No. 21-1566

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

BRIEF IN OPPOSITION

Jeffrey I. Weinberger
Ted G. Dane
Peter E. Gratzinger
Adam R. Lawton
MUNGER, TOLLES & OLSON LLP
350 S. Grand Ave., 50th Fl.
Los Angeles, CA 90071

Geoffrey D. Biegler
FISH & RICHARDSON, P.C.
12390 El Camino Real,
Ste. 100
San Diego, CA 92130

E. Joshua Rosenkranz
Counsel of Record
ORRICK, HERRINGTON & SUTCLIFFE LLP
51 West 52nd Street
New York, NY 10019
(212) 506-5000
jrosenkranz@orrick.com

Melanie L. Bostwick
Jeremy Peterman
Robbie Manhas
ORRICK, HERRINGTON & SUTCLIFFE LLP
1152 15th Street, NW
Washington, DC 20005

Counsel for Respondent

QUESTION PRESENTED

Petitioners own a patent covering genetic material that encodes a three-part protein. One part is defined in terms of its function—its ability to bind to a particular structure. Although there are millions of billions of possibilities for that part, only an uncertain fraction would make the protein bind as claimed, and the patent discloses nothing that would allow scientists to predict which possibilities would.

The Federal Circuit held that the patent's claims were impermissibly broad because the inventors attempted to capture vastly more than they had actually invented and disclosed. Specifically, it held that the claims failed the requirement of 35 U.S.C § 112 that the patent include a "written description of the invention" because the patent's disclosure did not show that the inventors actually invented the extremely broad invention that they had claimed—the various possibilities that would bind.

The question presented is whether—as precedent has held for over 50 years—§ 112's requirement of a "written description" is distinct from the requirement to "enable any person skilled in the art to make and use the" invention.

CORPORATE DISCLOSURE STATEMENT

Kite Pharma, Inc. is a wholly owned subsidiary of Gilead Sciences, Inc. BlackRock Inc. owns 10% or more of Gilead Sciences, Inc.'s stock.

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INTRODUCTION

Over a decade ago, in *Ariad Pharmaceuticals*, *Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010), the en banc Federal Circuit reaffirmed a longstanding interpretation of patent law: that 35 U.S.C. § 112(a) contains both a "written description" requirement and a distinct "enablement" requirement. Both requirements are essential to preventing overbroad patent monopolies and realizing the patent bargain's quid pro quo. Whereas enablement asks whether a patent discloses enough for a person of ordinary skill to *make and use* the claimed invention, written description asks whether the inventor *described* the invention in sufficient detail to show that she actually invented it. *Ariad*, 598 F.3d at 1352. The written-description requirement is particularly important "when a patent claims a genus by its function or result." *Id.* It prevents "claims [that] merely recite a description of the problem to be solved while claiming all solutions to it"—claims which task others with "complet[ing] an unfinished invention." *Id.* at 1352-53.

Ariad's interpretation accords with the statutory text as well as this Court's precedents dating back to the mid-1800s. The Government—an amicus in *Ariad*—endorsed this interpretation as a matter of text, precedent, and policy. *See generally* Brief for United States as Amicus Curiae (*Ariad* U.S. Amicus Br.), *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc) (No. 2008-1248), 2009 WL 4832140, https://tinyurl.com/USAriad.[1] And

[1] Citations to other amicus briefs from *Ariad* will likewise take the form of "*Ariad* [Party Name] Amicus Br."

Congress, despite many amendments to the Patent Act, has never repudiated that understanding, not even in a comprehensive overhaul enacted just a year after *Ariad*.

It is no wonder, then, that this Court has repeatedly rejected invitations to review the question presented. Before *Ariad,* this Court had denied petitions raising whether there is a separate written-description requirement. Two years after *Ariad*, this Court denied a petition contending that *Ariad* "departs sharply from" the statutory text. Pet. 10, *Janssen Biotech, Inc. v. Abbott Labs.*, 2011 WL 5548738 (U.S. Nov. 10, 2011), *cert. denied*, 565 U.S. 1197 (2012). Since then, patentees have filed multiple petitions raising the question and challenging various ways in which the Federal Circuit has articulated the separate written-description requirement. This Court has denied each—one as recently as last year. *See Idenix v. Gilead*, 141 S. Ct. 1234 (2021). And the inventing community—including the PTO and innovative biopharmaceutical companies like Kite—has relied on that settled understanding.

Juno presents no sound justification for this Court to intervene now. Juno sought an extremely broad patent monopoly. But broad claims reward broad disclosure. Respecting that principle, the Federal Circuit has consistently and recently upheld claims to broad biological classes, even those defined by their function, where the patent's supporting disclosure is commensurate with the scope claimed. Patent claims to large classes of biological inventions are thus not "impossible," Pet. 4—so long as the inventor has actually invented, and disclosed to the public, all

that the patent captures. This case is just the patent bargain's flip side: The Federal Circuit invalidated Juno's claims because they tried to monopolize—and block everyone else from investigating—millions of billions of possible drug candidates at the infancy of a field without teaching the public which candidates perform the claimed function.

That ruling and the principles behind it protect innovation, for reasons *Ariad* explained at length. For the over half century in which modern articulations of these legal rules have existed, the biopharmaceutical industry has flourished. *Ariad* preserved a balanced written-description requirement that supports this growth, by rewarding only the actual extent of a patent's inventive contribution. Juno's position would upset the balance. It would reward preliminary investigators with monopolies over immature areas still requiring extensive research. This would make overbroad claims the norm and deter countless researchers from investigating promising drug candidates in favor of less promising options that do not threaten injunctions and massive damages.

Juno's story underscores how terrible this result would be for innovation. Juno failed to develop any treatment with its patent, abandoning the patented technology after multiple patients died in Juno's FDA clinical trials.

The petition should be denied.

STATEMENT OF THE CASE

Juno's Patent Claims A Vast Category Of Potential Solutions To A Research Problem In A Wildly Unpredictable Field

Chimeric antigen receptor T-cell (CAR-T) therapy involves reprogramming a patient's T-cells—a type of white blood cell that fights enemy cells, such as cancer cells. Key to the therapy is the T-cell's ability to recognize and bind only to a specific antigen, a structure on an enemy cell's surface. The reprogramming enables a patient's T-cells to grow a new receptor, called a chimeric antigen receptor, or "CAR." Pet. App. 2a-3a. The receptor is essentially a biological vise perfectly shaped to recognize and bind to a specified antigen. Once bound, the CAR triggers an immune response that both attacks the enemy cell and produces more T-cells to join the battle. Pet. App. 3a-4a; C.A. App. 32,912-14.

