No. 21-___

IN THE

Supreme Court of the United States

JUNO THERAPEUTICS, INC.; SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,

Petitioners,

v.

KITE PHARMA, 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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QUESTION PRESENTED

Section 112(a) of Title 35, United States Code, requires that a patent include a "specification," which "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."

The question presented is:

Is the adequacy of the "written description of the invention" to be measured by the statutory standard of "in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the same," or is it to be evaluated under the Federal Circuit's test, which demands that the "written description of the invention" demonstrate the inventor's "possession" of "the full scope of the claimed invention," including all "known and unknown" variations of each component?

PARTIES TO THE PROCEEDING

Petitioners Sloan Kettering Institute for Cancer Research ("Sloan Kettering") and Juno Therapeutics, Inc. ("Juno") were plaintiffs-appellees in the Federal Circuit below. Respondent Kite Pharma, Inc. ("Kite") was a defendant-appellant in the Federal Circuit below.

CORPORATE DISCLOSURE STATEMENT

Sloan Kettering does not issue stock and has no corporate parent. Juno is a wholly owned subsidiary of Celgene Corporation. Celgene Corporation is a wholly owned subsidiary of Bristol Myers Squibb Company. Other than the listed entities, no publicly held corporation owns 10% or more of the stock of Juno or its corporate parents.

STATEMENT OF RELATED PROCEEDINGS

Present Patent Infringement Litigation:

United States District Court for the Central District of California:

Juno Therapeutics, Inc. v. Kite Pharma, Inc., No. 2:17-cv-7639 (judgment entered April 8, 2020)

United States Court of Appeals for the Federal Circuit:

Juno Therapeutics, Inc. v. Kite Pharma, Inc., No. 20-1758 (judgment reversed August 26, 2021; rehearing petition denied January 14, 2022)

Inter Partes Review:

Patent Trial and Appeal Board:

Kite Pharma, Inc. v. Sloan Kettering Institute for Cancer Research, No. IPR2015-01719 (Final Written Decision holding challenged claims of

U.S. Patent No. 7,446,190 not unpatentable issued December 16, 2016)

United States Court of Appeals for the Federal Circuit:

Kite Pharma, Inc. v. Sloan-Kettering Institute for Cancer Research, No. 17-1647 (Board decision summarily affirmed June 24, 2019)

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

CONSTITUTIONAL AND STATUTORY AUTHORITIES

TABLE OF AUTHORITIES
(continued)

Page(s)

OTHER AUTHORITIES

INTRODUCTION

This case concerns a provision of American patent law that has existed since the first Patent Act of 1790. Now located in 35 U.S.C. § 112(a), this provision prescribes what an inventor's "specification" must disclose to the public to obtain a patent: "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." This provision embodies the "carefully crafted bargain," *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998), that lies at the core of patent law: In exchange for a limited period of exclusivity, inventors must disclose their invention to the public. The question presented here is this: What scope of disclosure does § 112(a) require?

No modern case of this Court has turned on this question. But the Court has been consistent, throughout its history, in understanding Congress's language to require exactly what it says: Inventors must provide a written description of their invention in a way that enables a skilled worker "to make and use" it. Thus, "it is enough 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, 535-36 (1888). More recently, the Court has likewise stated that "Section 112 requires only a 'written 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 the same.'" *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012) (ellipses in original; quoting § 112).

The Federal Circuit, however, demands otherwise. Even though the statute plainly says that the measure of the "written description of the invention" is whether it allows skilled workers to make and use the invention, that court has burdened the straightforward textual provision with convoluted, judicially crafted requirements that the patent show the inventor "possessed the full scope of the claimed invention," including all "known and unknown" variations of individual components.

The consequences of this judicial embroidery have been devastating for innovation. It has led the Federal Circuit to invalidate numerous patents by demanding the impossible. The effect has been particularly lethal in the biological arts, where it "represents both bad law and bad policy" and "may threaten innovation." Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim ("KLS")*, 35 Harv. J. L. & Tech. 1, 1, 4 (2021).

This case is the poster child for those devastating consequences. It involves the erasure of patent protection for a lifesaving technology in the CAR-T therapy field. In this field, the "T" is a "T-cell," an immune cell native to the human body. And the "CAR" is a "chimeric antigen receptor," made up of one or more "signaling domains" that kill cancer cells, along with a "binding element"—usually a "single chain variable fragment" ("scFv")—that attaches the

CAR-T cell to the cancer cell so that the signaling domains can kill it. In CAR-T therapy, T-cells are extracted from a patient's blood, the CAR is inserted, and the newly formed CAR-T cells are replicated in the laboratory and then returned to the patient's body to kill the targeted cancer cells.

Led by Dr. Michel Sadelain, a team of Sloan Kettering inventors developed a CAR that did even more. Their inventive advance was the addition of a specific second signaling domain that allowed the creation of CAR-T cells that not only kill cancer cells in the body, but also replicate, building an army of CAR-T cells inside the patient that will destroy even more cancer cells. Sloan Kettering's invention has thus been hailed as the world's first "living drug."

No one disputes that the patent granted to the Sloan Kettering team for this groundbreaking invention adequately describes the two claimed signaling domains—indeed, it discloses the precise nucleotide sequence of each of them. The Sloan Kettering patent also describes scFvs as "[k]nown binding elements," and their production as "routine." So routine, in fact, that the patent cited an article published over a decade earlier by Orlandi et al. that taught a process for creating these binding elements for any target of interest, a process successfully followed by a laboratory employee who had been hired to wash dishes and wanted to try his hand at making scFvs.

When Kite, a rival company, copied Dr. Sadelain's invention and rushed its product to market, Sloan Kettering and its exclusive licensee, Juno, sued Kite for infringement. At trial, Kite sought to avoid

liability by challenging Sloan Kettering's patent as invalid, but the jury disagreed. The jury also found Kite's infringement willful, and awarded close to a billion dollars in damages.

