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

BRIEF OF ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC., ALBERT EINSTEIN COLLEGE OF MEDICINE, THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER, AND OTHER ACADEMIC RESEARCH INSTITUTIONS AS *AMICI CURIAE* IN SUPPORT OF THE PETITION

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STATEMENT OF INTEREST[1]

Amici have an interest in the outcome of this case, and they offer perspectives that will assist this Court. St. Jude Children's Research Hospital, Inc. is the only National Cancer Institute-designated Comprehensive Cancer Center devoted solely to children. For more than 60 years, Albert Einstein College of Medicine has set the standard for excellence in medical and graduate education and patient-centered clinical care, and it has made major contributions to scientific research enhancing human health. The University of Texas M. D. Anderson Cancer Center ranks as one of the world's most respected centers focused on cancer patient care, research, education, and prevention. Temple University Health System and its Fox Chase Cancer Center are together an academic health system based in Philadelphia, driving medical advances through clinical innovation, pioneering research and world-class education. Fox Chase Cancer Center is one of the nation's first cancer hospitals and home to multiple Nobel laurates, and since its founding in 1904 it has been at the forefront of leading advancements in cancer care. Fred

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[1] The parties received timely notice of this brief under Rule 37.2(a). Petitioners and Respondents have consented to the filing of this brief. As directed by Rule 37.6, *Amici* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *Amici*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. To secure Kite's consent, *Amici* note that King & Spalding represented non-party Bristol Myers Squibb Company ("BMS") in connection with a third-party subpoena issued to BMS in the underlying district court proceedings.

Hutchinson Cancer Center, which is home to three Nobel laureates, was the first National Cancer Institute-designated cancer center in the Pacific Northwest, and its global leadership in bone marrow transplantation, HIV/AIDS, immunotherapy, and COVID-19 has made it one of the world's leading cancer, infectious disease, and biomedical research centers. The Wisconsin Alumni Research Foundation ("WARF") helps steward the cycle of research, discovery, commercialization, and investment for the University of Wisconsin–Madison. Founded in 1925 as an independent, nonprofit foundation, WARF manages more than 2,000 patents and an investment portfolio as it funds university research, obtains patents for campus discoveries, and licenses inventions to industry.

Amici are familiar with the patent-in-suit, and the significant benefits that this patent's scientific foundation provides to further research and cancer treatment. *Amici* are likewise conversant in researching, developing, and bringing to bear new and innovative therapies for fighting cancer, including technologies that are the subject of existing patent protection and pending patent applications. Because the patent-in-suit represents groundbreaking technology in the treatment of cancer, and because it stands as an exemplar of what patent protection can provide to institutions dedicated to cutting-edge research to eradicate the toll levied by cancer, *Amici* offer important perspectives unique from any party.

SUMMARY OF THE ARGUMENT

The innovative research conducted by *Amici* and other academic research institutions improves and

saves lives with groundbreaking new therapies. But without effective patent protection, *Amici* cannot attract the substantial investment needed to fully develop those innovations (at significant risk of failure) and ultimately bring them to commercial market where they can help patients. U.S. patent law is founded on this understanding: patent protection incentivizes valuable commercial innovation, for the benefit of the country and the people.

In this case, however, the patent system has gone astray. Sloan Kettering, a research institution like *Amici*, obtained a patent for its revolutionary, lifesaving invention in the field of chimeric antigen receptor ("CAR") therapy—which was commercially developed under an exclusive license to Juno, but was also developed without license by Kite. The Federal Circuit invalidated Sloan Kettering's patent by applying an unworkable "written description" standard that strays from the statutory text and traditional understanding of 35 U.S.C. § 112(a).

This case deserves this Court's review because the Federal Circuit's decision below entrenches an incorrect approach to a vitally important question, and it threatens to disrupt lifesaving research in the process. *See* S. Ct. R. 10(c). *Amici* rarely file amicus briefs in patent-related cases like this one, but they are compelled to do so here to underscore the threat this case poses to academic research.

The Federal Circuit's decision adopts a flawed interpretation of the written description requirement under 35 U.S.C. § 112 that is contrary to statutory language and at odds with this Court's precedents and the historical understanding of the law. The decision

morphs the written description requirement into an unfeasible standard—most deleteriously affecting cutting-edge innovations in the biotechnology and pharmaceutical fields—that significantly threatens the innovative lifesaving efforts of *Amici* and their partners.

