Section 112(a) Strife at the Federal Circuit: A Call for Congressional Amendment to Save the Genus Claim and Preserve Patent Protection in the Biological Arts

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I. INTRODUCTION

This Comment examines written description, a tenet of American patent law that dates to the first Patent Act of 1790.[1] Today, this principle is encapsulated in 35 U.S.C. § 112(a), describing what a

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[1] Patent Act of 1790, ch. 7, § 1, 1 Stat. 109–12 (1790).

patent's specification must disclose to the public in return for patent protection.[2] 35 U.S.C. § 112(a) states:

> 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.[3]

Written description works to animate the patent system's "carefully crafted bargain."[4] In exchange for sufficient public disclosure of new and useful inventions, the patent system rewards inventors with exclusive rights to make, use, sell, and import their inventions for a limited duration.[5] A foundational patent policy is served: by making a clear and exact disclosure, the inventor enables any person of ordinary skill in the art ("POSA") to make, use, and sell the invention once the patent claims have expired.

The following question remains disputed: how much disclosure does 35 U.S.C. § 112(a) require? Until recently, the statute required a patent's specification to disclose a written description of the invention in a manner that enables a POSA to "make and use" the invention.[6] Now, the United States Court of Appeals for the Federal Circuit's interpretation requires an inventor to demonstrate that he "possessed the full scope of the claimed invention," including all "known and unknown" variations of each component of the invention.[7] This Comment submits this interpretation is unworkable because it opposes 35 U.S.C. § 112(a), opposes Supreme Court jurisprudence, and jeopardizes innovation in the biological arts. In the absence of instruction from the Supreme Court of the United States, Congress must amend 35 U.S.C. § 112(a) to save the genus claim and preserve patent protection in the biological arts.

Part II of this Comment summarizes the Supreme Court's consistent interpretation of 35 U.S.C. § 112(a), introduces the Federal Circuit's contrary understanding of 35 U.S.C. § 112(a), and defines the genus claim. Part III discusses the function of the American patent system, analyzes the Federal Circuit's erroneous application of 35 U.S.C.

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2 35 U.S.C. § 112(a) (2018).

3 *Id.*

4 Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998).

5 *Id.*

6 35 U.S.C. § 112(a) (2018).

7 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336, 1338 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

§ 112(a) in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, argues that the Supreme Court should have granted certiorari in the case, and calls upon Congress to save the genus claim and preserve patent protection in the biological arts by amending 35 U.S.C. § 112(a).

II. BACKGROUND

The Supreme Court of the United States has yet to hear a contemporary case that asks how much disclosure 35 U.S.C. § 112(a) requires. The Court, however, has been firm in its interpretation of the statute and requires a patent's specification to disclose a written description of the invention in a manner that enables a POSA to "make and use" the invention.[8] For example, the Court explained in 1888 that "it is enough if [an 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."[9] In a modern example, the Court explained in 2012 that "[s]ection 112 requires only a 'written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same.'"[10]

Despite the Court's consistency in its interpretation of 35 U.S.C. § 112(a), which is whether a written description allows a POSA to make and use the invention, the Federal Circuit requires inventors to meet a more burdensome standard. In *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, the Federal Circuit answered the question of how much disclosure 35 U.S.C. § 112(a) requires.[11] The Federal Circuit held that an inventor must demonstrate that he "possessed the full scope of the claimed invention," including all "known and unknown" variations of each component of the invention.[12]

The Federal Circuit's heightened standard for written description has wreaked havoc on innovation, especially in the context of the biological arts, where the genus claim is the primary form of patent protection. The genus claim "covers a group of structurally related products that incorporate the basic advance of the patented

8 35 U.S.C. § 112(a) (2018).

9 Dolbear v. Am. Bell Tel. Co., 126 U.S. 1, 536 (1888).

10 Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 90 (2012) (quoting 35 U.S.C. § 112(a) (2018)).

11 *Juno Therapeutics*, 10 F.4th at 1336, 1338.

12 *Id.*

invention."[13] Inventors utilize this type of claim "to make sure that no one can copy their basic idea by making a small change to it to avoid infringing the patent."[14] In requiring inventors to demonstrate all "known and unknown" variations of each component of their inventions, the Federal Circuit mandates that inventors disclose the impossible.[15] Consequently, the Federal Circuit has invalidated patents for lack of sufficient written description under its test, which "represents both bad law and bad policy."[16]

One must look no further than the Federal Circuit's decision in *Juno Therapeutics* to see the destructive effects of this test in practice.[17] *Juno Therapeutics* eliminated patent protection for a lifesaving CAR-T cell therapy.[18] T-cells are a type of lymphocyte that contribute to the body's immune response.[19] CARs are chimeric antigen receptors that consist of at least one signaling domain that kills targeted cancer cells.[20] CARs usually contain a single chain variable fragment ("scFv") that binds the CAR-T cells to cancer cells.[21] In this therapeutic method, scientists separate a cancer patient's T-cells from their blood.[22] CARs are then attached to these T-cells and replicated.[23] Finally, the resulting CAR-T cells are returned to the patient to attack targeted cancer cells.[24]

Dr. Michel Sadelain and his team at Memorial Sloan Kettering Cancer Center ("Sloan Kettering") improved CAR-T cell therapy by adding a second signaling domain to a CAR.[25] This addition allows CAR-T cells to replicate inside the patient, effectively killing even more targeted cancer kills.[26] U.S. Patent No. 7,446,190 ("the '190 patent") granted to Dr. Sadelain and his team discloses the specific nucleotide

13 Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 3, 13 (2021) (providing the following example of a genus claim: a claim to a plastic-coated steel screw, naturally encompassing numerous plastics, such as nylon, polystyrene, and polypropylene).