The Federal Circuit, however, reversed the judgment as a matter of law on the ground that Sloan Kettering's patent failed that court's atextual "written description" requirement as to the well-known "binding element" component of the claims. In the Federal Circuit's view, it was not enough for Sloan Kettering's patent to teach skilled workers to make and use the binding element; the patent had to additionally demonstrate that the inventors "possessed," in some amorphous sense, the "full scope" of their claimed invention at the time of application, including all possible binding elements, "known and unknown." Particularly for inventions in the biological sciences, such a "possession" test is simply impossible to meet. And, since the same statute governs all patents, the problems with this atextual interpretation affect all kinds of technologies.

The Court should grant certiorari. The Federal Circuit's approach contravenes the plain statutory text and is erasing vast swaths of patents for failing to satisfy a disclosure standard found nowhere in the statute. And because the Federal Circuit has exclusive jurisdiction over patent appeals, 28 U.S.C. § 1295, no other court of appeals will be able to address this question.[1]

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[1] In *Amgen Inc. v. Sanofi* (No. 21-757), this Court has called for the Solicitor General's views on the very same statute, albeit with respect to the Federal Circuit's distinct "enablement" requirement. Because both cases involve the same sentence in

OPINIONS BELOW

The Federal Circuit's opinion (Pet.App.1a-22a) is reported at 10 F.4th 1330. The opinion of the U.S. District Court for the Central District of California denying Kite's post-trial motion for judgment as a matter of law (Pet.App.26a-81a) is unreported but available at 2020 WL 10460622. The jury verdict (Pet.App.82a-84a) is unreported. The district court's judgment (Pet.App.23a-25a) is unreported. The Federal Circuit's order denying rehearing (Pet.App.85a-86a) is unreported.

JURISDICTION

The Federal Circuit issued its opinion on August 26, 2021, and denied Plaintiffs' timely rehearing petition on January 14, 2022. On March 7, 2022, Chief Justice Roberts granted an extension of time to file this petition by June 13, 2022. No. 21A461 (U.S.). Jurisdiction in this Court exists under 28 U.S.C. § 1254(1).

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the statute, the Court may also wish to call for the Solicitor General's views here prior to granting review.

STATUTORY PROVISION INVOLVED

35 U.S.C. § 112 states, in relevant part[2]:

(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.

(b) Conclusion.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

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[2] Although the pre-America Invents Act ("AIA") version of § 112 governs this case, the AIA left the statute's operative language unchanged. *Compare* 35 U.S.C. § 112(a)-(b) (post-AIA), *with* 35 U.S.C. § 112, ¶¶ 1-2 (pre-AIA); *see generally Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1341 n.5 (Fed. Cir. 2021) (AIA's amendments "bear no significance for purposes of [the Federal Circuit's] written-description analysis"). For ease of reference, this petition generally refers to the AIA version's lettered sections.

STATEMENT

A. The Patent System's Fundamental Quid Pro Quo

The American patent system rests on the Constitution's Intellectual Property Clause, which gives Congress the "Power … To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. 1, § 8, cl. 8. The Framers' insight that incentives are essential to innovation underlies the patent system's fundamental quid pro quo: the inventor teaches the public to make and use the invention, and the public gives the inventor the exclusive right to make, use, and profit from it for a limited period of time.

To effectuate this bargain, Congress has consistently required that a patent application contain written disclosures allowing skilled artisans to make and use the invention. This requirement, which has existed in substantially the same form since George Washington's presidency, involves "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); *see* Patent Act of 1793 § 3, 1 Stat. 318, 321 ("written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to … enable any person skilled in the art or science … to make, compound, and use the same").

Initially, the patent statutes contained no separate requirement for patent "claims" as that term is now used, so the written description itself also "distinguish[ed] the [invention] from all other things before known" and set out the invention's boundaries. *See* Patent Act of 1793 § 3, 1 Stat. at 321. Over time, though, the numbered "claim" format developed and became cemented as a separate statutory requirement.

Now housed in 35 U.S.C. § 112(b), the claim requirement states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." That provision traces back to 1836. *See* Patent Act of 1836 § 6, 5 Stat. 117, 119 (directing inventors to "particularly specify and point out the part, improvement, or combination, which [they] claim[] as [their] own invention or discovery"). Meanwhile, § 112(a) maintains essentially the same language regarding an enabling written disclosure from the pre-1836 Patent Act: "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."

Thus, as this Court explained in a case involving the claim requirement, "[u]nder the modern American system," these disclosure "objectives are served by two distinct elements of a patent document." *Markman v. Westview Instruments*, 517 U.S. 370, 373 (1996). The first is "a specification describing the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the

same.'" *Id.* (quoting 35 U.S.C. § 112, ¶ 1 (pre-AIA), now § 112(a)). And the second is "one or more 'claims,' which 'particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention.'" *Id.* (quoting 35 U.S.C. § 112, ¶ 2 (pre-AIA), now § 112(b)) (brackets in original). Patent applications may also contain nucleotide or amino-acid "sequence listings" relevant to an invention, 37 C.F.R. § 1.821. Although claims and sequence listings are technically part of the "specification," 35 U.S.C. § 112(b); 37 C.F.R. § 1.821(c), courts often use the term "specification" to refer to just the inventor's written disclosure. *E.g.*, *Markman*, 517 U.S. at 373 (distinguishing between the "specification" and the "claims").

