No. 21-1566

IN THE

# Supreme Court of the United States

JUNO THERAPEUTICS, INC., *et al.*,

*Petitioners,*

*v.*

KITE PHARMA, INC.,

*Respondent.*

**ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

## BRIEF OF REGENXBIO INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER


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## INTEREST OF *AMICUS CURIAE*[1]

REGENXBIO Inc. is a clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. *Amicus* has no interest in the present matter, other than ensuring that the U.S. patent system appropriately incentivizes and protects groundbreaking and life-saving innovations.

Millions of people are affected by genetic changes—mutations or deletions in their DNA—or other metabolic dysfunctions that adversely impact their health. They face chronic disease and require expensive medications to control their symptoms. Gene therapy offers a revolutionary alternative: a chance to treat the underlying cause of the disease—by introducing a therapeutic gene that corrects the course of disease—and potentially provide lasting results from a single therapeutic dose.

Gene therapy uses a "vector" to transport therapeutic DNA into the body's cells. REGENXBIO has exclusive rights to innovative viral vectors developed at the University of Pennsylvania, known as NAV® Vectors, to treat genetic defects or supply therapeutic factors such as antibodies to treat other serious conditions. Upon administration to a patient, the vectors deliver functional genes to the nucleus of affected cells. Once there, they serve as a genetic blueprint, supplying the function needed to treat or cure the disease.

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1. Pursuant to Supreme Court Rule 37.2, counsel of record for all parties received timely notice of *Amicus*'s intention to file this brief and all parties consented to filing. No counsel for any party authored this brief, in whole or in part. No person or entity other than *Amicus* contributed monetarily to its preparation or submission.

REGENXBIO focuses on diseases with significant unmet needs, such as retinal, metabolic, and neurodegenerative diseases. As a key aspect of its business, REGENXBIO also licenses the patented NAV® Vector technology to other companies developing their own gene therapies. Like many other biotechnology companies, REGENXBIO relies on the patent system to protect its inventions. Patents are critical to its business and its ability to fund future research.

## SUMMARY OF ARGUMENT

The Federal Circuit's "possession"-based written description test is the erroneous product of a 1997 Federal Circuit decision that does not comport with the text and purpose of 35 U.S.C. § 112. The "possession" analysis, as it is, was imported from disputes about the timing of inventions. It now creates damaging obstacles to obtaining patent protection for pioneering biomedical inventions. This misapplication lessens inventors' likelihood of recouping the costly investments necessary for groundbreaking biotechnology and biomedical innovation, and it impedes the objective of the patent system to promote the progress of the useful arts. The Court should grant the petition to restore the correct interpretation of the written description requirement of 35 U.S.C. § 112.

## ARGUMENT

### I. The Federal Circuit's "Possession" Analysis Does Not Comport with the Text and Purpose of 35 U.S.C. § 112

The Federal Circuit currently applies a possession-based written description analysis that finds no support in the statute. This possession standard is an incorrect product of a 1997 Federal Circuit decision that strays from the statute's text. Rather than stay true to the statute, the appeals court imposed, for the first time, a "possession"-based written description standard to original claims.

#### A. The Text of § 112 Does Not Contemplate a "Possession" Analysis

The statute's language is plain. A patent must contain a written description of the invention and the manner and process of making and using the invention. The description must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use" the invention.

The "written description of the invention" and of "the manner and process of making and using the invention" is not a mere abstract mandate read in isolation. The structure and syntax of § 112 command that this written description requirement is not separate and apart from the enablement requirement. Rather, the statute's "enablement" element establishes the requirement that the written description must satisfy.

Reading the "written description of the invention" element of § 112 divorced from the enabling requirement

leads to the conceptual problem as to what qualifies as a satisfactory "written description of the invention." In other words, reading the phrase in isolation—as the Federal Circuit does—provides no textual context of what constitutes a "written description of the invention."

For these reasons, *Amicus* agrees with the Petition's analysis. The plain-text requirement of an enabling "written description"—and not any "inventor possession" standard—is what Congress prescribed by § 112. It should be the one applied, especially when the unduly demanding "possession" standard invalidates patents disclosing pioneering, lifesaving inventions.

