory standard, not a diffuse "possession" test found nowhere in the Act. See *The Telephone Cases*, 126 U.S. at 536. It was "enough," this Court declared, that the inventor "describe[d] his method"—a method for "transmitting speech telegraphically"—"with sufficient clearness and precision to enable those skilled in the matter to understand what the process is" and "some practicable way of putting it into operation." *Ibid.*; see also *Le Roy* v. *Tatham*, 63 U.S. (22 How.) 132, 138-139 (1860) (upholding patent where "the machinery described" was "sufficiently explicit to show the nature of the invention" and how "to produce" the desired "result[ ]"). Conversely, the Court struck down Samuel Morse's patent claim seeking to cover "the use of * * * electromagnetism, *however developed*, for making or printing intelligible characters, letters, or signs, at any distances," because he "claim[ed] more than he sufficiently described" as the actual invention in the specification. *O'Reilly*, 56 U.S. (15 How.) at 86, 121 (emphasis added). In neither case did the Court ask whether the patentee had "possession" of the invention.

Before the Federal Circuit's creation, the regional courts of appeals hewed to statutory text as well. They understood that § 112 requires that "the patentee shall

make 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) (ellipses in original) (emphasis added); see also *Philip A. Hunt Co.* v. *Mallinckrodt Chem. Works*, 177 F.2d 583, 585 (2d Cir. 1949) (similar); *Ill. Tool Works, Inc.* v. *Foster Grant Co.*, 547 F.2d 1300, 1309 (7th Cir. 1976) (similar). None imposed proof of "possession" as the written-description standard.

For at least a decade after the 1952 Act was enacted, the Federal Circuit's predecessor also adhered to the statutory standard.[3] Early cases understood that the "essence" of § 112 "is that a specification shall disclose *an invention* in such a manner as will enable one skilled in the art to make and utilize it." *In re Gay*, 309 F.2d 769, 772 (C.C.P.A. 1962) (emphasis added). The Federal Circuit's departure from that precedent warrants review.

II. THE ISSUE IS EXCEPTIONALLY IMPORTANT

The Federal Circuit's "inventor had possession" standard for written description of the invention under § 112 has spawned a series of indeterminate and ever-changing subtests. The practical consequences are severe, especially in the biotechnology industry where uncertain application of the standard threatens to curtail development of

---

[3] See, *e.g.*, *In re Ruschig*, 379 F.2d 990, 994-996 (C.C.P.A. 1967) (description "*of the invention*" insufficient because it failed to clearly convey the claimed compound to those skilled in the art); *In re Dileone*, 436 F.2d 1033, 1034 (C.C.P.A. 1970) (affirming Patent Office decision rejecting patent for failing to "point out the disclosed invention," holding the disclosure insufficient for failing to describe full class of claimed polyimides); *Fields* v. *Conover*, 443 F.2d 1386, 1391-1392 (C.C.P.A. 1971) (disclosure insufficient because it lacked "full, clear, concise, and exact" description of the claimed compounds).

life-saving drugs. These problems have become increasingly pressing. The Federal Circuit's "possession" jurisprudence continues to fracture incomprehensibly, with significant costs for innovation.

A. The Federal Circuit's Ever-Changing Standards Impede Innovation

1. Even as the Federal Circuit cemented its "possession" standard for written description of the invention en banc in *Ariad*, the court admitted that the possession standard "has never been very enlightening." 598 F.3d at 1351. Indeed, "possession" is particularly misleading insofar as it suggests the patentee must actually have reduced the invention to practice, something § 112 "does not demand." *Id.* at 1352. It is no wonder that the Federal Circuit's decisions creating a new "possession" standard for the "written description of the invention," later enshrined in its en banc decision in *Ariad*, *id.* at 1351, prompted a wave of dissents and intense academic criticism.[4]

Unmoored from statutory text, the Federal Circuit's "possession" standard has continued to drift erratically. It has metastasized into unstable judicial subtests also not found in the statute. For example, *Ariad* held that, where the claim covers a "genus" of pharmaceutical compounds,

---

[4] See, *e.g.*, *Enzo*, 323 F.3d at 976 (Rader, J., dissenting from denial of rehearing en banc); *id.* at 987 (Linn, J., dissenting from denial of rehearing en banc); *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, 1314-1325 (Fed. Cir. 2004) (Rader, J., dissenting from denial of rehearing en banc) (listing myriad scholarly articles); *id.* at 1325 (Linn, J., dissenting from denial of rehearing en banc); *LizardTech, Inc.* v. *Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting from denial of rehearing en banc); *Ariad*, 598 F.3d at 1361-1362 (Rader, J., dissenting-in-part).