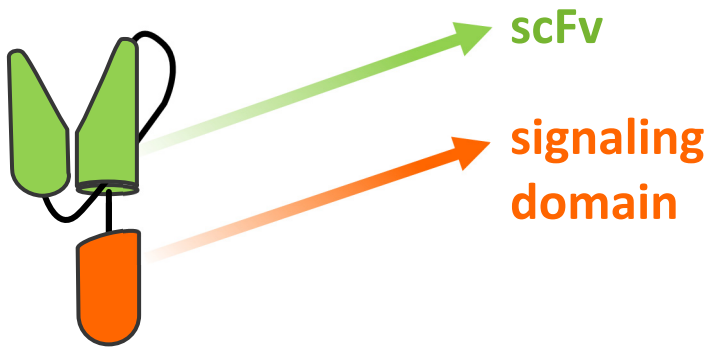
In addition to § 112's requirements, the Patent Act defines the scope of patent-eligible inventions, 35 U.S.C. § 101, and requires that claimed inventions be novel, *id.* § 102, and nonobvious, *id.* § 103. This Court has recently interpreted each of these cornerstone Patent Act provisions. *E.g.*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) (§ 101); *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S. Ct. 628 (2019) (§ 102); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (§ 103). So too has it interpreted the claim requirement now found in § 112(b). *Markman*, 517 U.S. 370. But § 112(a) and its predecessors have escaped the Court's attention.

B. Sloan Kettering's Invention

1. Dr. Michel Sadelain directs the Center for Cell Engineering at Sloan Kettering and is the lead

inventor on Sloan Kettering's patent. He is a world-recognized expert in CAR-T therapy.

Early CARs, which date to the 1990s, had two components.



The first component was a "signaling domain," which activates the cancer-bound T-cell to destroy the cancer cell.

The second component in these early CARs was an scFv, an antibody-derived component that pairs with a protein called an antigen on the surface of cancer cells and attaches—in CAR lingo, "binds"—the CAR-T cell to the cancer cell. scFvs were well-known biological tools, including as binding elements in CARs, long before Sloan Kettering's patent. *E.g.*, C.A.App.33931-33935; C.A.App.35766-35768. For example, a 1989 paper by Orlandi et al. provided the "cookbook" or "recipe" to make scFvs that would bind to any target antigen (the "Orlandi method"). C.A.App.36185-36189.

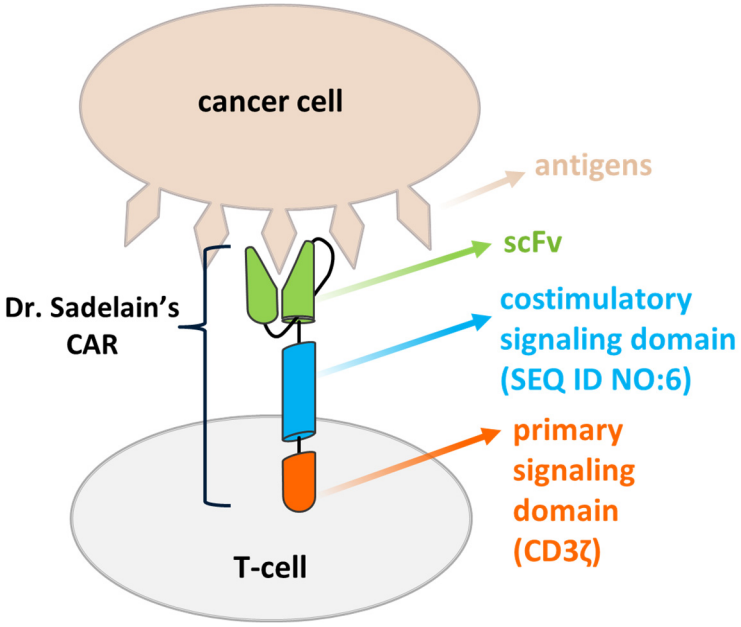
Although these early CARs allowed T-cells to bind to targeted antigens, the signaling domain failed to produce sufficiently robust immune responses to

successfully treat the cancer. Researchers, including Dr. Sadelain and his co-inventors, sought to improve upon the early CARs' signaling domain by adding another amino-acid sequence to stimulate a better immune response. The original signaling sequence became known as the "primary signaling domain," and the newly added signaling sequence became known as the "costimulatory signaling domain," with both together called the "backbone." The other component—unchanged from earlier CARs—was the scFv for binding.

2. Dr. Sadelain's groundbreaking invention was his use of a particular amino-acid sequence as the backbone's costimulatory domain. Although the field believed this sequence would not work in this role, Dr. Sadelain's remarkable two-part backbone not only killed the targeted cancer cells, but also caused the CAR-T cells to replicate, creating a growing army of CAR-T cells to kill even more cancer cells. Dr. Sadelain's invention was celebrated as the world's first "living drug" because its cancer-treating CAR-T cells reproduce in the patient's body, bolstering the patient's own immune system and creating a sustained anti-cancer effect. C.A.App.32913-32914, 33930.

In 2008, the Patent Office granted a patent to Dr. Sadelain and his team; their employer, Sloan Kettering, became the assignee. The claims at issue recite three elements:

1. "a zeta chain portion comprising the intracellular domain of human CD3 ζ chain" (the primary signaling domain). Pat.App.23b.
2. "a costimulatory signaling region" that "comprises the amino acid sequence encoded by SEQ ID NO:6." *Id.*
3. "a single chain antibody" (*i.e.*, scFv) "binding element that specifically interacts with a selected target," further limited in two asserted claims to an scFv that "binds to CD19," an antigen associated with blood cancer. *Id.*



This patent epitomizes the enabling of a skilled artisan to make and use the invention. Its sequence listings disclose the precise nucleotide sequence for both signaling elements of the backbone. And although the scFv binding element remained unchanged from the prior art, and the patent describes it as "known" and its making as "routine," the patent's specification nevertheless provides examples of scFvs, including one that binds to the CD19 protein found on blood cancer cells. Pat.App.12b, 14b. It also describes the Orlandi method for making additional scFvs for binding the inventive two-part backbone to other cancer-cell antigens, and cites and incorporates Dr. Orlandi's article by reference. Pat.App.12b.

C. Kite's Willful Infringement

Unbeknownst to Sloan Kettering, its invention was being copied and exploited by Kite, a commercial manufacturer. As scientists at nonprofit research institutions often do, Dr. Sadelain had shared information about the invention with the National Cancer Institute ("NCI"). C.A.App.32929-32931, 32934. He was unaware that NCI would later share his invention with Kite, and that Kite would pursue a commercial embodiment of his invention. Kite, though, knew it needed Dr. Sadelain's inventive backbone, and Kite's product, Yescarta, copied it.