The reprogramming is achieved by extracting a patient's T-cells and sending them to a laboratory, which inserts new genetic material that instructs the cell to grow the receptor and to multiply. The modified cells are then infused back into the patient. Pet. App. 2a-3a.

Even today, CAR-T therapy remains in its infancy. By the time of trial here, the FDA had approved only two therapies, both in 2017, neither from Juno. C.A. App. 33,143, 33,161. The technology was even more embryonic in 2002, Juno's patent's filing date. The patent's lead inventor, Dr. Michel Sadelain,

called that period "the birth of the CAR-T field." Pet. App. 3a (quoting C.A. App. 32,976).

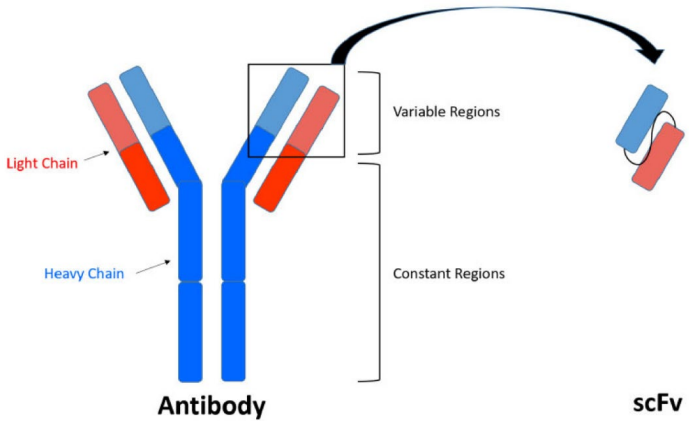
Nonetheless, Juno's patent broadly claims monopoly power over a massive genus of CARs that target *any* possible antigen (and thus treat any possible disease). The claims recite "[a] nucleic acid polymer encoding a chimeric T cell receptor." Pet. App. 23b (25:30-31). In other words, the patent claims a single chain of genetic material with instructions for creating a CAR when integrated into a patient's T-cells as described above. The genetic material encodes a CAR with three parts: (1) "a zeta chain portion comprising the intracellular domain to human CD3 ζ [the Greek letter, zeta]"; (2) a specified "costimulatory signaling region"; and (3) "a binding element that specifically interacts with a selected target." Pet. App. 23b (25:32-38); *see* Pet. App. 3a-4a.

Juno's petition emphasizes the CAR's first two portions—which Juno (though not its patent) calls the CAR's "backbone." It downplays that the third portion—the critical "binding element"—is what allows the CAR to actually achieve its claimed function. Only that portion recognizes and binds to the target antigen (allowing the CAR to trigger an immune response). Pet. App. 3a-4a. As Dr. Sadelain conceded, the binding element is "integral to CAR function." C.A. App. 32,973, 37,086. A CAR cannot bind to a target antigen—the function claimed and a prerequisite to treating disease—without that component. Pet. App. 3a-4a.

What drove the Federal Circuit's decision in this case, and what Juno ignores, is that achieving this

critical piece of the claimed invention is wildly unpredictable. Juno's patent claims a CAR with any binding element that binds to any antigen to target any disease. Juno claimed its invention this broadly even though, as the inventors conceded, many *targets* for various cancers were not known at the filing date (or even today), let alone the elements that could bind to those unknown targets. Indeed, the patent provides no roadmap for predicting which of millions of billions of possible binding elements would perform the requisite binding to even one specific antigen (much less to every possible antigen).

In the asserted claims (claims 3, 5, 9, and 11), the binding element is a "single chain antibody," also known as an "scFv." Pet. App. 23b (25:41-42, 26:35-36); *see* Pet. App. 4a-5a; Pet App. 11b (1:34-36). An scFv is engineered from an antibody's highly unpredictable "variable regions." Two pieces—one from the "heavy chain" and one from the "light chain"—are linked together as depicted below. Pet. App. 4a.



C.A. App. 2,644. Each variable region has a unique sequence of amino acids (the building blocks of proteins) linked in a chain. That sequence dictates how the chain folds into a three-dimensional shape, which in turn determines whether and how the antibody—and thus the scFv—binds to a target. Pet. App. 4a. Undisputedly, even minor differences in an amino-acid sequence change an scFv's ability to bind to a particular antigen. Pet. App. 15a (citing C.A. App. 33,938).

It is undisputed that neither the patent nor any record evidence allows scientists to predict whether an scFv will bind to a given antigen. *See* Pet. App. 11a-13a, 15a, 17a, 21-22a. Even today, there is no way to make that prediction; scientists must make and test each scFv to know how it will function. C.A. App. 33,676, 33,682-83, 33,687-88, 35,643. CARs likewise must be made and tested to ascertain their functionality, C.A. App. 2,6415, 32,897-88, 33,683-85, especially because scFvs "behave differently" "in the CAR context," such that even scFvs that by themselves bind to an antigen might not once formed within a CAR, C.A. App. 33,685, 37,086; *see* C.A. App. 37,437.

Juno's Patent Covers CARs With Millions Of Billions Of scFv Candidates But Identifies Only Two

It is undisputed that even the narrowest asserted claims encompass millions of billions of potential scFvs. Pet. App. 17a-18a; C.A. App. 33,687-88. The possibilities are so numerous because the patent puts no limit on the scFv's structure—no so-called "structural limitation" specifying which scFvs will work in

the claimed CARs. It discloses the goal but not the solution, providing only the unpredictable "functional limitation" that the scFv must bind to a selected target. Moreover, although the two scFvs the patent mentions are derived from mice, the claims cover scFvs from any antibody source—including fully and partially human antibodies, which are particularly valuable. C.A. App. 33,344; *see* C.A. App. 37,442. However, Dr. Sadelain's lab did not make either variety of scFv until at least seven years after the patent's filing date. C.A. App. 32,974-76. And Juno's expert admitted that, even today, making fully human scFvs is "extremely difficult." C.A. App. 33,954-55.

The broadest asserted claims (3 and 9) cover CARs with "*any* scFv for binding *any* target," including antigens not yet known. Pet. App. 10a; *see* Pet. App. 23b (25:41-42, 26:35-36). The narrowest claims (5 and 11) "are limited to scFvs that bind CD19," a target prevalent on the surface of one type of cancer cell. Pet. App. 17a; *see* Pet. App. 4a; Pet App. 23b (25:45-46, 26:40-41). Even these claims do not winnow down the millions of billions of possible scFv candidates because, as discussed above (at 7), the patent provides no way to predict whether a particular scFv would bind to *any* target, let alone CD19 specifically.