"possession" may be demonstrated by "disclosure of either" "a representative number of species falling within the scope of the genus," or "structural features common to the members of the genus." 598 F.3d at 1350. Section 112(a) does not mention, much less require, such disclosures.

The Federal Circuit provides little guidance on how to satisfy its subtests. For example, "a representative number of species" does not mean disclosure of some specified "number" of embodiments. *Ariad*, 598 F.3d at 1350. Instead, the applicant must demonstrate possession of the "structural diversity of the claimed genus" by identifying an array of sufficiently exemplifying embodiments, *AbbVie Deutschland GmbH & Co., KG* v. *Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014)—whatever that means. Patentees cannot reliably predict when the Federal Circuit will deem the test satisfied. In "some cases," the Federal Circuit has found that "broad or generic disclosures can adequately describe particular constituent species." *Novozymes*, 723 F.3d at 1347. But in *AbbVie*, the Federal Circuit held that describing the amino-acid sequences of 300 antibodies was insufficient because they did not "qualitatively represent other types of antibodies encompassed by the genus." 759 F.3d at 1300. Patent applicants have little idea what disclosures the Federal Circuit will find sufficient to satisfy the representative-species test, because its recent decisions only show what will fail it and the test is a constantly moving target.

The Federal Circuit has applied the common-structural-features test in a similarly unpredictable manner. The court initially required a chemical genus to be precisely described by reference to chemical structure, formula, or chemical name. See *Regents of the Univ. of Cal.* v. *Eli Lilly & Co.*, 119 F.3d 1559, 1568-1569 (Fed. Cir. 1997). It

then held that disclosure of the *function* to be achieved would suffice when "coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." *Enzo Biochem, Inc.* v. *Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). But the court failed to provide any meaningful guidance on what degree of "correlation" is required. Compare *Noelle* v. *Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004), with *Amgen Inc.* v. *Sanofi*, 872 F.3d 1367, 1377-1379 (Fed. Cir. 2017).

The Federal Circuit's extra-statutory standards are so unstable that they do not merely evolve; the Federal Circuit itself overturns them. For example, starting in 2002, the Federal Circuit adopted a written-description standard that was specific to antibody-related inventions. The court held that, under its "newly characterized antigen" test, *Amgen*, 872 F.3d at 1377, inventors could claim an antibody (1) by fully describing the antigen to which the antibody binds, (2) so long as generating the claimed antibody would be routine for those skilled in the art, *Enzo*, 323 F.3d at 964; see *Noelle*, 355 F.3d at 1349; *Centocor Ortho Biotech, Inc.* v. *Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011). The Patent Office adopted that standard, see MPEP §2163(II)(A)(3)(a) ¶5 (9th ed., rev. July 2015), inventors tailored their patent applications to satisfy that standard, and the Patent Office issued thousands of patents consistent with that standard, *Ex Parte Dickson*, No. 2007-4125, 2007 WL 5108541 (B.P.A.I. Nov. 5, 2007). Despite significant reliance on that standard for 15 years, the Federal Circuit had no difficulty reversing course and holding that describing the antigen is *not* sufficient, sloughing off its precedent as "dicta." *Amgen*, 872 F.3d at 1376 (remanding for a new trial with jury instructions under *Ariad*'s "possession" subtests).

2. Path-marking innovations often require billions of dollars of investment and years of research and development. The promise of robust "patent protection is vital" to provide companies the incentives to make those investments. K. Stone, *Written Description After* Ariad v. Eli Lilly*: 35 USC § 112's Third Wheel*, 11 J. High Tech. L. 191, 228 (2010). The Patent Act cannot foster progress if the standard for the written description of the invention required by § 112 is a constantly moving target.

One of the justifications for the Federal Circuit's creation was to "reduce the * * * uncertainty of legal doctrine" that undermines incentives to innovate. *Christianson* v. *Colt Indus. Operating Corp.*, 486 U.S. 800, 813 (1988). But the Federal Circuit's treatment of written description—"at worst indecipherable, and at best unruly"—continues to thwart the predictability and consistency in patent law necessary to spur innovation. M. 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); C. Holman, *Developments in Synthetic Biology Are Altering the IP Imperatives of Biotechnology*, 17 Vand. J. Ent. & Tech. L. 385, 412-413 (2015) (critiquing written-description standard as a "doctrinal wildcard" creating "uncertainty" in biotechnology). The Federal Circuit's creation of a vast "zone of uncertainty" that "discourage[s] invention" underscores the need for review. *United Carbon Co.* v. *Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