Kite eventually sought a license from Sloan Kettering so that it could use the technology legitimately. Sloan Kettering, however, chose to exclusively license the patent to Juno, an entity founded by experts affiliated with various research institutions.

When Kite's licensing attempts failed, it tried to avoid infringement liability by seeking to invalidate the patent through the AIA's *inter partes* review mechanism. The Patent Office rejected Kite's challenge and reaffirmed the patent grant. The Federal Circuit summarily affirmed the Patent Office's decision, and Kite did not seek this Court's review.

After it failed to license or invalidate the patent, Kite barged ahead and "chose to accelerate [its infringing product] YESCARTA® to market to its own advantage and to Plaintiffs' corresponding detriment, all while knowing that Plaintiffs' assertion of the Patent in this litigation was … 'inevitable.'" C.A.App.42. Kite's pirated use of Sloan Kettering's invention allowed it to exploit a first-mover advantage in the market. Kite leveraged that advantage into a lucrative $11.9 billion buyout from Gilead Sciences, one of the world's largest pharmaceutical companies.

D. The Federal Circuit Applies Its "Written Description" Test And Overrides The Work Of The Patent Office, The Jury, And The District Court

1. Once Kite commercially launched Yescarta, Sloan Kettering and Juno sued Kite for infringement. Kite stipulated that Yescarta literally infringes the patent, C.A.App.7706-7709, but argued the patent was invalid because, in Kite's view, it did not satisfy the Federal Circuit's written-description standard.[3]

[3] Kite also argued that it did not infringe if the "Certificate of Correction" the Patent Office issued in 2013 to correct a typographical or clerical error regarding the costimulatory

As noted above, the Federal Circuit interprets § 112(a) to require not only an enabling written description of the invention and manner and process of making and using it, but also, as a "separate" requirement, that the inventor demonstrate "possession" of the "full scope" of the invention, including every possible variation of each component. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014). For so-called "genus" claims,[4] the Federal Circuit's "possession" test asks whether the patent "disclos[es] … 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." *Ariad*, 598 F.3d at 1350.

The Federal Circuit's inventor-possession test originated in cases from the Court of Customs and Patent Appeals, and then from the Federal Circuit itself, involving questions of timing—for example, the

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signaling domain was invalid, and that the patent did not satisfy the Federal Circuit's "enablement" test, which requires that "the specification teach those in the art to make and use the invention without undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The jury and district court rejected these arguments, and the Federal Circuit did not reach them.

[4] A "genus claim" "covers a group of structurally related products that incorporate the basic advance of the patented invention." *KLS*, *supra*, 35 Harv. J. of L. & Tech. at 3. They are "[t]he central feature of patent law in the chemical, biological, and pharmaceutical industries" because they ensure "that no one can copy the[] basic idea by making a small change to it to avoid infringing the patent." *Id.* at 1, 3.

statutory bars on adding "new matter" to existing patents via amendment or "reissue" patents, *e.g.*, 35 U.S.C. § 132(a), and the question of an applicant's entitlement to the effective priority date of an earlier application. *See, e.g.*, *In re Ruschig*, 379 F.2d 990, 995-96 (C.C.P.A. 1967); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560-64 (Fed. Cir. 1991). But the Federal Circuit then "broke new ground" by morphing this timing question into a requirement applicable "not only to later-filed claims but also to claims filed in the *original* patent." Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 Wake Forest L. Rev. 827, 834 (1999)—first in a panel decision in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), and, ultimately, in that court's en banc opinion in *Ariad*.

According to Kite, the Patent Office's determination that Sloan Kettering's disclosure met this "inventor possession" test was wrong. Kite did not argue that the patent lacked written description for either part of Dr. Sadelain's revolutionary backbone, but instead directed this attack solely at the old, well-known scFv component of the CAR.

At trial, Sloan Kettering refuted this argument by demonstrating that scFvs were well known, that they had been used as CAR components for years, and that skilled artisans would have no difficulty making and using them with Dr. Sadelain's two-part backbone. In particular, Sloan Kettering established that public scFv knowledge included Dr. Orlandi's 1989 paper—summarized, cited, and incorporated by reference in the patent—that explained how to make scFvs that would bind to any selected target antigen.

C.A.App.36185-36189. As Kite's own expert testified, scientists using this method to obtain an scFv for a specific target essentially reverse-engineer to the scFv: they inject the target antigen into a mouse, which makes corresponding antibodies from which binding scFvs can be extracted. C.A.App.33678-33679. This process was so routine that a self-taught employee, hired as a dishwasher in a trial expert's research laboratory, successfully used it. Pet.App.39a.

The jury rejected all of Kite's theories for escaping infringement liability, concluding that the inventors had upheld their end of the bargain under § 112 and that Kite failed to carry its burden of overcoming the presumption that the Patent Office had validly issued the patent. Pet.App.82a-84a; *see* 35 U.S.C. § 282. As relevant here, the jury found Kite failed to establish that the patent lacked adequate "written description." The jury also found Kite's admitted infringement willful and awarded damages to compensate Sloan Kettering and Juno for Kite's infringement.

2. The district court rejected all of Kite's post-trial motions challenging the jury's verdict. As the court reasoned, "[t]hat Defendant disputes Plaintiffs' testimony and evidence, or presented its own conflicting evidence, is not grounds for JMOL." Pet.App.39a-40a. Having upheld the verdict, the court exercised its discretion to award enhanced damages for Kite's egregious piracy of Sloan Kettering's invention, *see* 35 U.S.C. § 285, and ordered Kite to pay royalties on all sales of Yescarta and any other infringing products until the patent's expiration in 2024. Pet.App.23a-25a.