14 *Id.* at 3.

15 *Juno Therapeutics*, 10 F.4th at 1338.

16 Karshtedt et al., *supra* note 13, at 3.

17 *Juno Therapeutics*, 10 F.4th at 1342.

18 *Id.*

19 *Id.* at 1333.

20 *Id.*

21 *Id.*

22 *Id.*

23 *Juno Therapeutics, Inc.*, 10 F.4th at 1333.

24 *Id.*

25 *Id.*

26 *Id.*

sequence of the two signaling domains.[27] The '190 patent also describes scFvs as "known binding elements" and notes that their synthesis "has become routine."[28] To support these assertions, the '190 patent cites an article published in 1989 that instructs a POSA on how to synthesize scFvs for any desired target.[29]

Kite Pharma, a competitor, stole Dr. Sadelain's addition of a second signaling domain and utilized it to fast-track a competitive product, YESCARTA®, to market.[30] Juno Therapeutics, the exclusive licensee of Dr. Sadelain's invention, and Sloan Kettering sued Kite Pharma for patent infringement.[31] At trial, Kite Pharma challenged the validity of Sloan Kettering's patent.[32] After a two-week trial, the jury found Sloan Kettering's patent valid and Kite's infringement willful.[33] After the district court updated the jury's award to account for additional YESCARTA® revenues, the district court awarded Sloan Kettering nearly one billion dollars in damages.[34]

Kite Pharma appealed the district court's judgment, and the Federal Circuit reversed as a matter of law.[35] The Federal Circuit explained that Sloan Kettering's patent failed to satisfy its interpretation of 35 U.S.C. § 112(a) when applied to the well-known scFv component of the claims.[36] The Federal Circuit was not satisfied that Sloan Kettering's patent enabled a POSA to make and use the scFv.[37] Sloan Kettering's patent had to demonstrate that Dr. Sadelain and his team possessed the full scope of the claimed invention, including all known and unknown possible scFvs.[38] In this narrow example, the biological arts as a whole, and other technological fields, the Federal Circuit's test is unworkable. Juno Therapeutics petitioned the Court to provide a definitive answer to the question of how much disclosure 35 U.S.C. §

27 Nucleic Acids Encoding Chimeric T Cell Receptors, U.S. Patent No. 7,446,190 (filed May 28, 2003).

28 *Id.* at col. 4 l. 45–58.

29 Rosaria Orlandi et al., *Cloning Immunoglobulin Variable Domains for Expression by the Polymerase Chain Reaction*, 86 PROC. NAT'L. ACAD. SCI. USA 3833 (1989) [https://doi.org/10.1073/pnas.86.10.3833].

30 *Juno Therapeutics*, 10 F.4th at 1334.

31 *Id.*

32 *Id.*

33 *Id.*

34 *Id.*

35 *Id.* at 1342.

36 *Juno Therapeutics*, 10 F.4th at 1342.

37 *Id.*

38 *Id.* at 1336, 1338.

112(a) requires.[39] Unfortunately, the Court denied Juno Therapeutics' petition.[40]

III. ANALYSIS

A. The Vital Give and Take of the American Patent System

The United States Constitution's Intellectual Property Clause is the foundation of American patent law.[41] Article 1, section 8, clause 8 of the Constitution states, "[t]he Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[42] The Framers well understood the power of incentives in driving innovation. Consequently, the Framers guaranteed inventors an exclusive monopoly limited in duration to make, use, and sell their inventions in exchange for teaching the public to make and use their inventions once the patent term expires. Simply put, a patent is a quid pro quo.

Congress requires inventors to deliver this teaching in the form of a written disclosure that allows POSAs to make and use their inventions. The particulars of this disclosure have remained essentially constant since the end of the eighteenth century. According to current patent statutes, an inventor's disclosure must contain "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same."[43] Compare this with text from the Patent Act of 1793, "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 . . . enable any person skilled in the art or science . . . to make, compound, and use the same."[44]

Unlike modern patent statutes, the Patent Act of 1793 did not dictate any distinct requirements for patent claims. Instead, the Patent Act of 1793 stated that a written description must also "distinguish the [invention] from all other things before known."[45] A system of

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39 Petition for Writ of Certiorari, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2022 WL 2181595, at *i (U.S. Nov. 7, 2022).