Juno's patent offers no "meaningful guidance" on this key question. Pet. App. 16a-17a. As the Federal Circuit noted, "the written description of the '190 patent discloses only two scFv examples [both derived from mice] and provides no details regarding the characteristics, sequences, or structures that would allow a person of ordinary skill in the art to determine which scFvs will bind to which target." Pet. App. 17a;

Pet. App. 14b (7:43-8:17); Pet. App. 16b (11:12-17). All that is disclosed about the two scFvs—only one of which binds to CD19—are alphanumeric codenames referring to proprietary antibodies that were not publicly accessible. Pet. App. 10a, 18a; *see* C.A. App. 33,689-90, 33,702. These proprietary scFvs were the only ones the inventors had successfully used for their CAR when the was patent filed. Pet. App. 12a; *infra* 35-36 & n.3.

Juno's petition implies (at 3, 10, 13, 16-17, 34) that the patent's reference to the "Orlandi method" closes the gap. But Orlandi teaches only a generic method to make scFvs from *already-existing* mouse antibodies. Pet. App. 12b (4:57-63); C.A. App. 33,705, 36,185. Putting aside that Orlandi can use only mouse source antibodies, relying on Orlandi assumes that one *has already performed* the essential first step of identifying antibodies that bind a particular target, itself a highly unpredictable and time-consuming process. The problem is not how to make an scFv when given an antibody—which is all Orlandi teaches. The "whole problem," as Chief Judge Moore put it at the Federal Circuit, is that "nobody knew which scFvs were going to bind to [an] antigen." Oral Arg. 59:09-15; *see* C.A. App. 26,410, 33,682-83, 33,705-07, 35,643, 36,182 (various failures to make CD19-specific scFvs); *accord* Pet. App. 19a-20a n.4. Neither Orlandi nor anything else in the record answers that problem.

Juno Fails In The Clinic But Succeeds In The Courtroom

Contrary to Juno's grandiose assertion, no one "celebrated" Dr. Sadelain's discovery as "the world's

first 'living drug.'" Pet. 11. On the contrary, neither Sloan Kettering nor Juno ever created a successful therapy with the claimed invention.

In 2017, the FDA approved the first two CAR-T therapies. One was Kite's YESCARTA®. C.A. App. 33,160-61. YESCARTA® dramatically improved outcomes for patients suffering from lymphoma, saving thousands of lives. *See, e.g.*, C.A. App. 33,132-33, 33,592-95.

Developing this lifesaving blood-cancer treatment required tremendous research and investment by Kite and its partner, the National Cancer Institute (NCI). NCI created the CAR and disclosed it in seminal papers reporting clinical results, including the "first report[]" of an "[e]ffective clinical treatment" of a human patient "with anti-CD19 CAR T cells." C.A. App. 37,443 (citing C.A. App. 35,881-84).[2] But constructing the right CAR, including the scFv, was just the first step. Using NCI's CAR, Kite overcame numerous clinical, logistical, and manufacturing challenges unaddressed by Juno's patent. *See, e.g.*, C.A. App. 33,597, 33,799.

No one else has ever succeeded in developing a treatment that practices Juno's patent. Juno tried but abandoned that therapy after the FDA twice halted clinical trials due to patient deaths. *See* C.A. App. 33,143, 33,152-55. Juno now uses a CAR without the

[2] Contrary to Juno's suggestion (at 13), NCI, which conducted its work before Juno's patent issued, did not copy Dr. Sadelain's CAR. NCI's CAR contains a different scFv from any that the patent discloses or Dr. Sadelain used. C.A. App. 32,969.

"backbone" it touts as so miraculous. The only use Juno ever got out of its patent was to sue Kite. A jury found Juno's patent valid and infringed, resulting in a judgment of over $1.2 billion. Pet. App. 2a.

The Federal Circuit Unanimously Invalidates Juno's Overbroad Claims

Kite appealed on multiple grounds, including that (1) the claimed inventions are not sufficiently described; (2) the claimed inventions are not enabled; and (3) the inventors improperly broadened the patent post-issuance. Pet. App. 6a. Because the Federal Circuit agreed with Kite's written-description argument, the court did not address Kite's other defenses, each of which would wipe out the judgment. *Id.*

A unanimous Federal Circuit panel issued a comprehensive opinion systematically addressing the written-description arguments and evidence. The court applied long-settled written-description precedent, which "ensure[s] that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution … as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000). Under that precedent, a patent may claim a genus defined by function rather than structure. *Ariad*, 598 F.3d at 1349-53. But the claim must be supported by a disclosure that allows an artisan to understand which structures perform the claimed function. *Id.* "Generally, a genus can be sufficiently disclosed by '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.'" Pet. App. 8a (quoting *Ariad*, 598 F.3d at 1350; some internal quotation marks omitted). The inquiry is holistic, employing several "factors … , including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" Pet. App. 8a (quoting *Ariad*, 598 F.3d at 1351).

Giving due deference to the jury's findings and construing the evidence "in the light most favorable to [Juno]," Pet. App. 7a, the court found Juno's patent disclosure insufficient to satisfy the written-description requirement.

For example, the court acknowledged that "scFvs in general were known, and even known to bind," but observed that "the record demonstrates that, for even the narrowest claims at issue, the realm of possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most)." Pet. App. 21a. Meanwhile, the patent "provides no details about which scFvs bind to CD19 in a way that distinguishes them from scFvs that do not bind to CD19." Pet. App. 21a-22a. That disclosure is inadequate because it does not "allow a person of ordinary skill … to distinguish between scFvs that achieve the claimed function and those that do not." Pet. App. 22a. "Simply put, [Juno]'s patent claims a 'problem to be solved while claiming all solutions to it … cover[ing] any compound later actually invented and determined to fall within the claim's functional boundaries,' which fails to satisfy the written

description requirement." Pet. App. 15a (quoting *Ariad*, 598 F.3d at 1353).

The Federal Circuit denied rehearing en banc without dissent. Pet. App. 85a-86a.

REASONS TO DENY CERTIORARI

I. This Court Has Recently, Repeatedly, And Correctly Denied Challenges To The Federal Circuit's Interpretation Of 35 U.S.C. § 112's Written-Description Requirement.

Juno's petition challenges over 50 years of precedent about 35 U.S.C. § 112(a)'s requirement that a patent provide a "written description of the invention." *See* Pet. 18-29. The settled interpretation is that the requirement is separate from the same statute's demand that the disclosure "enable any person skilled in the art … to make and use the" invention.