The CAR technology at issue in this case is emblematic of the valuable lifesaving research coming out of academic research institutions, whose further development efforts may be stymied by the decision below. This case is the perfect vehicle for this Court to address the Federal Circuit's misguided, atextual approach and to clarify the written description requirement.

The Federal Circuit has put *Amici* and other academic research institutions in an untenable position as they continue to undertake innovative research with CARs and other critical biotechnologies. If *Amici* pursue only narrow patent protection in which even well-established technology elements cannot be claimed generically, such patents may be readily evadable by copycats using routine, preexisting technology—thereby disincentivizing further investment towards developing treatments for patients. Or, if *Amici* and their researchers expend their limited resources and time attempting to satisfy the Federal Circuit's heightened written-description standard by exhaustively making, characterizing, and testing innumerable embodiments of old technology, their mission to advance innovative research will suffer. Both options will harm innovation without any corresponding benefit to the public or to health outcomes for patients. The Federal Circuit's

reimagined standard has never been the rule; nor should it be. This Court should grant the petition.

ARGUMENT

I. The Federal Circuit's Approach to the Written Description Requirement Calls for Review.

The Federal Circuit's opinion interprets the "written description" requirement of 35 U.S.C. § 112(a)[2] to demand that inventors demonstrate their possession of all "known and unknown" embodiments of patent claim elements directed to prior-art technology—even if those variations have nothing to do with the novel innovation of their claimed invention. *See* Pet. App. 13a. This super-heightened description requirement has no foothold in the text of the statute or this Court's precedents, and it undercuts the Patent Act's incentives for innovation.

A. The Decision Misapprehends the Patent Act, Precedent, and the Historical Understanding of an Adequate Written Description—Imposing an Onerous Burden on Innovation in Biotechnology and Pharmaceuticals.

1. The text and historical understanding of the Patent Act (Title 35) cannot bear the weight of the

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[2] 35 U.S.C. § 112, ¶ 1 was replaced with § 112(a) by section 4(c) of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, § 4, 125 Stat. 284, 296–97 (2011). AIA § 112(a) remains identical to pre-AIA § 112, ¶ 1 as it pertains to the written description requirement. For ease of reference, this brief uses "§ 112(a)" to refer to both the pre-AIA and AIA versions.

decision below. 35 U.S.C. § 112(a) requires a patent applicant to provide "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."

According to the Federal Circuit, § 112 "contains two separate description requirements": a "written description requirement" and an "enablement requirement." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1342 (Fed. Cir. 2010) (en banc). Under the Federal Circuit's approach, the first of these requirements—that is, a "written description of the invention"—requires the inventor to "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* at 1342, 1351.[3] Under the "enablement requirement," the written description must "identif[y] the invention so as to enable one of skill in the art to make and use it." *Id.* at 1344.

While the Federal Circuit's "possession" concept in *Ariad* has been subject to question,[4] the panel's reasoning below in this case illustrates the damaging mischief that can result when a judicially created test becomes completely unmoored from its anchor of statutory language—thereby upending the operation of the Patent Act as a whole. Through common-law judging, the Federal Circuit has transformed a

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[3] Unless otherwise noted, all emphasis is added, and all internal citations and internal quotation marks are omitted.

[4] *See, e.g.*, *id.* at 1361–63 (Rader, J., dissenting in part); *id.* at 1367–68 (Linn, J., dissenting in part).

straightforward statutory requirement of "descri[bing] . . . ***the invention***" into an impossible burden of inexhaustibly exemplifying all "known and unknown" embodiments of ***prior art*** technology.

2. The decision below invalidates Sloan Kettering's patent for a groundbreaking innovation in the field of Chimeric Antigen Receptors ("CARs")—a promising cancer-fighting technology. CARs are engineered synthetic chemical structures that (1) enable certain blood cells called lymphocytes to locate cancer cells by recognizing the unique antigens (proteins or other molecules) on their surface and then (2) signal the lymphocytes to destroy those cancer cells. CARs are part antibody and part lymphocyte (most commonly T cells, which can kill other cells). The CAR-modified lymphocytes thus act as a potent, targeted anti-cancer agent, by recognizing, attaching to, and eliminating certain cancer cells.