B. The Federal Circuit's Atextual Standard Has a Disparate Impact on Biotechnology

1. Although this Court has warned against technology-specific applications of the Patent Act, see *Bilski*, 561 U.S. at 605 (plurality opinion), the Federal Circuit's "possession" standard and subtests for written description impose

unique barriers on biotechnology—barriers that would be "inconceivable in other industries," D. Burk & M. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1653-1654 (2003); see D. Karshtedt *et al.*, *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 39-46, 53 (2021) ("extra hurdle for biotechnological inventions"); C. Nard & J. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 Nw. U. L. Rev. 1619, 1664 (2007) (tests "erect[ ] a more demanding disclosure standard for biotechnology-related inventions"); D. Kelly, *The Federal Circuit Transforms the Written-Description Requirement into a Biotech-Specific Hurdle To Obtaining Patent Protection for Biotechnology Patents*, 13 Alb. L.J. Sci. & Tech. 249, 250 (2002). That is extremely problematic, given that "[p]harmaceutical, biotechnology, and chemical companies rely more heavily on the patent system than do other industries." Karshtedt, *supra*, at 3; see C. Holman, *For Monoclonal Antibodies, Compliance with the Written Description Requirement Has Become a Moving Target*, 36 Biotech. L. Rep. 273, 273 (2017) ("[E]ffective patent protection" is "an important consideration in a company's decision to develop new monoclonal antibody-based products.").[5]

Indeed, the biotechnology inventions most deserving of patent protection—the genuine breakthroughs with the

[5] See also Testimony of Robert Deberardine (Chief IP Counsel at Johnson & Johnson) before the Senate Committee on the Judiciary Subcommittee on Intellectual Property (June 11, 2019) ("Without a predictable patent system, * * * many new medicines would go undiscovered."), https://perma.cc/3BM3-WHBM; D. Ware & N. Littlefield, Foley Hoag LLP, *Follow-on Biologics and Patent Reform: Will They Discourage Venture Capital Investment in the Biotechnology Industry?*, at 3 (2009) ("[W]ithout assurance that there exists adequate market exclusivity to allow a successful biologic product to earn adequate profits, [venture capital] investors * * * will be hesitant to direct their funds [to biotech]."), https://perma.cc/L5ZY-QPMQ.

broadest applications—are the least likely to survive the Federal Circuit's "possession" standard for written description of the invention. In the biotechnology industries, significant breakthroughs often involve identifying the mechanism for producing a desired effect and making a working substance, like an antibody, that achieves the effect. That mechanism, however, may have the same effect when implemented in any number of structurally similar variations. Antibodies, for example, are often composed of chains of hundreds of amino acids, many of which can be substituted through routine and well-known processes without altering function. See *Moba*, 325 F.3d at 1325 (Rader, J., concurring); see also R. Lu *et al.*, *Development of Therapeutic Antibodies for the Treatment of Diseases*, 27 J. Biomed. Sci. 1, 22 (2020) (describing how "antibody engineering" has "dramatically evolved" since 1986).

First-movers often seek to protect such inventions through so-called "genus" claims, which "use functional language or generic formulas to cover individual embodiments of the invention, or species, that share a common attribute or property." Karshtedt, *supra*, at 13. The larger the number of species within a genus claim, however, the more likely it is to flunk the Federal Circuit's "possession" standard—without regard to whether the patent describes the invention sufficiently for skilled artisans to make and use those species. Accused infringers will always be able to argue that the "representative number of species" disclosed in the patent as "falling within the scope of the genus," *Ariad*, 598 F.3d at 1350, is somehow not representative *enough*. And the Federal Circuit seems predisposed to agree. See p. 13, *supra*.

The Federal Circuit would seem to demand "tedious" rote development and "disclosure of thousands of potential permutations" just to prove the diversity of species in the

inventor's "possession"—requirements that would be unthinkable for software inventions or mechanical arts. *Moba*, 325 F.3d at 1325 (Rader, J., concurring). Due to inherent variability and the large number of modifications that can be made to biotechnology inventions, providing a detailed disclosure of every single member of a genus would be impossible without years' worth of labor- and cost-intensive work. That escalates costs and uncertainty for all biotechnology innovators and may price smaller innovators (like universities and start-ups) out of the field entirely. *Id.* at 1326; see C. MacDougall, *The Split over Enablement and Written Description: Losing Sight of the Purpose of the Patent System*, 14 Intell. Prop. L. Bull. 123, 139-140 (2010). And when one considers the cumulative effort required for *every* inventor to perform that work for *every* patent application, the costs imposed on the industry are truly staggering.