This Court has denied certiorari on at least five petitions presenting the same challenge—most recently just last year. *See Idenix*, 141 S. Ct. 1234 (2021); *Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019); *Janssen*, 565 U.S. 1197; *Chiron Corp. v. Genentech, Inc.*, 543 U.S. 1050 (2005); *Univ. of Rochester v. G.D. Searle & Co.*, 543 U.S. 1015 (2004). The more recent petitions have objected to the same phrases that Juno challenges in the Federal Circuit's articulation of how to satisfy the written-description requirement. *E.g.*, *Idenix*, 141 S. Ct. 1234; *Amgen*, 139 S. Ct. 787.

This Court should deny certiorari here too. Nothing distinguishes Juno's petition from the others previously denied.

A. Section 112(a)'s Written-Description And Enablement Requirements Are Distinct.

Section 112(a) identifies three distinct disclosures a patent specification must contain: "a written description of the invention"; a description that "enable[s] any person skilled in the art ... to make and use" the invention; and a description of "the best mode ... of carrying out the invention." These requirements have been separate since they have appeared in the patent statutes, with written description and enablement dating back to the original Patent Act of 1790. And both this Court and the courts of appeals have consistently interpreted these requirements as distinct.

1. The text imposes a separate written-description requirement.

The text of § 112(a) provides:

> 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.

35 U.S.C. § 112(a). When Congress established that the patent specification must describe both "the invention … *and* … the manner and process of making and using it," Congress plainly established two distinct requirements, then added "best mode" as a third.

Juno does not dispute that the text requires a patent to disclose three things: (1) "the invention," (2) "the manner and process of making and using it," and (3) "the best mode of carrying it out." But Juno effectively nullifies the first requirement. Juno's theory is that the modifying clause—"in such, full, clear, concise and exact terms as to enable"—limits both the first and second requirements, thereby melding them together. Pet. 19-21.

Juno's reading is incorrect for three reasons.

First, as the en banc Federal Circuit explained in *Ariad*, the proper reading of the statute "follows from the parallelism of the language." 598 F.3d at 1344. The clause that begins "to enable" requires a disclosure sufficient for an artisan "to make and use" the invention. Of the three disclosures recited in § 112(a), only the middle one uses that same language: a disclosure of "the manner and process of making and using" the invention. These two terms naturally fit together. How does one test whether an inventor has sufficiently disclosed "the manner and process of making and using" their invention? By asking whether the disclosure "enable[s]" a person of ordinary skill "to make and use" it. By contrast, the required "description of the invention" has no similar parallel in the rest of § 112(a)—demonstrating that this initial requirement is separate.

Second, Juno's interpretation violates the rule that "a limiting clause or phrase … should ordinarily be read as modifying only the noun or phrase that it immediately follows." *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003); *see Jama v. ICE*, 543 U.S. 335, 342-44 (2005). Juno's only basis for extending the modifier further is that it is offset by a comma. Pet. 20 (citing *Facebook, Inc. v. Duguid*, 141 S. Ct. 1163, 1170 (2021)). "But a purported plain-meaning analysis based only on punctuation is necessarily incomplete and runs the risk of distorting a statute's true meaning." *U.S. Nat'l Bank of Oregon v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 454 (1993). And, unlike *Facebook*'s modifier, the modifier here does not follow a "concise, integrated clause." 141 S. Ct. at 1169. It follows two discrete phrases.

Third, the Federal Circuit's interpretation avoids surplusage. *Ariad*, 598 F.3d at 1344-45. If the "to enable" clause modifies "the invention," as Juno proposes, then the clause "and of the manner and process of making and using it" is wholly unnecessary. Striking that clause would still leave a requirement to describe the invention in a way that enables an artisan to make and use it. The Federal Circuit's interpretation properly gives effect to all the statute's words. Juno's does not. *See id.* at 1344-45; *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017). Juno's reads out an entire clause.

Juno suggests (at 23) that there is "good reason" for superfluity—namely, that the statute retains language "from the earliest versions of the Patent Act, when 'claims' were not required to separately define the invention." While that might explain why a

description was necessary before the advent of claiming in 1836, it does not explain why Congress repeatedly retained the written-description requirement after requiring claims. Plainly, written description requires something more than the separate subsection's requirement of "particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). Rather than simply requiring a definition of the patent monopoly's metes and bounds, as a claim does, written description requires substantive disclosure "put[ting] the public in possession of what the party claims as his own invention." *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-35 (1822) (pre-claiming precedent distinguishing this purpose from enablement as "[t]he other object of the specification"); *see infra* 19-22 (post-claiming precedent).

Congress has had ample opportunity to remove the written-description clause if it wanted the specification to describe the invention only in a way that enables its making and use. But Congress has never done so. *See Ariad* U.S. Amicus Br. 15; *see also id.* at 6-12. Congress has rewritten the surrounding statutory text many times in the nearly 200 years since patent law first required claims. *See Ariad*, 598 F.3d at 1345-47. Most notably, when Congress in 1952 adopted the modern structure of the patent laws and created the first version of § 112, Congress did not eliminate the separate requirement that a patentee provide "a written description of the invention." Nor did Congress do so in the America Invents Act of 2011 (AIA), a comprehensive overhaul to the Patent Act passed a year after *Ariad*. The AIA not only restructured § 112 but also, in another provision, made

substantive changes to the best-mode requirement, demonstrating that Congress was attuned to and willing to change § 112's requirements. *See* Pub. L. No. 112-29, § 15, 125 Stat. 284, 328 (2011). Over and over, Congress preserved the separate written-description and enablement requirements, notwithstanding the claiming requirement. The Federal Circuit's precedent respects that choice.

2. A separate written-description requirement is firmly embedded.

a. Juno insinuates that a separate written-description requirement is recent. *See* Pet. 15-16, 19-20. That is incorrect. As the Government has explained, the independent written-description requirement is "firmly embedded in the operation of the patent system" and "only the most extraordinary justification could warrant" "upsetting statutory interpretations as settled as this." *Ariad* U.S. Amicus Br. 25-26.

A separate written-description requirement has been a crucial feature of patent law for over 200 years—long before the first precedents (over 50 years ago) interpreting the modern statute, § 112. From the Patent Act of 1793 through every subsequent revision, Congress has required inventors to provide *both* "a written description of [the] invention, *and* of the manner of using … the same." Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321-22 (emphasis added); *see* Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119; Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198, 201; 35 U.S.C. § 112; *see* Act of Apr. 10, 1790, ch.7, § 2, 1 Stat. 109, 110-11 (original Patent Act's similar language). This separate requirement "plays a vital role in

curtailing claims" where the patent may be sufficiently enabling (for example, because techniques for experimentation that would yield the invention are known), yet the full scope claimed "ha[s] not been invented, and thus cannot be described." *Ariad*, 598 F.3d at 1352; *see Ariad* U.S. Amicus Br. 21, 23-24.