Sloan Kettering's patent reflects an innovative discovery that overcame the significant limitations of earlier CAR technologies. First-generation CAR constructs typically had two main parts: (1) an intracellular (inside the cell) "signaling" domain, which would activate the CAR-modified cells against target cancer cells, and (2) an extracellular binding element such as a single-chain antibody variable fragment ("scFv"), which could bind the CAR-modified cell to a target cancer cell. To enhance the limited activity of these first-generation constructs, researchers designed second-generation CARs with an improved signaling domain—a CAR "backbone" including a "costimulatory domain" in addition to the primary signaling domain—along with a conventional

scFv binding element as before. But it still proved challenging to find a CAR backbone yielding sufficient killing activity to treat cancer in practice.

The patent at issue in this case reflects how Sloan Kettering's researchers overcame these limitations, by their breakthrough discovery of an innovative, improved CAR backbone with a novel costimulatory domain. This novel backbone not only stimulated killing activity, but it also enabled the CAR-modified cells to replicate—essentially acting as "living drugs" in the body that could amass a potent killing force against the target cancer cells.

The patent claims at issue thus recite Sloan Kettering's breakthrough CAR backbone, including the novel costimulatory domain defined by its specific amino acid sequence. Certain claims further recite the well-established prior-art technology of using a generic "single chain antibody" (*i.e.*, an scFv) as the CAR "binding element." As explained to the jury who returned a verdict for Petitioners, a person of ordinary skill in the art would have found it routine to use scFvs as CAR binding elements, and to identify known scFvs suitable for a given target (or to make new scFvs as needed). An ordinary artisan also would have understood that the patent's description of two scFvs, including one specifically targeting CD19, were representative examples of well-known scFv technology.

3. In reversing the jury's verdict, the Federal Circuit's decision flipped the written description requirement on its head—all while arrogating the jury's factfinding role and neglecting that "the patent specification is written for a person of skill in the art,

and such a person comes to the patent with the knowledge of what has come before." *See Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed. Cir. 2012); *see also In re Storrs*, 245 F.2d 474, 478 (C.C.P.A. 1957) ("In determining the certainty required [of the disclosure under 35 U.S.C. § 112], it cannot be forgotten that the disclosure is not addressed to the public generally, but to those skilled in the art."). As the jury recognized, the "ordinary" artisan in biotechnology can be highly skilled relative to the general public; and what is well-established, routine, and predictable to those of ordinary skill within the field may often seem complex and unpredictable to those outside it. Nonetheless, the Federal Circuit's decision rejected these factual findings, and subsumed them to baseless legal abstractions.

According to the Federal Circuit, Sloan Kettering's claims to a novel, innovative CAR backbone could not satisfy the written description requirement unless the specification described all "***known and unknown***" embodiments of a ***prior art*** technology element—the scFv binding element that an ordinary artisan would have understood as described by the patent's disclosure of specific scFvs known in the art and well-established laboratory methods to make other scFvs (*see* Pet. App. 13a, 36a–39a). Even for the dependent claims to the specific target "CD19," the Federal Circuit engrafted a legal requirement that "***millions of billions***" of potential CD19-binding scFvs be made and tested before an adequate written description could be realized. *See* Pet. App. 17a–21a.

4. But that has never been the law—even under the prior precedent of the Federal Circuit and its predecessor court (the U.S. Court of Customs and Patent Appeals ("CCPA")), on which research institutions could justifiably rely prior to the decision below. Rather, the law has always been that "an applicant is ***not required*** to describe in the specification every conceivable and possible future embodiment of his invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003). That was so because requiring the disclosure of every possible embodiment would "impose an impossible burden on inventors and thus on the patent system." *See In re Hogan,* 559 F.2d 595, 606 (C.C.P.A. 1977). "There cannot, in an effective patent system, be such a burden placed on the right to broad claims." *Id.* Then as now, that reasoning is correct.