3. The Federal Circuit, however, reversed the jury's factual finding as a matter of law. That court took no issue with the adequacy of the patent's description of the novel, two-part backbone that Kite copied. Instead, it invalidated the patent based solely on its remarkable conclusion that the patent's disclosure with respect to the old, standard, scFv binding element did not satisfy its own "written description" standard. Reaching even beyond its prior articulations of that standard, it held that, in addition to providing an enabling written description, "the inventors needed to convey that they possessed the claimed invention, which encompasses all scFvs, known and unknown, as part of the claimed CAR that bind to a selected target." Pet.App.13a.

Without recorded dissent, the Federal Circuit rejected the plaintiffs' petition to reconsider its interpretation of § 112 en banc. Pet.App.85a-86a.

REASONS FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT'S PERSISTENT INTERPRETATION OF § 112 IS CONTRARY TO THE STATUTE AND THIS COURT'S PRECEDENT.

A. The Federal Circuit's Interpretation Contradicts The Statute.

1. Section 112 states, in pertinent part: "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).

"Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 175 (2009). Accordingly, there is a "basic and unexceptional rule that courts must give effect to the clear meaning of statutes as written, giving each word its ordinary, contemporary, common meaning." *Artis v. District of Columbia*, 138 S. Ct. 594, 603 n.8 (2018) (brackets, ellipses, and internal quotation marks omitted). These principles apply fully here because "[p]atent law is governed by the same … methods of statutory interpretation … as other areas of civil litigation." *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954, 964 (2017) (brackets in original).

The statute's plain language—both its syntax and punctuation—compels the conclusion that both the "written description of the invention" and the "written description … of the manner and process of making and using it" are subject to the same modifier: "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 [*i.e.*, the invention]." That—not any "inventor possession" standard—is the test Congress prescribed for an adequate "written description."

The Federal Circuit's contrary, atextual reading cannot be sustained. In its 2010 en banc decision in *Ariad* (which was never presented to this Court for review), that court parsed the statute's language by holding that the "in such full, clear, concise, and exact terms as to enable" phrase "modifies only 'the written description … of the manner and process of making

and using [the invention].'" *Ariad*, 598 F.3d at 1344 (ellipses and brackets in original). By so holding, the Federal Circuit freed itself to maintain its extratextual, judicially imposed "possession" requirements for the "written description of the invention."

That was error. The comma in the statute following "and of the manner and process of making and using it" establishes that the "in such … terms as to enable" modifier applies to both the "written description of the invention" and the "written description … of the manner and process of making and using it." "As several leading treatises explain, 'a qualifying phrase separated from antecedents by a comma is evidence that the qualifier is supposed to apply to all the antecedents instead of only to the immediately preceding one.'" *Facebook, Inc. v. Duguid*, 141 S. Ct. 1163, 1170 (2021) (brackets omitted) (quoting Eskridge and citing Singer & Singer; Sutherland; and Scalia & Garner).

Here, the statute's structure and punctuation confirm that the "written description" of both "the invention" and "the manner and process of making and using it" are qualified by the language that follows—"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." Congress thereby supplied the standard by which the adequacy of a patent's written description should be measured.

Congress's chosen language allows no room for additional mandates. Requirements stated in this "in such … as to" form—as the Patent Act's specification requirement has been since 1793—set out complete

tests that do not permit additional, judicially crafted encumbrances. When Congress makes it a crime, for example, "to operate a vessel [in a particular area] *in such* a way *as to* disrupt or in any other way adversely affect the activities of traditional and locally based fishermen and fishing vessels," 16 U.S.C. § 973c(b)(5) (emphasis added), a violation occurs if the vessel's operation "disrupt[s] or in any other way adversely affect[s] the activities of traditional and locally based fishermen and fishing vessels," regardless of whether it also disrupts other types of boats. Just so here. By commanding that a "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) (emphasis added), Congress provided not just the requirement of "a written description of the invention," but the standard by which that description is to be measured. The specification is adequate if its written description of the invention (and "the manner and process of making and using it") fulfills the test that the "in such … as to" language defines—that is, if it enables the skilled artisan to make and use the invention—regardless of whether it also demonstrates the inventor's "possession."

2. The Federal Circuit, however, holds that § 112(a)'s "in such … terms as to enable" language applies only to what it calls the "enablement requirement," which requires that "the specification teach those in the art to make and use the invention without undue experimentation." *Wands*, 858 F.2d at 737. By parsing the statute in this odd fashion, the

Federal Circuit cleaved "written description of the invention" from the rest of § 112(a), and concluded that the statute imposes an additional "written description" requirement independent of the remaining statutory text. *Ariad*, 598 F.3d at 1347.

Reading the statute as containing a separate, standardless "written description of the invention" requirement has allowed the Federal Circuit to pile gloss after judicial gloss onto its atextual test. When that court, en banc, entrenched this "separate" "written description" requirement in *Ariad*, it framed its test as whether the patent specification "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date," 598 F.3d at 1351—a "quixotic" and "vague" test with "no statutory support," *see id.* at 1362 (Rader, J., concurring in part and dissenting in part). That court further suggested that, for "genus" claims, its "possession" test requires "the 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 so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 1350 (majority op.). That subsequently evolved into a requirement that any such "representative" disclosures must "support the full scope of the claims." *AbbVie Deutschland*, 759 F.3d at 1301. And in this case, it arrived at the astonishing conclusion that an inventor must demonstrate "possession" of all possible variations of each individual component of the invention—both "known and unknown." Pet.App.13a. These judicially imposed requirements have nothing to do with § 112's

textual mandate that the ordinary worker be able to pick up the patent, read it, and practice the invention.

In departing from the straightforward, textually supported reading of § 112, the Federal Circuit suggested that divorcing the "written description of the invention" from the statutory measuring stick of "such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same" is necessary to prevent the parallel clause set off in commas—"and of the manner and process of making and using it"—from being superfluous. *See Ariad*, 598 F.3d at 1344-45. But there is both good reason and a good explanation for why the statute reads as it does. The parallel language—present in the patent statutes for centuries—is readily understandable as a continuation of the language from the earliest versions of the Patent Act, when "claims" were not required to separately define the invention. That language in no way transforms the "written description of the invention" into a super-claiming requirement, as the Federal Circuit's test demands.