Even after claiming's institution in 1836, this Court has recognized and applied the separate written-description requirement. In *O'Reilly v. Morse*, the Court struck down Samuel Morse's overbroad patent claim covering every conceivable way of printing characters using an electric current. 56 U.S. (15 How.) 62, 112-13 (1853). The Court reasoned that the claim improperly awarded Morse "an exclusive right" over something "*which he has not described and indeed had not invented*." *Id.* (emphasis added). This Court emphasized that "[h]e can lawfully claim only what he has invented and described, and if he claims more his patent is void." *Id.* at 121.

Although Juno ignores *O'Reilly*, that case alone refutes Juno's mantra (at 23, 33, 34) that an adequate written description requires only that an artisan be enabled to "practice the invention"—which, in Juno's view, means that a patent need only enable one to practice just "one functioning" embodiment within a vast universe of possibilities claimed. Pet. 33. This Court invalidated Morse's claim even though his patent enabled electric telegraphs to be made and used (and thus satisfied Juno's proposed one-functioning-embodiment standard). *O'Reilly*, 56 U.S. at 112-21; *see Ariad*, 598 F.3d at 1346 n.4.

This Court's subsequent caselaw has cemented the separate written-description requirement. For example, in *Schriber-Schroth Co. v. Cleveland Trust Co.*, the Court invalidated claims for a gas engine with flexible webs because the patent did not describe them, even if it did enable them. 305 U.S. 47, 56-59 (1938). The patentee had argued that "[f]lexibility … is well known" as an "inherent property of the metal out of which the webs [could be] made." *Id.* at 57-59. This Court held that, even if those "skill[ed] in the art" would have been able to "substitute a flexible" web for a rigid one, "that was not the invention which [the inventor] described by his references to an extremely rigid web." *Id.*

Similarly, in *Gill v. Wells*, the Court invalidated claims to a machine for making hat bodies using a "plate, deflector, or side guides." 89 U.S. (22 Wall.) 1, 25-27 (1874). The patent was invalid because it did not contain "any description whatever" of that invention, but rather a "description of [a] chamber or tunnel" for the same function. *Id.* at 26-27; *see id.* at 21-24. The Court explained that disclosing "how to make, construct, and use the invention" was insufficient; the Patent Act also required disclosure sufficient for "the government [to] know what they have granted and what will become public property when the term of the monopoly expires" and "other inventors [to] know what part of the field of invention is unoccupied." *Id.* at 25-26*; see Ariad*, 598 F.3d at 1345-46 (discussing *Schriber-Schroth* and *Gill*); *Ariad* U.S. Amicus Br. 23-24. In keeping with these precedents, an influential contemporaneous treatise understood the requirements to be distinct. William C. Robinson, *The Law of Patents for Useful Inventions* § 484 (1890) ("According

to the statutes, the Description must contain full explanations of *three different subjects:* the invention itself; the manner of making it; and the mode of putting it into practical use,--a complete knowledge upon all these points being necessary to render the invention available to the public without further experiment or exercise of inventive skill." (emphasis added)); *id.* §§ 487, 515 (similar).

This Court's more recent precedent, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), confirms the separate written-description requirement. This Court, addressing the substantively identical pre-AIA version of § 112(a), identified three distinct "requirements" that "must be satisfied": "[T]he patent application must [1] describe, [2] enable, and [3] set forth the best mode of carrying out the invention." 535 U.S. at 736 (numbering added).

Juno (at 28) ignores this passage in *Festo* in favor of another that says: "What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue." 535 U.S. at 736. That does not help Juno. Overclaiming is precisely the problem with Juno's patent, which attempts to monopolize all scFvs in the claimed CAR that would bind to a selected target—without distinguishing what works from what does not. *Supra* 7-9, 12-13.

b. The foregoing cases belie Juno's contention (at 24) that this Court "has consistently understood" the statute to require enablement only. *See Ariad* U.S. Amicus Br. 3, 8-11, 26. Juno's cases suggest no such thing. Juno's lead authority (at 24-25) is to opposite

effect. *The Telephone Cases* upheld a patent claim to using electric current to transmit sound. 126 U.S. 1, 535 (1888). In doing so, the Court held that the inventor satisfied two distinct disclosure requirements. First, a description of the invention: "the exact … condition" of *what* had to be made "to accomplish" the function claimed. *Id.* ("[H]e did describe accurately, and with admirable clearness, his process,—that is to say, the exact electrical condition that must be created to accomplish his purpose."). And second, a description of *how* to make it: "[H]e also described, with sufficient precision to enable one of ordinary skill in such matters to make it, a form of apparatus which, if used in the way pointed out, would produce the required effect, receive the words, and carry them to and deliver them at the appointed place." *Id.*

Juno's remaining Supreme Court cases (at 25-26) fare no better. One did not involve the precursor to § 112, and regardless states that a patent's disclosure must allow those "skilled in the art [to] understand the invention" in addition to "put it to use." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933). The other cases neither directly concerned § 112 nor equated written description and enablement. At most, they observed that enablement is necessary, not that it is sufficient. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90-91 (2012); *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001); *Universal Oil Prods. Co. v. Globe Oil & Refin. Co.*, 322 U.S. 471, 483-85 (1944).

Juno is similarly mistaken (at 25) about regional-circuit precedent. Two of the cited cases enforced the

written-description requirement, invalidating claims because patents failed to describe and disclose the full scope claimed. *Donner v. Am. Sheet & Tin Plate Co.*, 165 F. 199, 206 (3d Cir. 1908) ("The evidence satisfies us the problem of continuous sheet-rolling was neither solved nor disclosed by this patent."); *Philip A. Hunt Co. v. Mallinckrodt Chem. Works*, 177 F.2d 583, 585-87 (2d Cir. 1949) (claims invalid because "they extend[ed] the monopoly beyond the proper limits of the 'invention,'" as determined by the patent's "disclosure," even though some embodiments could be made). The last case analyzed only the "'how to make' requirement of" § 112; the court did not hold that this was all § 112 required. *Ill. Tool Works, Inc. v. Foster Grant Co.*, 547 F.2d 1300, 1309 (7th Cir. 1976).

c. The interpretation the Federal Circuit followed here has been long-settled in that court too. "Since its inception, [the Federal Circuit] has consistently held that § 112 … contains a written description requirement separate from enablement." *Ariad*, 598 F.3d at 1351. So did its predecessor, the Court of Customs and Patent Appeals, more than 50 years ago. *Id.* at 1350-51; *In re Ruschig*, 379 F.2d 990, 995-96 (C.C.P.A. 1967). *Ariad* only reaffirmed that longstanding interpretation—by a lopsided 9-2 vote, relying on the statutory text, this Court's precedents, and statutory stare decisis. *Ariad*, 598 F.3d at 1343-54.