40 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

41 U.S. CONST. art. I, § 8, cl. 8.

42 *Id.*

43 35 U.S.C. § 112(a) (2018).

44 Patent Act of 1793, ch. 11, § 3, 1 Stat. 318–323 (1793).

45 *Id.*

numbered claims, however, later developed. Today, a separate claim requirement exists in 35 U.S.C. § 112(b).[46] This claim requirement states, "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."[47]

35 U.S.C. § 112(b) originates from the Patent Act of 1836.[48] The Patent Act of 1836 requires an inventor to "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery."[49] Concurrently, 35 U.S.C. § 112(a) effectively preserves the written disclosure language from the Patent Act of 1793. Again, 35 U.S.C. § 112(a) states, "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."[50]

In *Markman v. Westview Instruments*, a case involving the distinct claim requirement, the Court opined that "[u]nder the modern American system," the goals of disclosure "are served by two distinct elements of a patent document."[51] The first of these elements is "a specification describing the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same.'"[52] The second of these elements is "one or more 'claims,' which 'particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention.'"[53] In the biological arts, a patent may disclose nucleotide or amino acid "sequence listings" that pertain to the invention.[54] Even though claims and sequences are considered part of a patent's specification, courts use the term specification to denote an inventor's written disclosure.

The Patent Act addresses specification requirements in 35 U.S.C. § 112(a).[55] Moreover, the Patent Act addresses patent-eligible inventions in 35 U.S.C. § 101, the novelty requirement in 35 U.S.C. § 102, and the non-obviousness requirement in 35 U.S.C. § 103.[56] The Court has readily construed all three of these provisions in recent years. For example, the

46 35 U.S.C. § 112(b) (2018).
47 *Id.*
48 Patent Act of 1836, ch. 357, § 6, 5 Stat. 117 (1836).
49 *Id.*
50 35 U.S.C. § 112(a) (2018).
51 Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996).
52 *Id.* (quoting 35 U.S.C. § 112, ¶ 1, pre-AIA, now 35 U.S.C. § 112(a) (2018)).
53 *Id.* (quoting 35 U.S.C. § 112, ¶ 2, pre-AIA, now 35 U.S.C. § 112(b) (2018)).
54 37 C.F.R. § 1.821(c) (2021).
55 35 U.S.C. § 112(a) (2018).
56 *Id.* §§ 101–03.

Court interpreted patent-eligible inventions in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, the novelty requirement in *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, and the non-obviousness requirement in *KSR Int'l Co. v. Teleflex Inc*.[57] The Court has even construed the separate claim requirement of 35 U.S.C. § 112(b) in *Markman*.[58] The Court, however, has yet to face 35 U.S.C. § 112(a) and its long history.

B. The Paradigmatic '190 Patent

The Court's denial of certiorari in *Juno Therapeutics* surprised the patent community, given its desperate need for clarification on 35 U.S.C. § 112(a) and the case's clean presentation of the relevant issue.[59] The lead inventor of the disputed '190 patent, Dr. Sadelain, is a globally recognized expert in CAR-T cell therapy and the Director of Sloan Kettering's Center for Cell Engineering.[60] The first CARs consisted of a signaling domain and an scFv.[61] The signaling domain component of a CAR "activates the cancer-bound T-cell to destroy the cancer cell."[62] The scFv component of a CAR "pairs with a protein called an antigen on the surface of cancer cells and attaches . . . the CAR-T cell to the cancer cell."[63] Prior to the publication of the '190 patent, scFvs were well understood, even in the context of CAR use.[64] To this point, the '190 patent cites a 1989 article instructing a POSA on how to synthesize scFvs for any desired target.[65]

While the first CARs were successful in attaching T-cells to targeted antigens, the signaling domain component failed to cause an adequate immune response to combat cancer.[66] Dr. Sadelain and his team came

57 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 139 S. Ct. 628 (2019); KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

58 35 U.S.C. § 112(b) (2018); Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

59 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

60 Petition for Writ of Certiorari, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2022 WL 2181595, at *9–10 (U.S. Nov. 7, 2022).

61 *Id.* at *10.

62 *Id.*

63 *Id.*

64 *Id.*

65 Orlandi et al., *supra* note 29.

66 Petition for Writ of Certiorari, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2022 WL 2181595, at *10–11 (U.S. Nov. 7, 2022).

up with the idea to bolster the immune response by adding a second signaling domain.[67] The team, however, made no changes to the scFv component from the first CARs.[68] Therefore, the groundbreaking invention captured by the '190 patent is the use of a second signaling domain in a CAR.[69] Despite doubt from others in the field of CAR-T cell therapy, Dr. Sadelain and his team's trailblazing addition of a second signaling domain triggered an adequate immune response to combat cancer.[70] This addition not only accomplished targeted cancer cell death but also caused CAR-T cell replication, rendering the treatment much more effective.[71]

The '190 patent is a prime example of a written description that enables a POSA to make and use the invention. First, the patent expressly discloses the nucleotide sequence of the first and second signaling domains.[72] Second, the patent discloses examples of scFvs, even though the invention features the same scFv as the first CARs and scFv synthesis is known and routine.[73] Third, the patent cites an article published in 1989 that instructs a POSA on how to synthesize scFvs for any desired target.[74] Nevertheless, the Federal Circuit was not satisfied that Sloan Kettering's patent enabled a POSA to make and use the scFv.[75]

C. The Copyist

Without Sloan Kettering's knowledge, Kite Pharma copied Dr. Sadelain's invention.[76] Dr. Sadelain had shared the details of his invention with the National Cancer Institute.[77] Dr. Sadelain, however, was neither told that the National Cancer Institute would share this information with Kite Pharma nor that Kite Pharma would use this invention to bring a product to the market.[78] Kite Pharma used Dr.