### B. "Full, Clear, Concise, and Exact Terms"

The statute specifies that the written description invention must be in "full, clear, concise, and exact terms." The terms used must be be full, clear, concise, and exact enough "to enable any person skilled in the art . . . to make and use the same." These words cannot be ignored when interpreting the statute.

Notably, the statutory directive that the written description be "concise" is equally important, but it is too often overlooked. At its base, the conciseness requirement is a congressional recognition that it is impractical and, in fact, counterproductive to force an inventor to include all potentially relevant information in a patent's "written description." Almost every invention builds on another, and there is no basis for a patent specification to ignore the "conciseness" requirement by including information that is known or to explicate every single possible example of the invention within a given genus.

Historically, courts have recognized the conciseness requirement, though less so in current Federal Circuit decisions. For instance, it is well settled that the patent need not include a "written description" of what one of ordinary skill in the art already knows. *Paperless Accounting v. Bay Area Rapid Transit*, 804 F.2d 659, 664 (Fed. Cir. 1986) ("A patent applicant need not include in the specification that which is already known to and available to the public.").

Without the conciseness requirement, patent applications would balloon to thousands of pages. Almost fifty years ago, the Court of Customs and Patent Appeals ("CCPA") recognized this very problem with an alternative interpretation of the written description requirement that would mandate the inclusion of all possible embodiments of a genus. Writing for the CCPA, Judge Rich (one of the architects of the 1952 Patent Act) explained why this "alternative" interpretation of § 112 was not feasible and not correct:

> The alternative places upon patent applicants, the Patent Office, and the public the undue burden of listing, in the case of applicants, reading and examining, in the case of the Patent Office, and printing and storing, in the case of the public, descriptions of the very many structural or functional equivalents of disclosed elements or steps which are already stored in the minds of those skilled in the arts, ready for instant recall upon reading the descriptions of specific elements or steps.

*In re Smythe*, 480 F.2d 1376, 1384 (C.C.P.A. 1973). Thus, under accepted practice, an applicant need not include

every example within a genus to satisfactorily describe the genus.

### C. This Court's Precedent Does Not Require "Possession"

The Federal Circuit's focus on "possession" also does not conform to this Court's precedent. Adequacy of a patent's written description should be assessed in conjunction with whether that patent enabled a skilled artisan to make and use the invention.

The Court applied its view of § 112 (and its earlier equivalents) through several notable cases. *See, e.g.*, *The Telephone Cases*, 126 U.S. 1, 536 (1887) ("It is enough if [the inventor] describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation."); *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933) (explaining that "the law requires such disclosure to be made in the application for patent that others skilled in the art may understand the invention and how to put it to use").

Notably, in the twenty-five years that the Federal Circuit has applied its possession requirement for the written description standard, it has not once found support in this Court's precedents. This Court has never applied the written description requirement—under its current form in § 112 or the predecessor statutes, going back to the Patent Act of 1790—to require a distinct possession-based written description requirement. The imposition of the "possession" standard for assessing original written

description of a patent is entirely a product of the Federal Circuit.

## II. The Federal Circuit's Atextual "Possession" Analysis Has Been Imported from Priority and Timing Disputes to Incorrectly Invalidate Original Claim Scope

With the concept of "possession" entirely absent from the text of § 112, a pertinent question is how this undefined concept was imported into the "written description" requirement. A careful reading of Federal Circuit precedents reveals that the "possession" analysis is largely a product of certain unique inquiries necessary in patent disputes, namely disputes about priority of inventorship and "new matter" issues for amendments to claims. The "possession" inquiry is relevant in priority contests (unlike in the present case), where vast amounts of information beyond the patent specification is considered in order to ascertain the first inventor to have conceived of the invention. Before 1997, the Federal Circuit did not apply the "possession" standard to original claims or original description. The Federal Circuit's recent importation of its modern "possession" test overlooks the purpose of the court's earlier precedent.