That alone is important, because, as noted above (at 17-18), Congress has repeatedly acquiesced in this reading by "re-enact[ing] [the] statute without change." *Forest Grove Sch. Dist. v. T.A.*, 557 U.S. 230, 239-40 (2009) (quoting *Lorillard v. Pons*, 434 U.S. 575, 580 (1978)). Congress's acquiescence gives "*stare*

decisis … special force." *Watson v. United States*, 552 U.S. 74, 82 (2007). That is especially so because Congress amended the patent statute some 50 times, including after *Ariad*, making the acquiescence "as frequent and clear as this Court ever sees." *Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 456-57 (2015).

B. Juno's Challenges To How The Federal Circuit Implements The Written-Description Requirement Are Meritless.

Juno also criticizes how the Federal Circuit applies the separate written-description requirement, raising features of the standard that have long been in place. Those arguments are meritless.

Juno mainly argues that the Federal Circuit wrongly focuses on "possession" because that word is not in the text. Pet. 19-22, 24. But the Federal Circuit has not substituted "possession" for "written description." It has emphasized that the "term 'possession'" is an imperfect shorthand. *Ariad*, 598 F.3d at 1351. "[T]he hallmark of written description is disclosure": "[T]he specification must describe an invention understandable to [a] skilled artisan and show that the inventor actually invented the invention claimed." *Id.* That is exactly what the statute says—and what this Court's cases, like *O'Reilly*, require. Moreover, this Court has also explained the written-description requirement in "possession" shorthand. *Evans*, 20 U.S. at 434. Juno quibbles that this Court has spoken of "'put[ting] the public in possession' of the invention" rather than of "demonstrat[ing] the *inventor*'s possession." Pet. 27 (quoting *Evans*, 20 U.S. at 434). But the

public takes possession *from the inventor*'s written description.

Juno next suggests that the Federal Circuit has adopted an atextual subtest for genus claims, requiring 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." Pet. 22-23 (internal quotation marks omitted). But the court observed here only that those are two possible ways of accomplishing what the statute requires: a description of "the invention." *See* Pet. App. 8a ("[g]enerally, a genus can be sufficiently disclosed" in these two ways). Consistent with the statute, the court required merely that, if an inventor chooses to claim an entire genus that performs a particular function, he must provide enough description "to distinguish [the claimed subject matter] from other materials." *Id.* (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)); *accord Ariad*, 598 F.3d at 1350-52 ("the description requirement does not demand any particular form of disclosure"; "whether a patent complies with the written description requirement will necessarily vary depending on the context," including factors such as "the nature and scope of the claims and … the complexity and predictability of the relevant technology").

Juno then inconsistently asserts that, in this case, the Federal Circuit actually added a requirement that the patent describe "all possible variations of each individual component of the invention—both 'known and unknown.'" Pet. 22 (quoting Pet. App. 13a). The

court required no such thing. As discussed, the court does not mandate an exhaustive listing, but rather enough disclosure to identify patterns with predictive power. Here, the court simply rejected Juno's argument that the patent's description was adequate "because scFvs, in general, were known." Pet. App. 13a. In response, the court made the commonsense point that Juno's claims *covered* everything "known" and "unknown," as in not yet discovered, whereas "the specification provides no means of distinguishing which scFvs will bind to which targets." *Id.*; *see* Pet. App. 14a n.2, 19a.

Juno also complains that the Federal Circuit requires "the full scope of the claims" to be described. Pet. 22 (internal quotation marks omitted). The need for this requirement is self-evident. The statute unambiguously requires "a written description of *the invention*." And the statute makes equally clear that the claims define the scope of "the invention." 35 U.S.C. § 112(b) (the claims "particularly point[] out and distinctly claim[] the subject matter which the inventor … regards as the invention"). The statute thus dictates that the breadth of the patent's disclosure must be commensurate with the breadth of the claimed subject matter (the patent monopoly for which the patentee enjoys exclusive rights). Rightly so—a patent claim is not a "nose of wax" to be treated narrowly for purposes of determining validity (making it less susceptible to challenge) yet broadly for purposes of determining infringement (making it block more activity). *Sterner Lighting, Inc. v. Allied Elec. Supply, Inc.*, 431 F.2d 539, 544 (5th Cir. 1970) (quoting *White v. Dunbar*, 119 U.S. 47, 51 (1886)); *see, e.g.*, *Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465,

476 (1895); *Lovell Mfg. Co. v. Cary*, 147 U.S. 623, 628 (1893).

Juno does not even try to reconcile this statutory imperative with its assertion that the patent may describe something less than the full scope claimed—nor with its insistence that describing just "one functioning" embodiment suffices. Pet. 33. The only hint for why Juno even mentions the full-scope requirement appears in a footnote (at 4 n.1) mentioning this Court's call for the Solicitor General's views in *Amgen Inc. v. Sanofi*, No. 21-757. But Juno's petition does not raise either of *Amgen*'s questions presented: (1) whether enablement is a factual question or (2) what standard should govern the enablement inquiry.

II. Juno's Policy Arguments Are Meritless.

Juno and its amici complain that the Federal Circuit's written-description standard has "devastat[ed] innovation … particularly … in the biological arts." Pet. 2. Hardly. The written-description requirement promotes innovation by enforcing the patent bargain's quid pro quo, as this case illustrates.

1. To dispel one exaggeration up front: The Federal Circuit's application of a separate written-description requirement does not "demand[] the impossible." Pet. 2; *see* Pet. 32-33. The court upholds functional genus claims—when they are commensurate with their supporting disclosure.

For example, the Federal Circuit recently upheld claims to a "very large" and varied genus of drug

compounds treating a prostate-gland disease. *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 646 (E.D. Tex. 2017) (Bryson, J., sitting by designation), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018). As here, the claims defined the genus by its function: selective inhibition of a specific enzyme, PDE5. *Id.* at 644. But the *UroPep* patent provided what Juno's does not. The patent itself disclosed a multitude of representative species, with hundreds more known in the field, and the patent holder presented unrebutted evidence that common structural features among all these examples would allow a skilled artisan to predict which structures satisfy the claimed function. *Id.* at 644-59. They could make those predictions, in part, because the field was mature and researchers had extensive information about which structures would work. *Id.* at 646-47.