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67 *Id.* at *11.

68 *Id.*

69 *Id.*

70 *Id.*

71 *Id.*

72 Nucleic Acids Encoding Chimeric T Cell Receptors, U.S. Patent No. 7,446,190 (filed May 28, 2003).

73 *Id.*

74 *Id.*

75 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1342 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

76 Petition for Writ of Certiorari, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2022 WL 2181595, at *13 (U.S. Nov. 7, 2022).

77 *Id.*

78 *Id.*

Sadelain's second signaling domain to bring YESCARTA® to market.[79] Later on, Kite Pharma attempted to acquire a license from Sloan Kettering for the technology.[80] Sloan Kettering, however, decided to exclusively license the '190 patent to Juno Therapeutics.[81]

Kite Pharma then tried to avoid patent infringement liability by challenging the validity of the '190 patent at the Patent Trial and Appeals Board via an *inter partes* review.[82] This attempt failed because the Patent Office reaffirmed the patent grant, and the Federal Circuit summarily affirmed the decision.[83] Still, Kite Pharma moved forward with bringing YESCARTA® to market in the face of an impending patent infringement litigation.[84] Kite Pharma reaped the undeserved benefits of being the first to bring Sloan Kettering's invention to market, which included "a lucrative $11.9 billion buyout from Gilead Sciences."[85]

D. The Federal Circuit's Unworkable Written Description Test

Sloan Kettering and Juno Therapeutics sued Kite Pharma for patent infringement.[86] Kite Pharma stipulated the fact that YESCARTA® infringed the '190 patent but argued that the patent did not pass the Federal Circuit's written description test and was, therefore, invalid.[87] The Federal Circuit mistakenly construed 35 U.S.C. § 112(a) to require something more than a written description of the invention in a manner that enables a POSA to "make and use" the invention.[88] As an additional requirement, the Federal Circuit dictates that an inventor must demonstrate that he "possessed the full scope of the claimed invention," including all "known and unknown" variations of each component of the invention.[89] For genus claims, the Federal Circuit "requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the

79 *Id.*

80 *Id.*

81 *Id.*

82 Petition for Writ of Certiorari, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2022 WL 2181595, at *14 (U.S. Nov. 7, 2022).

83 *Id.*

84 *Id.*

85 *Id.*

86 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1334 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

87 *Id.*

88 35 U.S.C. § 112(a) (2018).

89 *Juno Therapeutics*, 10 F.4th at 1336, 1338.

genus so that one of skill in the art can 'visualize or recognize' the members of the genus."[90]

Kite Pharma asserted that the Patent Office wrongly reaffirmed the patent grant because it did not meet the Federal Circuit's written description test.[91] Kite Pharma focused its invalidity attack on the well-known scFv component of the invention, rather than the signaling domain components.[92] During trial, Sloan Kettering negated Kite Pharma's argument by showing that scFvs were well-known, utilized in CARs many times before, and used by POSAs in conjunction with Dr. Sadelain's signaling domains.[93] Once again, the '190 patent even cites a 1989 article instructing a POSA on how to synthesize scFvs for any desired target.[94] The jury found that the '190 patent's inventors met the requirements of 35 U.S.C. § 112(a), Kite Pharma failed to overcome the presumption that the Patent Office correctly granted the patent, and Kite Pharma willfully infringed.[95] The jury awarded damages to Sloan Kettering and Juno Therapeutics.[96] Additionally, the court rejected Kite Pharma's challenges to the jury verdict, enhanced the damages, and ordered Kite Pharma to pay royalties on all YESCARTA® sales.[97]

After all this, the Federal Circuit reversed the jury's factual findings as a matter of law.[98] The Federal Circuit was satisfied with the '190 patent's description of the signaling domain components.[99] The Federal Circuit, however, shockingly invalidated the '190 patent for lack of written description regarding the well-known scFv.[100] The Federal Circuit held that an inventor must demonstrate that he "possessed the full scope of the claimed invention," including all "known and unknown" variations of each component of the invention.[101]

E. Why the Supreme Court of the United States Should Have

90 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) (quoting Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997)).

91 Petition for Writ of Certiorari, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2022 WL 2181595, at *16 (U.S. Nov. 7, 2022).