### A. The Purpose of a Written Description Requirement and Its Accepted Role in Disputes about Priority and Timing

The written description requirement traces its roots to the early years of the U.S. patent system. For the vast majority of years, the requirement for a "written description of the invention" was never applied to original

claims, which themselves served as a description of the invention, and instead was used in two instances: (1) To confirm that a later-filed claim had "written description support" in the original or earlier-filed application; and (2) to resolve timing-of-invention disputes, such as in interferences or in validity challenges, such as under 35 U.S.C. § 102(g).

The first category is a natural consequence of the patent application process. Under current practice, a patent application's claims can be and are frequently amended during the examination process. A patent applicant can amend claims for any number of reasons, for example, to avoid prior art identified during the patent examination or to add additional claims to protect various aspects of the disclosed invention.

During the process of amending claims, an applicant need not use the same exact words in the original specification. This premise has long been accepted in patent law. *In re Lukach*, 442 F.2d 967, 969 (C.C.P.A. 1971) ("[T]he invention claimed does not have to be described *in ipsis verbis* in order to satisfy the description requirement of § 112.").

But later-added claims must still be supported by the earlier-filed specification, and an applicant cannot add "new matter" that was not part of the originally disclosed invention. 35 U.S.C. § 132; *Schriber-Schroth Co. v. Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938) (holding that a patent application "cannot be broadened by amendment so as to embrace an invention not described in the application as filed"). When assessing if later claim amendments were compliant with §§ 112 and 132, the Federal Circuit and its

predecessor court have asked whether the inventor had "possession" of the claimed invention at an earlier time. *E.g., Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) ("To meet this requirement, the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed."); *accord In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976).

In other words, "[t]he purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required 'to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)).

> When the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a different invention than was the original claim, it is proper to inquire whether the newly claimed subject matter was described in the patent application when filed as the invention of the applicant. That is the essence of the so-called 'description requirement' of § 112, first paragraph.

*In re Wright*, 866 F.2d 422, 424 (Fed. Cir. 1989). Thus, "until 1997, the new matter doctrine, cloaked either in the specific language of § 132 or the innovative new reading

of § 112, operated only to determine whether new claim language deserved priority back to the patent's original filing date." *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1324 (Fed. Cir. 2003) (Rader, J., concurring).

In the second context, courts used the written description requirement to determine issues of priority of invention, whether it concerned identifying the first true inventor of the claimed invention or whether earlier activity by a third-party invalidated a patent claim. Such disputes could arise in the context of an "interference" proceeding. *See* 35 U.S.C. § 135 (2006).[2] In an interference, two or more separate inventors would have claims directed to similar subject matter, and a court or the USPTO would determine which inventor was the first to have "invented" the claimed subject matter.

In other contexts, the patentability or validity of a claim would be assessed under 35 U.S.C. § 102(g) (prior to enactment of the America Invents Act). Section 102(g) defined certain prior art that could bar the patentability of a patent claim, including that "the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." *Id.* § 102(g)(2) (2006). If another party had made the same invention before the patent applicant, then the patent applicant could not get a patent on the invention.

Whether in the context of an interference or a validity challenge under § 102(g), the inquiry considered "the respective dates of conception and reduction to practice of

2. The America Invents Act ("AIA") amended the Patent Act to eliminate interference proceedings. Pub. L. No. 112–29, § 3, 125 Stat. 284, 290 (2011). In its place, the AIA authorized derivation proceedings, 35 U.S.C. § 135 (2012), which can involve priority issues.

the invention." *Id.* § 102(g)(2) (2006). In other words, the inquiry was not focused on what was necessarily disclosed in the patent specification, but instead on activities beyond the specification, to determine who was the first to "possess" the claimed invention. *See, e.g.*, *Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006) (applying the "possession" standard in an interference appeal).

This distinction yielded a line of cases concentrating on evidentiary issues about whether an application could prove "possession" of a claimed invention at some point prior to the patent application being filed. The possession analysis involved detailed inquiries into laboratory notebooks, diary entries, grant proposals, manuscripts, letters of correspondence, and the like—all intended to determine whether there had been a conception and thus possession of the claimed invention at a time early enough to establish priority of invention. *See, e.g.*, *Oka v. Youssefyeh*, 849 F.2d 581, 583 (Fed. Cir. 1988) ("Conception requires both the idea of the invention's structure and possession of an operative method of making it.").