Likewise based on disclosure of common structural features and representative species, the Federal Circuit recently upheld claims to a genus of bacteria genetically engineered to include "more potent promoters" that enhanced activity. *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1358-61 (Fed. Cir. 2019). Other biotechnology decisions are in accord. *See, e.g.*, *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336-37 (Fed. Cir. 2006) (upholding functional genus claims to enhanced CaMV promoters). *Ariad* itself favorably cited such decisions. 598 F.3d at 1352 (citing *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005) (upholding functional genus claims to polypeptides with certain activity)).

Plainly, the Federal Circuit's test is not "impossible" to meet.

Here, the Federal Circuit drew only the case-specific conclusion that Juno's broad functional claims overreach. As just one example, the inventors could have claimed genetic material encoding the two-part "backbone" along with the specific scFvs they actually used, if those two scFvs had been disclosed or publicly known. Such a claim would have been commensurate with what was invented. But they chose to pursue only extremely broad claims: *all functional versions* of a CAR, with any scFv, of any structure, from any source, to target any antigen and cure any disease. They *claimed* everything that could work, which required commensurate disclosure. Not necessarily in detail or exhaustively—and certainly not by describing every species individually—but with enough information to distinguish what works from what does not. Pet. App. 11a-12a, 22a. This is the patent system's essential quid pro quo. Of course, the more an inventor tries to claim in an unpredictable field, the harder it will be to satisfy that requirement. But that is how it should be: The quid should equal the quo.

In this regard, we agree: "This case is the posterchild," Pet. 2—but for overreach. The CAR component that the inventors failed to describe is not some trivial plug-and-play "charging cord," nor is it akin to ancient household objects that "accommodate a human posterior." Pet. 35. It is a portion of a genetically engineered protein—extremely complex biological material—designed to perform an autoimmune function when put into a living cell and injected into the human body. And, in that unpredictable context, it is *the* element that identifies the target enemy, grabs onto it like a vise, and triggers the rest of the attack sequence—to cure cancer. *Supra* 7-9, 12-13

(unpredictability and failures to make CD19-specific scFvs). Juno wants ownership over everything that works in that sphere, without knowing or disclosing what will (or why). The tailored patent the inventors could have gotten would have reflected the patent "bargain" Juno extols. Pet. 1, 7, 29, 30. The monopoly Juno wants is for a massive research plan. But patents reward inventions, not research plans.

2. Juno and its amici fail to prove that the balance the Federal Circuit has read § 112 to strike will "present[] severe dangers to research and innovation." Pet. 29 (capitalization omitted).

The very notion is counterintuitive. *Cancer* centers and biotechs will cease researching cures for cancers and other blockbuster drugs because the Federal Circuit adheres to the legal requirements for written description that have been in place for over 50 years? Of course not. They will not stop investigating a promising drug concept just because any resulting patent claims will be limited to their actual invention.

Confronted with the same policy arguments in *Ariad*, the Federal Circuit found "no evidence" that the separate written-description requirement it had been applying caused "any discernable impact on the pace of innovation." 598 F.3d at 1353. In fact, in *Ariad*, some of the biggest pharmaceutical companies—including Abbott, Amgen, and GlaxoSmithKline—supported that requirement. *Ariad* Abbott Amicus Br., 2009 WL 4832136; *Ariad* Amgen Amicus Br., 2009 WL 4616154; *Ariad* GlaxoSmithKline Amicus Br., 2009 WL 4616153. And companies from multiple other sectors agreed, arguing that it is vital to

innovation. *See, e.g.*, *Ariad* Microsoft Amicus Br., 2009 WL 4832139, at 6-18; *Ariad* RealNetworks Amicus Br., 2009 WL 4832129, at 9-16. All told, the amicus briefs in *Ariad* overwhelmingly (17 out of 25) favored the party defending the separate written-description requirement. *Ariad*, 598 F.3d at 1342; *see, e.g.*, *Ariad* Professor Oskar Liivak Amicus Br., 2009 WL 4616152, at 20-23; *Ariad* Public Patent Foundation Amicus Br., 2009 WL 4922508, at 22-29.

Juno has found some amici that would benefit from suspending the rule because they have pursued strategies of overclaiming. Two of Juno's headliners are recent converts, who took the opposite position in *Ariad*. *See Ariad* GlaxoSmithKline Amicus Br. 5-10; *Ariad* Amgen Amicus Br. 5-8. Notably, Juno has not garnered support from the organizations that broadly represent the pharmaceutical industry (PhRMA) and the biotech sector (BIO). These organizations are not shy about saying when they think a ruling "threatens innovation," as they did in connection with another pending certiorari petition, raising an entirely different issue, also concerning the written-description requirement. *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, No. 21-1567, PhRMA & BIO Amicus Br. 6 (capitalization omitted).

Juno's warnings of "severe danger," Pet. 29, and "devastati[on]," Pet. 2, ring hollow given the astronomical growth the biotechnology industry has enjoyed throughout the over 50 years that the modern statute, § 112, has been interpreted to contain a separate written-description requirement. *See* Malgorzata Kesik-Brodacka, *Progress in Biopharmaceutical Development*, 65 Biotech. &

Applied Biochem. 306, 319 (2017). Even Juno's favorite law-review article (*see* Pet. 2, 31, 33) concedes that "innovation … seem[s] to be proceeding apace in the pharmaceutical industry." Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 65 (2021).

3. In reality, it is Juno's approach that would devastate innovation. The sort of sweeping claims Juno would normalize would deter researchers from investigating promising drug candidates. If researchers see a patent monopolizing an enormous genus of potential—but undiscovered—treatments, they will shy away from the whole range. No one will invest the billions necessary to bring a drug to market only to face a suit for an injunction or billions of dollars. For example, under Juno's one-functioning-embodiment test (Pet. 33), a patentee could monopolize all vaccines against COVID-19 by just discovering one, simply because others can be discovered and made with known production techniques. That would discourage researchers from finding more.

Consider how things played out here: Juno's CAR "backbone" was fertile ground for research. Two decades later, Juno still has not developed a treatment with it. If Juno had a valid monopoly, its discovery would have yielded no therapy. Only Kite succeeded, finding a therapy that uses an scFv different from anything the patent identifies. That invention has miraculously cured thousands of people. *That's* the innovation the law needs to encourage.