92 *Id.*

93 *Id.*

94 Orlandi et al., *supra* note 29.

95 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1334 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

96 *Id.*

97 *Id.*

98 *Id.*

99 *Id.* at 1342.

100 *Id.*

101 *Juno Therapeutics*, 10 F.4th at 1336, 1338.

Granted Certiorari

1. The Federal Circuit's Unworkable Written Description Test is Inconsistent With 35 U.S.C. § 112(a) and Supreme Court Jurisprudence

The Federal Circuit's Test Opposes 35 U.S.C § 112(a). 35 U.S.C. § 112(a) states:

> 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.[102]

The Supreme Court of the United States instructs that "[s]tatutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose."[103] As such, there is a "basic and unexceptional rule that courts must give effect to the clear meaning of statutes as written[,] . . . giving each word its ordinary, contemporary, common meaning."[104] These teachings apply here because "[p]atent law is governed by the same common-law principles, methods of statutory interpretation, and procedural rules as other areas of civil litigation."[105]

Just by looking at the text of 35 U.S.C. § 112(a), the phrases including a "written description of the invention" and the "written description . . . of the manner and process of making and using it" are subject to "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."[106] In *Ariad Pharms., Inc. v. Eli Lilly & Co.*, however, which the Supreme Court never reviewed, the Federal Circuit exploited the statute's text by holding that "'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 . . .

102 35 U.S.C. § 112(a) (2018).

103 Gross v. FBL Fin. Servs., Inc., 557 U.S. 167, 175 (2009) (quoting Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist., 541 U.S. 246, 252 (2004)).

104 Artis v. D.C., 138 S. Ct. 594, 603 n.8 (2018) (quoting Star Athletica, L.L.C. v. Varsity Brands, Inc., 137 S. Ct. 1002, 1010 (2017)).

105 SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 137 S. Ct. 954, 964 (2017).

106 35 U.S.C. § 112(a) (2018).

of the manner and process of making and using [the invention].'"[107] In doing so, the Federal Circuit opened a Pandora's box of additional written description requirements.

The comma that follows the phrase "and of the manner and process of making and using it" indicates that "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" applies to the "written description of the invention" and the "written description . . . of the manner and process of making and using it."[108] The Court endorses the principle that "'[a] qualifying phrase separated from antecedents by a comma is evidence that the qualifier is supposed to apply to all the antecedents instead of only to the immediately preceding one.'"[109] Congress supplied the standard for written description. There was no need for the Federal Circuit to muddle the text of 35 U.S.C. § 112(a) and pave the way for additional requirements.

By holding that "'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],'" the Federal Circuit requires "that the specification teach those in the art to make and use the invention without undue experimentation."[110] Manipulating the statute's text in this manner isolates "written description of the invention" and erects an additional "written description requirement" for inventors to navigate.[111] This interpretation has allowed the Federal Circuit to add, again and again, to the written description requirement.

In *Ariad Pharms.*, the Federal Circuit articulated its test as "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."[112] This test has "no statutory support."[113] Additionally, the Federal Circuit here expressed that written description for genus claims "requires the disclosure of either a representative number of species falling within the scope of the genus

107 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (quoting 35 U.S.C. § 112(a) (2018)).

108 35 U.S.C. § 112(a) (2018).

109 Facebook, Inc. v. Duguid, 141 S. Ct. 1163, 1170 (2021) (quoting WILLIAM N. ESKRIDGE JR., INTERPRETING THE LAW: A PRIMER ON HOW TO READ STATUTES AND THE CONSTITUTION 67–68 (2016)).

110 *Ariad Pharms.*, 598 F.3d at 1344 (quoting 35 U.S.C. § 112(a) (2018)); *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

111 35 U.S.C. § 112(a) (2018); *Ariad Pharms.*, 598 F.3d at 1347.

112 *Ariad Pharms.*, 598 F.3d at 1351.

113 *Id.* at 1362 (Rader, J., concurring in part and dissenting in part).

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."[114] Only a few years later, written description for genus claims mutated into "representative examples to support the full scope of the claims."[115] Now, in *Juno Therapeutics*, the Federal Circuit concludes that an inventor must demonstrate that he "possessed the full scope of the claimed invention," including all "known and unknown" variations of each component of the invention.[116]

The Federal Circuit unconvincingly suggests that its interpretation that "'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]'" is necessary to prevent "surplusage."[117] There is good reason, however, for this surplus language. As mentioned above, unlike modern patent statutes, the Patent Act of 1793 did not dictate any distinct requirements for patent claims. This surplus language is simply an inheritance from the oldest versions of the Patent Act and not an invitation for the Federal Circuit to rewrite the written description requirement. This point alone should have convinced the Court to grant Juno Therapeutics' petition for writ of certiorari.

Additionally, the Federal Circuit's test opposes Supreme Court jurisprudence. The Court has been consistent in its understanding of 35 U.S.C. § 112(a). This consistency is not surprising, given the clarity of the statute's language. Ever since Congress embraced a separate claim requirement, the Court has required a patent's specification to disclose a written description of the invention in a manner that enables a POSA to "make and use" the invention.[118] In 1888, the Court explained, "it is enough if [an 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."[119] Further, in 1933, the Court noted "upon the expiration of [the patent term], the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it and

114 *Id.* at 1350 (quoting Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997)).