The priority disputes in the context of inventorship focused on the concept of possession because it was axiomatic that evidentiary support beyond what was in the patent application itself could be used to support an earlier date of invention. And because that other evidence—whether lab notebooks, witness testimony, or the like—had to be considered, the courts necessarily had to assess whether the inventor "possessed" a full conception of the invention, at a specific earlier time—before the full written description was set forth in the application. But despite the "possession" analysis having an accepted role in priority determinations, it had no

role in assessing the sufficiency of original claims to the invention, when the claimed invention was fully described in the claims themselves and in the application as filed. That is to say, the possession analysis did not have a role until 1997, when the Federal Circuit changed the law in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

### B. The Federal Circuit Has Imported Its "Possession" Analysis from Cases about Priority and Invention Timing

The Federal Circuit's importation of the possession analysis to apply to original claims was largely fueled by priority contests involving DNA patents. These priority disputes, by themselves, were not necessarily an improper application of the "possession" requirement, as they focused on ensuring that later-filed claims found support in an earlier application or were supported by evidence that the inventor was in fact the first to invent. But the problem arose when the possession/conception analysis was applied outside the context of priority/timing issues.

In hindsight, the legal disputes about the correct role of the written description can trace to this Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)—a decision before the Federal Circuit existed that correctly laid the legal foundation for the biotech revolution. In that case, the Court affirmed that biotech inventors could obtain broad patent protection on pioneering DNA-based inventions. While *Chakrabarty* decided patent-eligibility under 35 U.S.C. § 101, the breadth of the later-issued claims ensured that innovators in the early years of the biotech revolution could obtain sufficient patent protection

for their ground-breaking inventions. In essence, *Chakrabarty* reaffirmed the constitutional quid pro quo. Inventors would disclose their ground-breaking inventions as early as possible, and, in exchange, they would be granted the exclusive right. *See* U.S. Const. art I, § 8, cl. 8.

The quid pro quo worked. *Chakrabarty* promoted one of the greatest technological revolutions in human history—the biotechnology industry. The broad patent protection granted in *Chakrabarty* also enabled the United States to become the global biotechnology leader.

*Chakrabarty* incentivized inventors to disclose their inventions in patent applications, and this led to races between competing biotechnology inventors. These competitions encouraged the early disclosure of pioneering biotechnology developments, but they also led to disputes about who invented first (under the U.S. first-to-invent patent system). And as noted above, the "possession" standard was used to ensure that the inventor claiming to be first had the evidentiary proof (*i.e.*, written description plus other extrinsic evidence, such as laboratory notebooks, grant proposals, and reports) to show first "possession" of the invention. These priority disputes were particularly prevalent in the biotechnology field.

One early example is *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991). Amgen's patent claimed DNA encoding human erythropoietin ("EPO"). The defendant challenged the claims as anticipated under § 102(g), *i.e.*, that someone else had made the invention before Amgen's inventors. The defendants alleged that Fritsch, not Amgen, was

first to conceive of the cloning strategy to obtain the EPO gene. Fritsch's cloning strategy and experiments were not enough to establish a prior conception. What was required was the DNA sequence itself. The court opined that, in the case of genes, conception does not occur until the inventor reduced the invention to practice through a successful experiment.

> We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.

927 F.2d at 1206.

The next case on point, *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1983), involved a three-way interference over claims directed to the cDNA for fibroblast interferon-beta. The interference was unusual as it involved three foreign inventive entities who could not rely on their acts of invention outside the United States. They were therefore constrained to rely only on their patent filings. Sugano, the party first to disclose the DNA sequence (not just the method for cloning the gene), won. Citing *Amgen*, the *Fiers* court noted:

> An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.

***

> If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived.

*Id.* at 1170-71. Again, the appeals court invoked the "possession" concept when trying to assess which party was the first to have conceived of the claimed invention.