In any event, "[s]ometimes the better overall reading of the statute contains some redundancy." *Rimini Street, Inc. v. Oracle USA, Inc.*, 139 S. Ct. 873, 881 (2019); *see also Loving v. IRS*, 742 F.3d 1013, 1019 (D.C. Cir. 2014) (Kavanaugh, J.) ("[L]awmakers, like Shakespeare characters, sometimes employ overlap or redundancy so as to remove any doubt and make doubly sure."). To the degree § 112(a) contains any redundancy, this is just such a case. Indeed, it is unsurprising that, in setting forth the disclosure requirement for how to make and use a thing,

Congress would start with a reference to the thing itself ("the invention") to enhance clarity.

Having forsaken the statutory standard of an enabling "written description of the invention, and of the manner and process of making and using it," the Federal Circuit has crafted its "possession" standard—with all of its subsequent mutations—out of thin air. The statute makes no mention or even suggestion of "possession," let alone the inventor's clairvoyant demonstration of "possession" of all possible variations, "known and unknown," of each individual component. *See* Pet.App.13a. Moreover, the Federal Circuit's interpretation of § 112 improperly shifts the statutory focus—from what "any person skilled in the art" would understand, to the atextual question of what the inventors demonstrate in the specification that they "possessed." These deviations from the statute's plain language are alone ample reason to grant review and reject the Federal Circuit's interpretation of § 112.

B. The Federal Circuit's Interpretation of § 112 Conflicts With This Court's And Other Circuits' Interpretations.

1. Unsurprisingly given the statutory language's clarity, this Court has consistently understood it to mean exactly what it says—even though it last focused on the provision decades ago. Since Congress's adoption of a separate claim requirement, this Court has repeatedly described the disclosure required by § 112's predecessors as turning entirely on whether the written description of the invention enables skilled workers to make and use the invention. *The Telephone Cases*, 126 U.S. at 535-36

("[I]t is enough 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."); *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933) ("[U]pon expiration of [the patent term], the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it and profit by its use. To this end the law requires such disclosure to be made in the application for patent that others skilled in the art may understand the invention and how to put it to use." (internal citations omitted)); *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944) ("[T]he quid pro quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired ….").

Several regional circuits (before the Federal Circuit's creation) read the statute the same way. *Donner v. Am. Sheet & Tin Plate Co.*, 165 F. 199, 206 (3d Cir. 1908) ("statutory requirement 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'" (ellipses in original)); *Philip A. Hunt Co. v. Mallinckrodt Chem. Works*, 177 F.2d 583, 585 (2d Cir. 1949) (Hand, J.) (same); *Ill. Tool Works, Inc. v. Foster Grant Co.*, 547 F.2d 1300, 1309 (7th Cir. 1976) (same). No regional circuit recognized a different standard governing the "written description of the invention."

In the course of addressing other aspects of the Patent Act, this Court's more recent decisions have

likewise understood that § 112(a) requires only an enabling written description, to complement the claims' precise definition of the invention. Thus, a decade ago, while interpreting § 101's patent-eligibility language, this Court stated that "Section 112 requires only a 'written 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 the same." *Mayo*, 566 U.S. at 90 (ellipses in original; quoting § 112)). Before that, it had similarly stated, in a case involving the claim requirement, that patents must "contain[] a specification describing the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same.'" *Markman*, 517 U.S. at 373 (ellipses in original; quoting § 112). Likewise, when comparing the Patent Act (which concerns "utility patents") to the Plant Patent Act, the Court explained: "[T]o obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001); *see also id.* at 154 (Breyer, J., dissenting) (describing § 112 as requiring "an enabling written description of the invention"). All of this language suggests that the Court understands the phrase "written description of the invention" as tied to and modified by the phrase "in such full, clear, concise, and exact terms as to enable …"—an understanding that matches the text, but that the Federal Circuit says is wrong.

2. In *Ariad*, the Federal Circuit asserted that other opinions from this Court support its reading of

§ 112. *See* 598 F.3d at 1345-47. But none read § 112 or its predecessors as imposing the Federal Circuit's "possession" mandate for demonstrating a "written description of the invention." Indeed, in only one such case, *Evans v. Eaton*, 20 U.S. 356 (1822), did this Court use the word "possession" at all, and not in any way supportive of the Federal Circuit's approach. *Evans* explained that the specification served "to put *the public* in possession of what the party claims as his own invention"—not to demonstrate the *inventor's* possession. *Id.* at 434 (emphasis added). By "put[ting] the public in possession" of the invention, the inventor, consistent with the statute, both "enable[d] all persons to use [the invention] beneficially" after the patent's expiration and, in the absence of a separate claim requirement, "enable[d] them to avoid [inadvertently] making and using it" during the patent's term. *Id.* at 400. By contrast, demonstrating the inventor's own possession, as the Federal Circuit requires, does neither.

Other cases the Federal Circuit cited involved disputes over distinct issues—establishing whether later-added claims related to original patent applications or contained new matter. *See Schriber-Schroth Co. v. Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938) (patent application "cannot be broadened by amendment so as to embrace an invention not described in the application as filed," and the "object of the statute is to require the patentee to describe his invention *so that others may construct and use it* after the expiration of the patent and 'to inform the public during the life of the patent of the limits of the monopoly asserted'" (emphasis added)); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 25 (1874) (new claims in a reissue

patent must sufficiently relate back to the original patent). In these circumstances, the specification's written description could provide evidence of compliance *vel non* with separate requirements flowing from different portions of the Patent Act. *E.g.*, 35 U.S.C. § 132(a) ("No amendment shall introduce new matter into the disclosure of the invention."). But these cases neither mention "possession" nor support or reflect a standalone "written description" requirement unrelated to the statutory enablement test.