The demand for such detailed disclosure does not serve the inventive purposes of the Patent Act or "promote the Progress of Science." U.S. Const. art. I, §8, cl. 8. Once the invention has been described sufficiently for skilled artisans to make and use it, disclosing hundreds or thousands more examples of variations that achieve the same result contributes nothing significant to the store of human knowledge. Such brute-force generation of minor variants is often non-inventive in the biotechnology industry. First-movers (including universities and start-ups) should not have to conduct laborious and wasteful work to generate and characterize additional embodiments for no purpose other than to satisfy the Federal Circuit's poorly conceived standard. And innovators that would attempt the task would have to zealously guard their invention until they have completed the laborious undertaking of making as many embodiments as possible,

so as not to risk losing priority on their patent application. That is the opposite of what the Patent Act seeks to achieve: "[F]oster[ing] concealment rather than disclosure of inventions" is contrary to "one of the primary purposes of the patent system." *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950). As leading research hospitals have explained, "patients" are the ones who "will lose" as a result. City of Hope Amicus Br., *Juno Therapeutics, Inc.* v. *Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021) (No. 20-1758), 2021 WL 5358934.

2. The Federal Circuit's heightened standard for written description also creates a free-rider problem. If biotechnology innovators cannot obtain patent protection for the full genus they invented, they will have to limit patent claims to particular species or members of the class. But that allows copyists to easily "avoid infringement" by making a "minor change" to the claimed species while "still exploiting the benefits of [the] invention." *Enzo*, 323 F.3d at 966.

Such follow-on products add nothing to scientific progress or patient outcomes. Instead, they profit from the patentee's invention without any significant scientific contribution of their own. "The overall risk profiles of these [copycat] projects [are] quite favourable because the scientific and clinical proof of concept [have] already been delivered by another company * * * ." K. Nickisch *et al.*, *How Can Pharmaceutical and Biotechnology Companies Maintain a High Profitability?*, 15 J. Com. Biotech. 309, 311 (2009). In a field where success requires years of research and, on average, a $2.56 billion investment to bring a new product to market, such free-rider issues are destructive to innovation. See J. DiMasi *et al.*, *Innovation in the Pharmaceutical Industry: New Estimates of R&D*

Costs, 47 J. Health Econ. 20, 20 (2016); Nickisch, *supra*, at 316-320 (describing how just 10 percent of drugs reach the market and only 20 percent of marketed drugs recoup their investment).

The societal costs are obvious and overwhelming. Without a patent system focused on promoting "progress," there will be fewer pioneering drugs and therapies on the market. Companies will increasingly eschew high-risk research that addresses the most pressing and challenging medical problems in favor of chasing certain returns in the form of redundant therapeutics to known biological targets. But without any investment or appetite for innovation, the stock of new therapeutics to replicate will dry up. By some indications, this withdrawal from the forefront of biotechnology research is already playing out, with a "precipitous decline" in relative funding for the patent-dependent biotechnology sector. M. Schultz, *The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies* 32-33 (2020).

The nation's leading biopharmaceutical innovators have been ringing the alarm regarding the harmful effects of the Federal Circuit's "possession" standard for written description. See, *e.g.*, Amicus Br. of Bristol-Myers Squibb Co., Morphosys AG, Bavarian Nordic A/S, and UCB Biopharma SPRL, *Amgen Inc.* v. *Sanofi*, No. 18-127 (U.S. filed Aug. 27, 2018); GlaxoSmithKline Amicus Br., *Idenix Pharms. LLC* v. *Gilead Scis., Inc.*, No. 20-380 (U.S. filed Nov. 16, 2020); Amgen Inc. Amicus Br., *Idenix Pharms. LLC* v. *Gilead Scis., Inc.*, No. 20-380 (U.S. filed Nov. 16, 2020). The Federal Circuit's tests have left "the patent bar at sea without a reliable compass." *Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 572 U.S. 898, 912 (2014). The time for this Court's review is now.

CONCLUSION

The petition should be granted.

Respectfully submitted.

STUART L. WATT
WENDY A. WHITEFORD
STEVEN D. TANG
EMILY C. JOHNSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Counsel for Amgen Inc.

JOHN M. DESMARAIS
DESMARAIS LLP
230 Park Avenue, 26th Floor
New York, NY 10169
(212) 351-3420

Counsel for GlaxoSmithKline plc

JEFFREY A. LAMKEN
Counsel of Record
MICHAEL G. PATTILLO, JR.
SARAH J. NEWMAN
WALTER H. HAWES IV
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Ave., N.W.
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

Counsel for Amici Curiae

JULY 2022