The Federal Circuit decision below particularly conflicts with a 1979 CCPA decision that came out quite differently when addressing "written description" issues similar to those presented here. *See In re Herschler*, 591 F.2d 693, 700–01 (C.C.P.A. 1979); *see also Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 928 (Fed. Cir. 2004) (discussing *Herschler*). *Herschler* held that method claims reciting dimethylsulfoxide ("DMSO") as a skin penetration enhancer for a generic "physiologically active steroidal agent[]" were ***not*** invalid for lack of written description—even though the specification exemplified only a ***single*** "steroidal agent[]"—because (1) the invention was "steroids . . . as a class of compounds carried through a layer of skin by DMSO"—***not*** "novel 'steroidal agents'"; and (2) an ordinary artisan knew of additional "steroidal agents,"

and that DMSO would perform similarly for steroids generally. 591 F.2d at 700–01; *see also Rochester*, 358 F.3d at 928 ("The ***novelty*** in [*Herschler*'s] invention was the DMSO solvent, ***not the steroids***.").

Recognizing that the inventors did not seek to monopolize "novel steroidal agents" *per se*—*Herschler* held that § 112 did ***not*** require the inventors to have described every known and unknown "physiologically active steroidal agent[]," or to have made and tested innumerable putative "steroidal agents" for potential "physiological activity." *See* 591 F.2d at 700–01. *Herschler*'s permissive, pragmatic approach to the written description requirement for generic, prior-art technology elements has even been blessed as consistent with the Federal Circuit's modern-day written description requirement—*i.e.*, that "the patent specification set forth enough detail to allow a person of ordinary skill in the art to . . . recognize that the inventor invented what is claimed." *Rochester*, 358 F.3d at 928 (citing *Herschler*, 591 F.2d at 701).

5. *Herschler* should have controlled here: (1) the patent disclosed at least two exemplary scFvs; (2) those of skill in the art knew of other suitable scFvs and the well-established technology to generate more, and understood that the innovative claimed CAR "backbone" would perform similarly with scFvs generally; and (3) the novelty of the claimed invention was in its innovative CAR backbone, not the routine use of scFvs as a binding element. The inventors undisputedly described and enabled (and likewise "possessed") their claimed innovation—including the novel backbone's precise amino acid sequence—and did not seek to monopolize all "novel scFvs" *per se*.

In finding Sloan Kettering's patent invalid for failure to describe all "known and unknown" embodiments of routine scFv technology, the Federal Circuit privileged its own common-law dictates over the statutory text and historical practice. But no court has authority to hamper inventors with additional obligations beyond those imposed by statute. *See, e.g.*, *Bilski v. Kappos*, 561 U.S. 593, 602 (2010) ("This Court has more than once cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed.").

6. The written description requirement adopted below is also contrary to statutory history and this Court's early precedents. The U.S. patent laws have, since their inception shortly after the founding, contained similar language requiring a "written description of [the] ***invention***." And this Court has never interpreted that language to additionally require an inexhaustible written description of the ***prior art***. Rightfully so, because the statutory text lacks any such requirement, and instead implies the opposite. *See Herschler*, 591 F.2d at 700–01; *Pozen*, 696 F.3d at 1167; *Storrs*, 245 F.2d at 478.

Statutory requirements regarding a written description have existed since the 1793 Act, which included the following:

> [E]very inventor . . . shall deliver a 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 distinguish the same from all other things before known, and to enable any

> person skilled in the art . . . to make, compound, and use the same.

Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321–22.

The 1836 Act eliminated the need to distinguish the invention "from all other things before known," but otherwise left the remainder of the "written description" language intact. *See* Act of July 4, 1836, ch. 357 § 6, 5 Stat. 117, 119. The 1870 Act was the same in all relevant respects. *See* Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198, 201. And the 1952 Act continued this consistency—amending nothing that could be understood to substantively alter the statutory requirements for the "written description." *See* 35 U.S.C. § 112, ¶ 1 (pre-AIA). Rather, the present language and grammar of § 112(a) mirrors the patent statutes dating back to 1793.

Throughout that history, the Court has never interpreted this statutory language to require the kind of showing that the Federal Circuit imposed below. Take a famous invention: the telephone. When Alexander Graham Bell's patent came before the Court, the Court upheld it even though "Bell had not in fact completed his discovery." *The Telephone Cases*, 126 U.S. 1, 535 (1888). That is, "[t]he particular instrument which he had, and which he used in his experiments, did not . . . reproduce the words spoken so that they could be clearly understood." *Id.* But it was "enough" that Bell "describe[d] his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process [was], . . . [and] point[ed] out some practicable way of putting it into operation." *Id.* at 536; *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370,

373 (1996) (describing the "modern American system" as requiring "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'" (quoting 35 U.S.C. § 112)).