As noted above, in 1997, the Federal Circuit's written-description jurisprudence drastically changed. For the first time, the court applied the "possession" standard to original claims, and in the absence of any priority issues, in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). This sea-change required the patent specification to do all the work of extrinsic evidence that was routinely relied on to establish "possession," such as laboratory notebooks and the like. This new standard was later applied by the Federal Circuit to each aspect of the disclosure, whether novel or routine. *See infra*.

In *Lilly*, the University of California's patent claimed rat, human, vertebrate, and mammalian insulin cDNAs. *Id.* at 1563. The specification as originally filed disclosed the sequence of rat cDNA and the human protein; a process for obtaining the human cDNA; and a definition of the claimed genus of DNAs, *i.e.*, vertebrate, mammalian, and human insulin. *Id.* Lilly attacked the claims as invalid for lack of an adequate written description under 35 U.S.C. § 112.

Even though there was no issue of priority in *Lilly*, the Federal Circuit imported the possession standard from the interference context in *Fiers*. Relying on *Fiers*, the *Lilly* court stated: "An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Id.* at 1566 (quoting *Fiers*, 984 F.2d at 1171). Invoking the *Fiers* analysis, the *Lilly* court applied the written description analysis to original claims as requiring "a description of the DNA itself." *Id.* at 1567. The Federal Circuit majority thus held that, as a matter of law, the patent's original description was adequate for the rat cDNA but not for the genus of vertebrate and mammalian DNAs or for the claimed human DNA. *Id.*

The dramatic shift caused by *Lilly* was quickly noticed. *See, e.g.*, Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 Berkeley Tech. L.J. 615, 617 (1998) ("The *Lilly* decision establishes uniquely rigorous rules for the description of biotechnological subject matter that significantly contort written description doctrine away from its historic origins and policy grounding."); *see also* Arti Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 Wake Forest L. Rev. 827, 834-35 (1999) (explaining that, in *Lilly*, the Federal Circuit "broke new ground by applying the written description requirement not only to later-filed claims but also to claims filed in the original patent"); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. Rev. 123, 128 (2006) ("In a controversial move, the [Federal

Circuit] has applied the written description requirement to originally filed claims."); Christopher M. Holman, *Enablement Invoked as a "Super-Written Description Requirement" to Overturn $2.5 Billion Jury Verdict*, 37 Biotech. L. Rep. 63, 63 (Nov. 2, 2018) (noting *Lilly* as a "landmark decision" that "dramatically expand[ed] the role of the written description requirement in policing claim scope").

Commentators presciently noted that the Federal Circuit's shift in written-description law created a "super enablement" requirement. *See* Rai, *supra*, at 834-35 ("[T]he *Lilly* court used the written description requirement as a type of elevated enablement requirement."); Mueller, *supra*, at 617 (noting that *Lilly* elevates "written description to an effective 'super enablement' standard").

Federal Circuit judges also took note of *Lilly*'s dramatic legal shift, leading to a string of dissents targeting the new written description requirement. This rift was center stage in the denial of an en banc rehearing petition concerning patent claims to specific bacterial DNA. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002). There, several judges expressed disagreement or concern with *Lilly* and its holding. *See, e.g.*, *id.* at 988 (Linn, J., dissenting from en banc denial) ("[Possession of the invention] was not and should not be a test for sufficiency of disclosure, per se. It should have no place in and does not aid in the disposition of cases where the claims in question are part of the original disclosure."). Judge Dyk likewise recognized *Lilly*'s potential impact: "The opinions of Judges Newman, Lourie, Rader, and Linn concerning the denial of en banc rehearing raise important and interesting questions, including questions

concerning the correctness of our earlier decision in [*Lilly*] that may someday warrant the court's en banc attention." *Id.* at 976.

The written-description issue simmered for several years and came before the full Federal Circuit in *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010). There, a fractured appeals court concluded that the statute imposes an additional, standardless "written description" requirement independent of the remaining text. *Id.* at 1358. The court engaged in a grammatical analysis of § 112 that separated the "written description of the invention" from the rest of § 112. *Id.* at 1347. That interpretation allowed the court to uphold the judicially imposed "possession" requirement to satisfy its version of "written description."