115 AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1301 (Fed. Cir. 2014).

116 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336, 1338 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

117 *Ariad Pharms.*, 598 F.3d at 1344–45 (quoting 35 U.S.C. § 112(a) (2018)).

118 35 U.S.C. § 112(a) (2018).

119 Dolbear v. Am. Bell Tel. Co., 126 U.S. 1, 536 (1888).

profit by its use."[120] To this point, "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."[121] In 1944, the Court stressed that the patent system's fundamental quid pro quo "is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired."[122]

Even multiple regional federal courts of appeal construed the statute in this manner before Congress transferred their jurisdiction to hear patent appeals to the Federal Circuit in 1982. For example, the United States Court of Appeals for the Third Circuit concluded, "the patentee shall make a written description of his invention or discovery, 'in such full, clear . . . and exact terms as to enable any person skilled in the art . . . to make, construct . . . and use the same.'"[123] The United States Court of Appeals for the Second and Seventh Circuits affirmed this interpretation.[124] In fact, historically, no regional court of appeals has concluded differently on the written description standard.

In judgments regarding other areas of the Patent Act, the modern Court has maintained interpretive consistency. While addressing patent-eligible inventions in 35 U.S.C. § 101 in 2012, the Court stated that "[s]ection 112 requires only a 'written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same.'"[125] Additionally, while addressing the claim requirement in 35 U.S.C. § 112(b) in 1996, the Court stated that a patent must feature "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.'"[126]

This all indicates that the Court understands that the "written description of the invention" and the "written description . . . of the manner and process of making and using it" are subject to "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

120 United States v. Dubilier Condenser Corp., 289 U.S. 178, 187 (1933).

121 *Id.* at 187.

122 Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944).

123 Donner v. Am. Sheet & Tin Plate Co., 165 F. 199, 206 (3d Cir. 1908) (quoting 35 U.S.C. § 112(a) (2018)).

124 Philip A. Hunt Co. v. Mallinckrodt Chem. Works, 177 F.2d 583, 585 (2d Cir. 1949); Ill. Tool Works, Inc. v. Foster Grant Co., 547 F.2d 1300, 1309 (7th Cir. 1976).

125 Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 90 (2012) (quoting 35 U.S.C. § 112(a) (2018)).

126 Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996) (quoting 35 U.S.C. § 112(a) (2018)).

and use the same."[127] The Federal Circuit's understanding that "'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]'" is neither supported by the statute nor in alignment with the Court's interpretation.[128]

In *Ariad*, the Federal Circuit attempted to argue that other precedent from the Court supports its interpretation of 35 U.S.C. § 112(a).[129] None of this cited precedent, however, supports the Federal Circuit's test of "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."[130] In fact, only one case cited by the Federal Circuit—a precedent from two centuries ago—even recites the term "possession[,]" and its use does not support the Federal Circuit's interpretation.[131] *Evans v. Eaton* explained that a goal of the specification is "to put the public in possession of what the party claims as his own invention."[132] The use of possession in this context referred to the public's possession of the invention, not to the inventor's possession of the invention.

Additionally, the Federal Circuit cited *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* as support for its interpretation.[133] In *Festo*, the Court stated, "[w]hat is claimed by the patent application must be the same as what is disclosed in the specification; otherwise, the patent should not issue."[134] This language, however, does not support the Federal Circuit's interpretation. This broad statement that harmony must exist between the patent application's claims and the specification's disclosure does not command an inventor to show that he "possessed the full scope of the claimed invention," including all "known and unknown" variations of each component of the invention.[135] The statute requires only a written description of the invention in a

127 35 U.S.C. § 112(a) (2018).

128 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (quoting 35 U.S.C. § 112(a) (2018)).

129 *Id.* at 1345–47.

130 *Id.* at 1351.

131 Evans v. Eaton, 20 U.S. 356, 434 (1822).

132 *Id.*

133 *Ariad Pharms.*, 598 F.3d at 1346–47.

134 Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002).

135 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336, 1338 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

manner that enables a POSA to "make and use" the invention.[136] Congress's instruction is clear.

2. The Federal Circuit's Unworkable Written Description Test Jeopardizes Innovation in the Biological Arts

The Federal Circuit's heightened standard for written description will have severe and far-reaching effects on society by destroying the incentive to innovate. The incentive to innovate is the cornerstone of the American patent system. Article 1, section 8, clause 8 of the Constitution states, "[t]he Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[137] The Framers understood the importance of incentives in fueling the development of new technology. Thus, the Framers guaranteed inventors an exclusive monopoly limited in duration to make, use, and sell their inventions in exchange for teaching the public to make and use their inventions. As the Supreme Court of the United States put it in *Pfaff v. Wells Elecs., Inc.*, "the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."[138] Moreover, this "quid pro quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired."[139]

The Federal Circuit's standard does not provide any additional benefits to inventors or the public. As long as "[t]he claim is the measure of the grant," in other words, "specific for the very purpose of protecting the public against extension of the scope of the patent," and the written description of the invention enables a POSA to "make and use" the invention, inventors have accomplished their part.[140] Requiring anything more from inventors eviscerates the incentive to innovate and poses a direct and serious threat to society. The Federal Circuit's heightened standard works against the Constitution by failing to "promote the Progress of Science and useful Arts."[141]

The '190 patent delineates the exact bounds of the protected invention. The '190 patent claims a CAR utilizing a signaling domain, Dr.