So too here. By identifying representative scFvs known in the art (including at least one specific to CD19), and incorporating the prior-art literature describing the routine techniques for making additional scFvs (*see, e.g.*, Pet. App. 36a–39a), Sloan Kettering's patent detailed the invention "with sufficient clearness and precision" to fully describe what was invented and claimed to a "person skilled in the art to which [the invention] pertains." 35 U.S.C. § 112; *see also The Telephone Cases*, 126 U.S. at 536. Under this state of play, a skilled artisan would (as the jury found) understand that Sloan Kettering's patent specification adequately described the invention that it claimed.

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In short, the Federal Circuit's expansion of § 112 to require the inexhaustible exemplification of routine, prior-art technologies is contrary to the uniform understanding reflected in centuries of statutory language and decades of this Court's decisions. As detailed below, it unduly burdens academic cancer research institutions whose focus is rightly on innovation to benefit patients. And it does so without good cause, textual justification, or sound reasoning. This Court should intervene.

B. This Case Presents an Ideal Vehicle for Addressing the Question Presented.

This case presents the ideal vehicle for this Court to clarify the written description requirement. The procedural posture raises no concerns; the Federal Circuit approach is enounced and will not change absent this Court's intervention; and the factual background of this case exemplifies the flaws and dangers of the Federal Circuit's severe rule.

1. First, there are no procedural hurdles to this Court's review. The decision below reversed a jury verdict in favor of Juno on a single issue: "[N]o reasonable jury could find the '190 patent's written description sufficiently demonstrates that the inventors possessed the full scope of the claimed invention." Pet. App. 9a; *see also* Pet. App. 2a. The question presented here was thus outcome determinative below. Granting the petition and ruling in favor of Petitioners would allow the Federal Circuit to reexamine the jury verdict under the proper "written description" framework. And no case, to *Amici*'s knowledge, better presents the important and costly concerns with the Federal Circuit's interpretation and application of the written description requirement.

2. The time is ripe for the Court's intervention on this issue. There is no need to wait for further lower-court percolation, because the Federal Circuit's decision reflects the culmination of decision-making on this topic. *See* 28 U.S.C. § 1295(a) (providing the Federal Circuit exclusive jurisdiction over patent appeals). And the Federal Circuit will not likely reverse course on its own, given that the court

expressly declined en banc review in this case. Additionally, it is uncertain when the Federal Circuit or this Court will have another opportunity to address this issue. In the meantime, the decision below will wreak havoc on important research and development, to the public's detriment.

3. The decision below demonstrates how the Federal Circuit's textually unsupported expansion of the written description requirement unduly targets pharmaceutical and biotechnology inventions, including unquestionably groundbreaking therapeutic innovations—here, an innovation so valuable that Kite used it for its own CAR product.

The Federal Circuit's application of the written description requirement in this case—requiring inventors to make, test, and disclose innumerable potential embodiments of claim elements directed to well-established, routine prior-art technology—exemplifies the damaging repercussions that its current approach will have on the biotechnology and pharmaceutical fields in which "genus" claims are common.[5]

The revised test laid out in the decision below—requiring inventors to describe an essentially infinite number of embodiments for routine, prior-art technology claim elements—threatens to sound the death knell for patenting pioneering biotechnology innovations like Sloan Kettering's. *Amici* and other

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[5] A genus claim is one "that covers a group of structurally related products that incorporate the basic advance of the patented invention." Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 3 (2021).

similarly situated research institutions now face massive uncertainty, placing at risk their innovative efforts both realized and yet-to-be realized.

Scholars have already identified this case as part of an unmistakable trend that "biotechnology, chemical, and pharmaceutical genus claims lose in court." Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 4 (2021). The lifesaving CAR therapeutic technology at issue in this case is representative of other critical research developments coming out of academic research centers that are jeopardized by the Federal Circuit's revamped approach.