> [W]e see nothing in the statute's language or grammar that unambiguously dictates that the adequacy of the "written description of the invention" must be determined solely by whether that description identifies the invention so as to enable one of skill in the art to make and use it. The prepositional phrase "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same" modifies only "the written description . . . of the manner and process of making and using [the invention]," as Lilly argues, without violating the rules of grammar.

*Id.* at 1344.

Even so, there remained disagreement about the role of the "possession" standard when assessing original claims. *See, e.g., id.* at 1361 (Gajarsa, J., concurring) ("Confining written description to the priority context would provide greater clarity to district courts and practitioners, both of whom are currently left to trudge through a thicket of written description jurisprudence that provides no conclusive answers and encourages a shotgun approach to litigation.").

The written-description jurisprudence since *Lilly* and *Ariad* has only worsened for pioneering biomedical inventions. Biomedical innovators have suffered the full brunt of the new atextual "possession" standard applied to original claims. Numerous patents covering groundbreaking, life-saving biomedical inventions have been invalidated. Under the court's opinions, couched under a misguided analysis of § 112 written description, patents that describe many examples supporting the genus claims are invalidated based on the lack of description of the single infringing embodiment. The infringers learned of the technology from the innovator patentee, copied it, and applied the patentee's teachings to derive the infringing species.

*AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014), is a particularly notable example. Despite AbbVie's disclosure of hundreds of antibody sequences to IL-12, the court affirmed a finding that the genus claims were invalid for lack of written description because the patent did not "describe representative species to support the entire genus." *Id.* at 1299.

In *Carnegie Mellon University v. Hoffman-La Roche Inc.*, 541 F.3d 1115 (Fed. Cir. 2008), the court affirmed the invalidity of patent claims for "recombinant plasmids that contain gene coding regions for the expression of DNA polymerase I from any bacterial source." The panel relied on *Lilly*, requiring that a written description of the genus of cDNAs required "a representative number of cDNAs, defined by nucleotide sequence" or "a recitation of structural features common to the members of the genus." *Id.* at 1122.

In *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011), the court affirmed the overruling of a jury verdict on written description. The court held that "no reasonable juror could conclude that the specification of the '662 patent discloses to a person of ordinary skill in the art that the inventors were in possession of the claimed invention." *Id.* at 1369.

In *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019), the appeals court invalidated claims directed to a method of treating hepatitis C by using a class of nucleoside compounds. Both the jury and the district court rejected the written description challenge, but the Federal Circuit struck down the claims because, in its view, the inventor did not have possession of specific compounds within the claimed group. *Id.* at 1163-65. The Federal Circuit punished the inventors for not specifically including the single infringing compound that was enabled by the patent.

These cases are upending biotech innovators' settled expectations. Late in 2021, applying *Lilly*, the Federal Circuit affirmed another invalidation of a biomedical

patent, leading to a notable dissent from a denial of a rehearing petition. *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 28 F.4th 1194 (Fed. Cir. 2022) (per curiam). Three judges dissented from the denial. Notably, one dissenter was Judge Lourie, who authored both *Lilly* and the en banc *Ariad* majority opinion. The other two dissenting judges had joined the *Ariad* majority.

The dissenting judges explained that the panel majority "affirmed a district court's erroneous broadening of the written description inquiry." *Id.* at 1203. The three dissenters also explained that "the panel majority and the district court erred by analyzing factual and legal considerations that are not properly contained within the written description analysis." *Id.* at 1198. While *Amicus* agrees that the panel may have erred in *Biogen*, the more fundamental errors are importing the "possession" analysis into the written description requirement and the current atextual written description standard.

In the twenty-five years since *Lilly*, the additional percolation has only confirmed the early predictions: *Lilly* has transformed the written description requirement in to a new "super enablement" standard. This transformed written description requirement is extremely difficult for pioneering biomedical inventions to satisfy.

## III. The Federal Circuit's Rule is Extremely Detrimental to Pioneering Biomedical Innovation

Twenty-five years of percolation since *Lilly* have led to only a worsening situation for biomedical innovators. The current trend is to strike down patents for pioneering biomedical inventions—ones that require enormous

investments in research and development. More troublingly, the court's reasoning leads to an almost impossible standard because it expects an inventor to describe routine variations within a genus and to describe unknown variations that will be developed later based on the patent's teachings. That latter point is particularly troubling because it overlooks the patent system's fundamental purpose—to teach the public about the invention so others can use it as a guide for further innovation.