136 35 U.S.C. § 112(a) (2018).
137 U.S. CONST. art. I, § 8, cl. 8.
138 Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998).
139 Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944).
140 *Id.*; 35 U.S.C. § 112(a) (2018).
141 U.S. CONST. art. I, § 8, cl. 8.

Sadelain's addition of a second signaling domain, and an scFv that attaches to an antigen. Kite Pharma's behavior reinforces these conclusions. By attempting to acquire a license from Sloan Kettering to use its technology and avoid patent infringement liability by challenging the patent's validity, Kite Pharma demonstrated that it knew it was infringing. Also, Kite Pharma's use of the claimed CAR with a common scFv demonstrates that it did not have a problem with making and using the invention. The claims do not forbid the public from making, using, or selling a CAR equipped with any scFv. The claims simply prevent the public from making, using, or selling a CAR equipped with Dr. Sadelain's second signaling domain for a limited time.

Though the Federal Circuit's written description standard does not provide any additional benefits to inventors or the public, it certainly burdens innovation by disincentivizing the development of new technology. The biotechnology, pharmaceutical, and other scientific industries will particularly suffer from this chilling effect. The Federal Circuit itself recognized that difficulties applying its standard are "particularly acute in the biological arts."[142] In the Federal Circuit's eyes, its standard "ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function."[143]

This decree for sufficient materials in the written description of a genus claim, however, is a dangerous addition. Inventions in the biological arts are laden with intrinsic variance and, in some cases, infinite immaterial adjustments. Because of this, "[t]he central feature of patent law in the chemical, biotechnology, and pharmaceutical industries is the genus claim—a patent claim that covers not just one specific chemical but a group of related chemicals."[144] It is imperative for all of those involved in the American patent system to recognize that "[g]enus claims are everywhere" and "are critical to effective patent protection."[145]

Understandably, the Federal Circuit's heightened standard for written description "represents both bad law and bad policy."[146] As one can easily imagine, "[i]f the doctrine continues down this path, it may threaten innovation in an important sector of the economy."[147] Multiple leaders in scientific innovation share this sentiment. For example, St.

142 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353 (Fed. Cir. 2010).
143 *Id.* at 1352.
144 Karshtedt et al., *supra* note 13, at 3.
145 Karshtedt et al., *supra* note 13, at 3.
146 Karshtedt et al., *supra* note 13, at 3.
147 Karshtedt et al., *supra* note 13, at 4.

Jude Children's Research Hospital, Inc., Albert Einstein College of Medicine, and the University of Texas MD Anderson Cancer Center filed a brief in support of Sloan Kettering's petition.[148] These parties explained that the Federal Circuit's interpretation "catches [them] in an impossible bind for their ongoing and future innovation efforts with chimeric antigen receptors (CARs) and other lifesaving biotechnologies" and "harm[s] innovation without any corresponding benefit to the public."[149] In another example, Amgen and Association of University Technology Managers also filed a brief in support of Sloan Kettering's petition.[150] These parties explained that the Federal Circuit's interpretation "harms first movers in the biologics field and does not reward pathbreaking innovation."[151] Finally, as the City of Hope formulated it, the Federal Circuit's interpretation "will have the unintended effect of jeopardizing the development of biopharmaceutical therapies at City of Hope and other research institutions."[152]

Innovators, like those mentioned above and Sloan Kettering, will better serve society and "promote the Progress of Science and useful Arts" by discovering the next trailblazing cancer therapy than by wasting valuable resources on describing superfluous scFvs.[153] Under the current test, courts will deny these innovators patent protection unless they commit resources to fruitless tasks. The Federal Circuit denies inventors the incentives that the Framers intended for them. As a result of the loss of patent protection, innovators will lose out on funding that they would use for further research to create a better tomorrow.

In a common circumstance like the one in *Juno Therapeutics*, the Federal Circuit's heightened standard for written description will be impossible to meet. Only one operative scFv is required to use the

148 Brief for St. Jude Child.'s Rsch. Hosp., Inc. et al. as Amici Curiae Supporting Petitioners, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2021 WL 5358932 (C.A.Fed. Nov. 10, 2021).

149 *Id.* at *4.

150 Brief for Amgen Inc. & Ass'n of Univ. Tech. Managers, Inc. as Amici Curiae Supporting Petitioners, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2021 WL 5358933 (C.A.Fed. Nov. 10, 2021).

151 *Id.* at *9.