Finally, the Federal Circuit in *Ariad* pointed to *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* 535 U.S. 722 (2002), as support for its distinct "written description of the invention" standard. *See* 598 F.3d at 1346-47. But the Court's general statement in *Festo* that "[w]hat is claimed by the patent application must be the same as what is disclosed in the specification," 535 U.S. at 736, does not support the Federal Circuit's judicially created "possession" standard. Nothing about that basic observation of concordance between claims and specification can be read as mandating disclosure of the "full scope" of the invention and each constituent component to show "possession" by the inventor. Besides, *Festo*'s statement came in the context of a case about different issues—estoppel arising from claim amendment during prosecution—and cannot compete with the text and grammar of the statute itself, nor the weight of this Court's consistent description of § 112's requirements as turning simply on whether there is an enabling disclosure. *E.g.*, *Mayo*, 566 U.S. at 90 ("Section 112 requires only a 'written 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 the same." (ellipses in original; quoting § 112)); *see supra* at 25-26.

* * *

At bottom, a "written description of the invention" requirement, measured by a standard "separate from enablement" using the Federal Circuit's judicially created "possession" inquiry, which that court has further defined to apply to the "full scope" of all "known and unknown" variations of all components and embodiments, is nowhere in the statutory text. Congress's language is clear that the written description of the invention and manner and process of making and using it must enable a skilled artisan to make and use the invention. Nothing more.

II. THE FEDERAL CIRCUIT'S ERRONEOUS INTERPRETATION PRESENTS SEVERE DANGERS TO RESEARCH AND INNOVATION, ESPECIALLY THE LIFE SCIENCES.

1. By undermining the incentive to innovate, the Federal Circuit's interpretation of § 112 has severe consequences for society. Those consequences carry special importance because they touch on the constitutional underpinnings of the patent system. *See* U.S. Const. art. 1, § 8, cl. 8. (permitting Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to … Inventors the exclusive Right to their respective … Discoveries"). The Framers recognized the importance of offering time-limited protections to spur scientific research and the development of new technology. "[T]he patent system represents a carefully crafted bargain that

encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." *Pfaff*, 525 U.S. at 63. Accordingly, the constitutionally grounded and statutorily defined "quid pro quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired." *Universal Oil Prods.*, 322 U.S. at 484.

2. Neither the public nor the skilled artisan derives any advantage from the Federal Circuit's grafting of its atextual "possession" inquiry onto the statutory mandate of a written description that enables. So long as the claims serve as "the measure of the grant" by clearly delimiting the boundaries of what is protected, *see id.*, and the written description of the invention and how to make and use it permits its practice by a skilled artisan, the inventors have upheld their side of the bargain. Demanding more prolixity, as the Federal Circuit's rule does, fails to "promote the progress of science and useful arts" in any way.

Here, the claims pinpoint the boundaries of what is protected—a CAR encompassing Dr. Sadelain's revolutionary backbone and an scFv (binding element) that attaches the CAR to the CD19 antigen (or, for the broader claims, a CAR encompassing the backbone and an scFv that binds to a different antigen). Kite's own actions demonstrate as much. Its furious attempts to license or invalidate the patent show it knew its activities were covered. And its use of the disclosed backbone with an off-the-shelf scFv shows it had no trouble making and using the invention. By contrast, the claims in no way prevent

any member of the public from selecting, making, and using any scFvs they want, except with Sloan Kettering's backbone.

3. While the Federal Circuit's interpretation yields no benefits, it imposes clear costs on innovation and the incentives to develop new technology—costs that are particularly stark in pharmaceutical and other life sciences fields. That court has admitted that its construction of § 112 has particular bite "in the biological arts" because, in its view, the requirement "ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function." *Ariad*, 598 F.3d at 1352-53. But the Federal Circuit's heavy-handed demand for "sufficient materials" in the written description of a "genus claim" is a bug, not a feature. Because of inherent variability and the large number of inconsequential modifications that can be made to inventions, "[t]he central feature of patent law in the chemical, biotechnology, and pharmaceutical industries is the genus claim." *KLS*, *supra*, 35 Harv. J. L. & Tech. at 1. Indeed, "any patent lawyer will tell you they are critical to effective patent protection." *Id.*

Accordingly, the Federal Circuit's interpretation "represents both bad law and bad policy" and "may threaten innovation in an important sector of the economy." *Id.* at 1, 4; *see also, e.g.*, *Univ. of 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 interpretation); 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).

The innovators most directly affected share these concerns. As St. Jude Children's Research Hospital, the Albert Einstein College of Medicine, and the University of Texas MD Anderson Cancer Center explained in supporting Sloan Kettering's unsuccessful en banc petition, the Federal Circuit's interpretation of § 112 "catches [them] in an impossible bind for their ongoing and future innovation efforts with [CARs] and other lifesaving biotechnologies" and "harm[s] innovation without any corresponding benefit to the public." C.A.Dkt. 93 at 4. The Association of University Technology Managers and Amgen, a leading biotechnology company, jointly concurred, noting that the Federal Circuit's interpretation "harms first movers in the biologics field and does not reward pathbreaking innovation." C.A.Dkt. 94 at 9. As City of Hope put it, the Federal Circuit's "interpretation of the written description requirement will have the unintended effect of jeopardizing the development of biopharmaceutical therapies at City of Hope and other research institutions," and, ultimately, "patients will lose." C.A.Dkt. 95 at 1, 8.

Sloan Kettering and these other centers of innovation serve society and promote the *useful* arts more effectively by researching the next breakthrough cancer treatment than by conducting rote work to, *e.g.*, characterize unnecessary, additional scFvs. But if they forgo this unproductive path, they lose any hope of meeting the Federal Circuit's test, and cannot secure the patent protection that the Framers and Congress intended to spur innovation, and that, in

turn, can produce funds for further groundbreaking research.