### A. Pioneering Biomedical Inventions Deserve and Need Broad Patent Protection

Groundbreaking biotech and biomedical innovation requires substantial resources. With that requirement come the need to have a reasonable means to recoup the investment of time and resources and the need to obtain additional resources for further development. The only way this is possible is with reliable patent protection for pioneering inventions. The Federal Circuit's "possession" analysis cuts against any sense of reliable protection for such pioneering innovation.

Emerging and growing biotech companies cannot reasonably decide to spend millions of dollars on research and development when there is the substantial risk that patent coverage will be invalidated under the written description requirement because the patent application does not contain enough examples, even though there is no question about what the invention is, the scope of the invention, or whether the invention is enabled. That troubling situation is the status quo under the Federal Circuit's possession-based written description analysis.

Moreover, emerging biotech companies cannot rationally devote resources to routine, prior-art experiments merely to provide "more examples" in the name of showing "possession" of a genus. That approach wastes precious resources that should be used for further innovation. It would lead to unnecessarily lengthy patent applications—in direct violation of the statute's requirement for a "concise" description, as explained by Judge Rich. *Smythe*, 480 F.2d at 1384.

### B. Broad Patent Protection Furthers the Constitutional Objective of Promoting Innovation

Fundamentally, the Federal Circuit's possession-focused written description analysis frustrates the basic objective of the patent system—to promote the progress of the useful arts. Rather than encouraging early disclosure of pioneering innovations, the possession-focused written description standard delays the disclosure of important innovation.

Under the Federal Circuit's analysis, the Sloan-Kettering inventors should not have filed their patent application until they had made enough scFv variants within the genus the inventors discovered. It did not matter that the svFc variants were not the invention's key innovative feature. Nor did it matter that known laboratory methods could be used to make additional scFv variants.

In this way, the invalidation of Petitioner's patent stands in stark contrast to the claims allowed in *Chakrabarty*. There, the pioneering invention covered a broad genus of man-made bacteria:

> 1. A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.[3]

The claim broadly covered any genetically engineered bacterium that had the two stable energy-generating plasmids. The plasmids could be for several different pathways—some known and others unknown at the time that patent was filed. And that underscores the purpose of allowing a broad, pioneering claim—to reward the inventors of fundamental breakthrough technology while instructing other researchers to key areas of follow-on development.

This recognition sheds light on two fundamental flaws in the Federal Circuit's approach. First, it punishes innovators who first identify and share their breakthrough technologies. Scientists frequently discover inventions that open many new lines of potential research. Those who first discover cannot possibly perform every experiment that will follow from the breakthrough innovation. But the patent system is structured to encourage the early dissemination of that innovation. In other words, reward the first innovator when he or she shares that innovation so that others may, in the words of Isaac Newton, stand on the shoulders of giants.

A second flaw with the Federal Circuit's approach is that, in many instances, no number of representative examples will ever fulfill the Federal Circuit's possession

3. U.S. Patent No. 4,259,444 (Mar. 31, 1981).

analysis. This is so because the inventor's own disclosure will inevitably increase the storehouse of knowledge of what constitutes a "representative number of examples."

Take, for instance, the Chakrabarty invention. Upon disclosing to the world that one can make a genetically engineered bacterium capable of breaking down crude oil components, *see* 447 U.S. at 305, the invention led other scientists and researchers to develop other variations of the genetically engineered bacterium. These later developed variations would, according to the Federal Circuit, undermine the patentability of Chakrabarty's pioneering invention.

Indeed, in Petitioner's case, the Federal Circuit expressly noted that the scope of the claim "encompasses all scFvs, known and unknown." Pet. App. 13a. If an inventor's "possession" of an invention is adjudged based on later-developed embodiments (unknown when the patent was filed), then few pioneering biomedical inventions can ever meet this standard.

## CONCLUSION

*Amicus Curiae* respectfully requests that petition be granted.

Respectfully submitted,

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