The Federal Circuit's unforgiving scrutiny of biotechnology "genus" claims is particularly pernicious here—where, as the CCPA recognized for the steroids in *Herschler*, Sloan Kettering's claims are ***not*** drawn to, and do ***not*** seek to monopolize, a genus of "novel [scFvs]." *Cf. Herschler,* 591 F.2d at 700–01. Yet the Federal Circuit here held that Sloan Kettering's fundamental innovation—a novel CAR "backbone" with remarkably improved therapeutic properties—could not patented without disclosure of all conceivable novel (*i.e.*, presently "unknown") scFvs.

4. Finally, granting certiorari would give the Court the opportunity to address a fundamental discriminatory error underlying the Federal Circuit's super-heightened description requirement: that the Federal Circuit incorrectly treats the biotechnology and pharmaceutical fields as categorically "unpredictable arts," and improperly requires a higher level of written description in these fields than for so-called "predictable arts." *Cf. Hologic, Inc. v. Smith &*

Nephew, Inc., 884 F.3d 1357, 1361–62 (Fed. Cir. 2018) (distinguishing the "level of detail . . . required" for "unpredictable arts" versus "predictable arts").

There is no reason biotechnology innovators writ large, but not those in "predictable" fields, should be held to the Federal Circuit's impossible standard. When finding adequate support for a claim generically reciting "local color displays"—a "predictable arts" case—the Federal Circuit did not require the inventors to describe every "color display" embodiment known and unknown as of their 1985 filing—but rather the court was satisfied with a specification mentioning "cathode ray tubes . . . or other display transducers" along with the statement that "the present invention can be applied to a wide variety of display and vision aid devices." *See Honeywell Int'l, Inc. v. United States*, 609 F.3d 1292, 1301–02 (Fed. Cir. 2010). When it found adequate support for claims reciting a generic "light guide," the Federal Circuit likewise did not insist on the disclosure of all known and unknown "light guides"—but was instead satisfied that the specification disclosed one "type of light guide," and that "various types of light guides were well-known in the art." *See Hologic*, 884 F.3d at 1361–62.

Biotechnology patent claims should be treated equally when they similarly generically recite well-established, routine prior art elements. It is implausible to think that Honeywell's inventors, in their 1985 application, should have described every "color display" technology available as of 2022 or thereafter, including those that were "unknown" (and perhaps inconceivable) to the inventors as of their

filing. Such a policy against claim elements generically reciting established technology—whether applied to the mechanical arts, the electrical arts, the biotechnology and pharmaceutical arts, or otherwise—would be "both shortsighted and unsound from the standpoint of promoting progress in the useful arts" (*i.e.*, "the constitutional purpose of the patent laws"), and would undermine "an effective patent system." *See Hogan*, 559 F.2d at 606.

This case presents the Court with the opportunity to anchor the requirement of a "written description of the invention" to text and tradition, and to cast away the Federal Circuit's unprincipled requirement that the inventor disclose "millions of billions" of embodiments of prior-art technology about which skilled artisans already know well. Pet. App. 9a, 17a–21a. The Court should step in and correct the wayward approach below.

II. The Question Presented Is Critical to Continued Research and Development of Innovative, Lifesaving Technologies.

The Federal Circuit's written-description standard propounded below forces *Amici* to either (1) obtain only exceedingly narrow, ineffective patent protection for inventions, or otherwise (2) divert their limited resources towards making innumerable embodiments of old technologies—in either case, damaging the efforts of *Amici* and their research collaborators to discover and to develop treatments of cancer and other life-threatening conditions.

1. The CAR technology before the Federal Circuit exemplifies why "narrow claiming" of elements

reflecting well-established technology is an illusory option. If the inventors had described the full sequence of all "four or five" CD19-binding scFvs extant as of their filing, and had they limited the scFv element of their claimed CAR constructs solely to those embodiments. Then, an infringer could easily copy the fundamental invention by "designing around" the claims, using the routine, well-established prior-art scFv technology to generate a new CD19-binding scFv. *See, e.g.*, *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 966 (Fed. Cir. 2002) (describing how without "broad claim scope," "copyists" making a "minor change" could "avoid infringement" while "still exploiting the benefits of [the] invention").

Scholars have long recognized that "limit[ing] the rights of a patentee to only those embodiments of the invention she has disclosed in her specification" would allow competitors to "find some minor variation over the disclosed embodiments" and thereby "render patents useless." Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839, 845 (1990). That concern is drastically exacerbated by the decision below.