Indeed, in situations like the one here, the Federal Circuit's test will frequently be impossible to meet. Here, although only one functioning scFv against a target antigen of interest, such as CD19, is needed to practice the invention, Sloan Kettering would have to waste years making and testing an essentially infinite number of scFvs to try to demonstrate possession of all scFvs that could be used with its inventive backbone. For inventions that have components with thousands, millions, or billions or more possible formulations and inherent variability, "[n]o matter how much testing the patentee does, there will always be untested species, and because those species aren't tested, the [skilled artisan] won't know whether they are properly included in the genus, so the claim would fail written description" under the Federal Circuit's test. *KLS*, *supra*, 35 Harv. J. L. & Tech. at 63. Large and naturally occurring variation, which arises frequently in the biological arts, also prevents inventors from obtaining meaningful protection by claiming only specific embodiments, since copyists could easily use routine modifications from the specific embodiments claimed. It also makes it impossible to predict *a priori* all molecular structures that may perform a particular biological function, such as all scFv structures that bind to a particular antigen, thus rendering cold comfort the Federal Circuit's assurances that representative examples are unnecessary if the inventor provides a structure-function relationship. *See Ariad*, 598 F.3d at 1350.

This case illustrates the peril inventors face. Nobody disputes that Dr. Sadelain's team discovered

a groundbreaking cancer-fighting tool, nor that Sloan Kettering disclosed this valuable tool and thereby added to the store of human knowledge, nor that those in the field would practice the invention by either using an already-known scFv (as Kite did for its conceded infringement) or employing the Orlandi method to produce an appropriate, working scFv that binds to the selected target antigen. Nor does anybody dispute that Kite understood the patent and copied Dr. Sadelain's inventive backbone. Applying the undisputed clear-and-convincing-evidence standard to Kite's challenge, the jury and district court found no fault with the Patent Office's conclusion that the patent adequately described the invention and permitted the person of skill in the art to make and use it.

Kite, however, exploited the Federal Circuit's increasingly draconian glosses on its "separate" "written description" requirement as a way to escape liability for its willful infringement. In the process, it destroyed Sloan Kettering's patent—which was supposed to be the reward for Sloan Kettering upholding its end of the bargain by publicly disclosing its invention. If the Federal Circuit were really right to set aside the jury's verdict *as a matter of law* because the applicants failed to demonstrate "possession" of all "known and unknown" variations of the scFv component, *see* Pet.App.13a, inventors like Dr. Sadelain and his team could never reliably secure meaningful patent protection. To "deprive [the inventor] of the benefit of his invention" in this way "would foster concealment rather than disclosure of inventions," thereby undermining "one of the primary

purposes of the patent system." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950).

4. While the problem is currently most acute in Federal Circuit jurisprudence involving the biological arts, it threatens to metastasize to other fields as well. The Federal Circuit has said it "eschew[s] judicial exceptions to the written description requirement based on the subject matter of the claims." *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1379 (Fed. Cir. 2017). And the biological arts are far from the only field in which inventions involve wide variability in some sense. For example, Professor Lefstin points to the simple example of a patent claim directed to a chair ("An object for supporting a human body, comprising [¶] a substantially flat surface sized to accommodate a human posterior and [¶] four legs supporting said surface."), and observes that even that simple claim encompasses an "infinite variety of embodiments," both known and unknown, because it does not account for the possibility that the chair might be made of specific materials not yet known or available. Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 Berkeley Tech. L.J. 1141, 1168-71 (2008). Under a "written description" test requiring "possession" of all "known and unknown" embodiments, *see* Pet.App.13a, that claim would be invalid.

Or, consider a patent claim to an electronic device that includes an "electrical charging cord" limitation, and whose written description gives the twin examples of a cord with (i) a two-prong connection to a household electrical outlet and (ii) a USB-A connection. Under the Federal Circuit's approach, that claim would be invalid for failure to describe

existing but well-known and smaller USB-C plugs, let alone for its failure to anticipate not-yet-available (and therefore not-yet-known) electrical connections. By its terms, the Federal Circuit's "possession" test would invalidate those claims, too.

Just as such a regime would stymie innovation in the electrical arts, it does the same in the biological arts. And just as that cannot be the law in the electrical arts, it cannot be the law in the biological arts.

III. THIS CASE IS AN IDEAL VEHICLE.

This case provides an excellent vehicle to take up this legal question—whether a patent's disclosure must not only provide an enabling written description, but also satisfy the Federal Circuit's "separate," atextual "possession" requirement. And this case is unburdened by the vehicle issues affecting prior petitions. *See Idenix Pharms. LLC v. Gilead Scis., Inc.* (No. 20-380) (Federal Circuit also found enablement lacking); *Amgen Inc. v. Sanofi* (No. 18-127) (questions regarding mootness and interlocutory posture); *Janssen Biotech, Inc. v. Abbott Labs.* (No. 11-596) (claims at issue were later-added).

Recent en banc practice in the Federal Circuit confirms that further percolation of the issue in that court will not solve the problem. Indeed, the addition of gloss after gloss on the "written description" requirement has produced disagreement over its contours to such a degree that three judges recently voted to grant en banc review of a decision that, in their view, "imports extraneous considerations into the written description analysis and blurs the boundaries between the written description

requirement and the other statutory requirements for patentability," thereby "muddying … the written description requirement." *Biogen Int'l GmbH v. Mylan Pharms Inc.*, 28 F.4th 1194, 1196 (Fed. Cir. 2022) (Lourie, J., joined by Moore, C.J. and Newman, J., dissenting from denial of rehearing en banc). At the same time, however, those three judges reiterated their support for *Ariad*'s general rule. *Id.* at 1199. In combination with the denial of rehearing en banc in the present case, and the fact that this issue can arise only in the Federal Circuit, that statement makes clear that the needed course correction will have to come from this Court.

In short, the numerous amici in this case, the underlying substance of other petitions, and academic and industry commentary all reflect the increasing drumbeat of the need for this Court's intervention. Both the time and the vehicle are ripe for the Court to take up this critically important issue.

CONCLUSION

The petition for a writ of certiorari should be granted.

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