This Court and the Government have made exactly this point, emphasizing that broad, poorly

described genus claims harm innovation by "foreclos[ing] others from pursuing 'efforts to discover a better specimen of [the] class' than the applicant has actually invented and described." *Ariad* U.S. Amicus Br. 24 (quoting *McKeesport*, 159 U.S. at 476); *see O'Reilly*, 56 U.S. at 120-21 (overclaiming "prevents others from attempting to improve upon the manner and process which [the patent] has described in [its] specification"); *McKeesport*, 159 U.S. at 475-76 ("unwarranted extension" of a claim "operate[s] rather to discourage than to promote invention"); *cf. Brenner v. Manson*, 383 U.S. 519, 536 (1966) ("[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

Ariad thus rightly recognized that a robust written-description requirement is an important protection against overclaiming—a problem "particularly acute in the biological arts." 598 F.3d at 1352-53. All too often, patentees in that context use functional language to capture "all solutions" to a "problem to be solved," "leaving it to the pharmaceutical industry to complete an unfinished invention." *Id.* at 1353. Eliminating or relaxing the written-description standard would only encourage such gamesmanship, "impose costs on downstream research, [and] discourag[e] later invention." *Id.* The "right balance" is achieved by instead "giving the incentive to actual invention and not 'attempt[s] to preempt the future before it has arrived.'" *Id.*; *see Ariad* U.S. Amicus Br. 16-17, 24.

4. Even if Juno's policy concern about impacts on biotechnology were sound, its recourse for a subject-matter-specific rule is with Congress. Congress passed the Plant Patent Act to address the concern

that plant patents were "not amenable to the 'written description' requirement of the patent law." *Diamond v. Chakrabarty*, 447 U.S. 303, 312 (1980); 35 U.S.C. § 162. Congress has created no such carveout here.

Acting where Congress has not is particularly inappropriate here because reliance interests run deep. Even before *Ariad*, "the inventing community" relied on the separate written-description requirement "in drafting and prosecuting patents" and "concluding license agreements." *Ariad*, 598 F.3d at 1347. Innovators relied on the requirement in evaluating the patent landscape to determine where to invest in research and development. *See, e.g.*, *id.*; *Ariad* Medtronic Amicus Br., 2009 WL 4616155, at 13-20; *Ariad* GlaxoSmithKline Amicus Br. 5-10 (citing "more than 2.5 million patents" that issued "based on the fundamental premise" of a "separate and distinct" written description requirement and arguing against any "dramatic changes in statutory interpretation"); *Ariad* Amgen Amicus Br. 5-8 (citing "nearly 200 years of Supreme Court jurisprudence" supporting the written-description requirement and explaining that it is "particularly important in high risk and large investment areas of research, such as human therapeutics"). The PTO also relied on the requirement in preventing overbroad claims from issuing and stifling innovation. *See Ariad,* 598 F.3d at 1347; *Ariad* U.S. Amicus Br. 20-24; Manual of Patent Examining Procedure § 2161 (6th ed. Sept. 1995), https://bit.ly/3QeOePR ("The written description requirement is separate and distinct from the enablement requirement.").

This reliance has only grown in the decade-plus since *Ariad*. The Federal Circuit has routinely applied *Ariad* without once coming close to reconsidering its holding, and Congress revamped the Patent Act in the AIA without changing the written-description requirement. "[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo*, 535 U.S. at 739. And "[c]onsiderations in favor of *stare decisis* are at their acme in cases involving property and contract rights, where reliance interests are involved." *Pearson v. Callahan*, 555 U.S. 223, 233 (2009) (internal quotation marks omitted).

III. This Case Is A Poor Vehicle.

This case is a poor vehicle for this Court to reverse course and revisit the written-description requirement. Juno objects to various formulations the Federal Circuit has employed to capture the level of disclosure required of those, like Juno, who seek to monopolize functional genuses. But Juno offers no alternative formulations. And even if it did, this case offers no opportunity to evaluate where to draw the line.

That is because Juno's disclosure is unusually thin, even among patents that fail the Federal Circuit's written-description test. The patent does not disclose any amino-acid sequence or other structural detail regarding the claimed scFv binding element. It mentions only two scFvs used as part of the claimed CAR. Both were proprietary and not publicly accessible. The patent offers no detail whatsoever—just

alphanumeric codenames. *Supra* 8-9.[3] Such a disclosure is uniquely deficient, especially for such a sweeping functional genus. *See, e.g.*, *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1157, 1161, 1163-65 (Fed. Cir. 2019) (insufficient written description of functional genus of many thousands of nucleoside candidates where four working examples were disclosed); *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1357-58, 1364-65 (Fed. Cir. 2011) (insufficient written description of functional genus of tens of thousands of drug-compound candidates where 39 working species were known in the art); *cf. Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1083, 1088 (Fed. Cir. 2021) (insufficient enablement of functional genus of millions of antibody candidates where 26 working species were disclosed with full amino-acid sequences, some with three-dimensional structure and place of binding depicted).

Juno's invocation of "[r]ecent en banc practice" backfires. Pet. 36-37. Its cited case, *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 28 F.4th 1194 (Fed. Cir. 2022), reinforces that Juno attacks only uncontroversial precedent: The dissenting judges there—consistent with the lack of dissent here—endorsed the

[3] The CD19-specific scFv did have a published amino-acid sequence associated with it, but that sequence was undisputedly wrong and, as one inventor conceded, "not functional as a receptor." C.A. App. 26,410; *see* C.A. App. 33,689-91. To make a workable CAR, the inventors used a *different* sequence based on having special access to the proprietary scFv. *See* C.A. App. 26,408-10, 32,930-31, 33,690-91. In other words, Juno's patent does not disclose even a single working CD19-specific CAR, and so would not meet even the absurdly lenient one-functioning-embodiment standard that Juno proposes, Pet. 33.

separate written-description requirement and *Ariad*'s articulation of it. As Juno itself acknowledges (at 37), *Biogen*'s dissenting judges "reiterated their support for *Ariad*'s general rule." Likewise, the principal trade organizations representing pharmaceutical and biotechnology companies, PhRMA and BIO, who filed in support of certiorari in *Biogen*—but not here (*supra* 31)—do not question *Ariad*. Ultimately, *Biogen* presents an entirely different question and does not support disturbing settled precedent on written description's separateness from enablement.

CONCLUSION

The Court should deny Juno's petition.

Respectfully submitted,

Jeffrey I. Weinberger
Ted G. Dane
Peter E. Gratzinger
Adam R. Lawton
MUNGER, TOLLES & OLSON LLP
350 S. Grand Ave., 50th Fl.
Los Angeles, CA 90071

Geoffrey D. Biegler
FISH & RICHARDSON, P.C.
12390 El Camino Real, Ste. 100
San Diego, CA 92130

E. Joshua Rosenkranz
Counsel of Record
ORRICK, HERRINGTON & SUTCLIFFE LLP
51 West 52nd Street
New York, NY 10019
(212) 506-5000
jrosenkranz@orrick.com

Melanie L. Bostwick
Jeremy Peterman
Robbie Manhas
ORRICK, HERRINGTON & SUTCLIFFE LLP
1152 15th Street, NW
Washington, DC 20005

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