152 Brief for City of Hope as Amici Curiae Supporting Petitioners, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2021 WL 5358934, at *1 (C.A.Fed. Nov. 10, 2021).

153 U.S. CONST. art. I, § 8, cl. 8.

invention described in the '190 patent. To satisfy the Federal Circuit's test, however, Sloan Kettering would have to expend an enormous amount of time and resources to synthesize and test what could be an infinite number of scFvs to prove possession of all possible scFvs that a POSA could use in tandem with a CAR that features Dr. Sadelain's second signaling domain. Further, there will always be untested variations for inventions laden with intrinsic variance and infinite immaterial adjustments, no matter how much testing inventors carry out. Therefore, a POSA would not know whether certain variations fall within the genus, and the claim would fail the Federal Circuit's written description test. Patent protection for these inventions is nothing but a pipedream.

Intrinsic variance and infinite immaterial adjustments, typical of inventions in the biological arts, prevent inventors from securing significant patent protection by claiming narrowly. The explanation for this is that potential infringers could slightly modify the invention with minimal effort to circumvent the scope of the narrow claims. Another point is that the Federal Circuit "held that functional claim language can meet the written description requirement when the art has established a correlation between structure and function."[154] It is impossible to imagine all possible molecular structures that could perform the biological function at issue. Thus, the Federal Circuit's promise that the structure-function relationship can satisfy the written description test is lackluster at best.

Despite the '190 patent being a prime example of a written description that enables a POSA to make and use the invention, the Federal Circuit invalidated it, and a willful infringer escaped unscathed. This case is a foreboding parable that inventors like Dr. Sadelain will remember moving forward. Divesting inventors of the advantages of their inventions is a treacherous practice. Such a practice "foster[s] concealment rather than disclosure of inventions."[155] As the Court well understands, disclosure itself is "one of the primary purposes of the patent system."[156] The Federal Circuit's standard undermines the work of the Framers in guaranteeing inventors an exclusive monopoly limited in duration to make, use, and sell their inventions in exchange for teaching the public to make and use their inventions.

154 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010).

155 Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950).

156 *Id.*

F. A Call for Congressional Intervention

The Federal Circuit's holding that an inventor must demonstrate that he "possessed the full scope of the claimed invention," including all "known and unknown" variations of each component of the invention, cannot be the rule of law.[157] Juno Therapeutics petitioned the Court to provide a definitive answer to the question of how much disclosure 35 U.S.C. § 112(a) requires.[158] Given the Court's denial of Juno Therapeutics' petition, the Court does not seem poised to provide much-needed guidance on this issue anytime soon.[159] Therefore, it is, for the time being, up to Congress to rectify this situation through an amendment of 35 U.S.C. § 112(a).

The source of all confusion and debate in the proper standard for written description is the text of 35 U.S.C. § 112(a). Again, 35 U.S.C. § 112(a) states,

> [t]he 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.[160]

By simply looking at the text, one can see that the "written description of the invention" and the "written description . . . of the manner and process of making and using it" are subject to "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."[161] The Federal Circuit, however, draws a different conclusion. The Federal Circuit believes that "'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].'"[162]

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157 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336, 1338 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

158 Petition for Writ of Certiorari, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023) (No. 21-1566), 2022 WL 2181595, at *i (U.S. Nov. 7, 2022).

159 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

160 35 U.S.C. § 112(a) (2018).

161 *Id.*

162 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (quoting 35 U.S.C. § 112(a) (2018)).

In the absence of any timely instruction from the Supreme Court of the United States, Congress must amend 35 U.S.C. § 112(a) by deleting the comma that follows the phrase "and of the manner and process of making and using it."[163] By doing so, Congress would confirm, once and for all, that "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" applies to the "written description of the invention[] and of the manner and process of making and using it."[164] This amendment would not only rectify the Federal Circuit's muddling of the text of 35 U.S.C. § 112(a) but also seal shut the freshly opened Pandora's box of additional written description requirements that threatens to disincentivize innovation in the biological arts and beyond.

IV. CONCLUSION

35 U.S.C. § 112(a) describes what a patent's specification must disclose to the public in return for patent protection.[165] The following question remains disputed: how much disclosure does 35 U.S.C. § 112(a) require? Until recently, the statute required a patent's specification to disclose a written description of the invention in a manner that enables a POSA to "make and use" the invention.[166] Now, the United States Court of Appeals for the Federal Circuit's interpretation requires an inventor to demonstrate that he "possessed the full scope of the claimed invention," including all "known and unknown" variations of each component of the invention.[167] This Comment submits this interpretation is unworkable because it opposes 35 U.S.C. § 112(a), opposes Supreme Court jurisprudence, and jeopardizes innovation in the biological arts. In the absence of instruction from the Supreme Court of the United States, Congress must amend 35 U.S.C. § 112(a) to save the genus claim and preserve patent protection in the biological arts.

163 35 U.S.C. § 112(a) (2018).

164 *Id.*

165 *Id.*

166 *Id.*

167 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336, 1338 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).