Without this Court's intervention, *Amici* risk being unable to satisfy the Federal Circuit's super-heightened requirement. Any patent application will have to describe (after exhaustive testing) countless "***known and unknown***" embodiments of an element—even if that element has nothing to do with the novelty of the claims. As non-profit, academic research institutions, *Amici* would be substantially drained of financial resources if they were to undertake such a costly (yet scientifically

insignificant) effort. And financial resources aside, the potentially endless work required to make and to test limitless embodiments would be a counterproductive distraction from innovative research aimed at treating cancer and other serious diseases.

2. Even the Federal Circuit has recognized, in other contexts, how an unduly burdensome disclosure requirement for well-established technologies can harm institutions like *Amici*, their researchers, innovation generally, and the public good:

> Requiring inclusion in the patent of known scientific/technological information would add an imprecise and open-ended criterion to the content of patent specifications, could greatly enlarge the content of patent specifications and unnecessarily increase the cost of preparing and prosecuting patent applications, and could tend to obfuscate rather than highlight the contribution to which the patent is directed.

Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1346–47 (Fed. Cir. 2000). That burden also redounds to patent examiners and others forced to sift through additional red-tape disclosures not meaningful to skilled artisans. For "a patent ***need not teach***, and preferably omits, what is ***well known in the art***." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

3. The Federal Circuit's decision thus puts research institutions like *Amici* in a challenging dilemma. They can claim narrowly even as to well-

known prior-art elements—but that will result in weak, readily designed-around patents that would struggle to attract the investment needed to bring innovative technologies to market for the benefit of patients. Or they can attempt to satisfy the Federal Circuit's new written description requirement for well-established technology elements, at extraordinary cost of time and resources and to the detriment of their basic research mission. Or they can abandon patenting entirely—while knowing that a "publish and hope" approach to academic research is rarely enough to spur further development. *See* Will D. Swearingen & Timothy F. Slaper, *Economic Impacts of Technology Transfer: Two Case Studies From the U.S. Department of Defense*, 47 les Nouvelles 163 (2012); Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 N. Engl. J. Med. 535 (2011).

This dilemma has not gone unnoticed. Scholars have identified the decision below as part of a "puzzling and troubling doctrinal shift" in patent decisions to "invalidate large genus claims" on written description and other grounds. Karshtedt, 35 Harv. J.L. & Tech. at 54 (coining this trend "The Death of the Genus Claim"). The decision below takes this trend to new heights, threatening to undermine the delicate patent and licensing ecosystem that drives development of pioneering early-stage academic discoveries into products that benefit the public.

4. The costs of the Federal Circuit's approach are not borne by academic research institutions and pharmaceutical companies alone—patients may end up paying the ultimate price. Without adequate

patent protections, research institutions and their development partners in industry may simply be unable to undertake the massive investment needed to bring new cancer therapies and other drugs to market. *See* Joseph A. DiMasi, Henry G. Grabowski, & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 31 (2016) (estimating an average cost of nearly $2.6 billion to bring a new drug to market).

At bottom, the Federal Circuit's decision below diminishes the economic incentive to invest in bringing groundbreaking biotechnology innovations to market. On one hand, costs of research will be extraordinarily high if inventors are required spend precious grant dollars towards endlessly making and studying all "known and unknown" embodiments of any generic prior-art technology element recited within their claims. On the other hand, it may be easier for competitors to elude infringement (if claims are narrowed to only specific examples of prior art elements) or challenge validity (if prior art elements are claimed generically)—in either case, disincentivizing critical investment and abandoning potential cutting-edge therapies on the laboratory bench. Under all scenarios, patients will lose out.

These results cannot be squared with either the text and purpose of § 112(a), or this Court's understanding of patent law. This is even more true given that "[c]ourts should not read into the patent laws limitations and conditions which the legislature has not expressed," *Bilski*, 561 U.S. at 602, and "must be cautious before adopting changes that disrupt the

settled expectations of the inventing community," *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). The Federal Circuit did both here, risking disastrous consequences.

CONCLUSION

This Court should grant the petition.

Respectfully submitted,

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APPENDIX

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APPENDIX

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Fox Chase Cancer Center

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Temple University Health System, Inc.

Wisconsin Alumni Research Foundation