No. 21-1566

In The
Supreme Court of the United States

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

Petitioners,

v.

KITE PHARMA, INC.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF *AMICI CURIAE* MARK D. JANIS AND TIMOTHY R. HOLBROOK IN SUPPORT OF PETITIONERS

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INTERESTS OF *AMICI CURIAE*[1]

Amici curiae are professors who teach and write about patent law and policy. *Amici* have no personal interest in the outcome of this case. Our interest in this case is to contribute to the development of patent law and policy.

SUMMARY OF THE ARGUMENT

This case presents the Court with the opportunity to speak for the first time to the Federal Circuit's "written description" requirement for patentability. In adopting that requirement, the Federal Circuit and its predecessor court have thrown the patent system out of balance, especially for inventions in the life sciences. In particular, the Federal Circuit's requirement imposes prohibitive costs on innovators without a corresponding public benefit. It threatens to impede the very innovation that the patent system is designed to induce.

The Federal Circuit's written description requirement is not supported by the text of the patent statute,

[1] Pursuant to Sup. Ct. R. 37.6, *amici curiae* affirm that no part of this brief was authored by counsel for any party, person, or organization besides *amici*, and that no person or entity, other than *amici curiae*, their members, or their counsel, has made a monetary contribution to the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.2, *amici* provided notice to both parties of the intent to file this brief more than ten days prior to the due date for filing this brief. Both parties consented to the filing of this brief.

nor found in this Court's precedent. Nevertheless, the Federal Circuit is deploying its requirement aggressively to strike down patents. The requirement's scope is expanding, and the Federal Circuit often applies it without discernible deference to district court fact-finding and without a clearly articulated standard. Moreover, the Federal Circuit has never been able to explain the relationship between its extra-statutory written description requirement and other related requirements that the patent statute does explicitly impose, such as the requirement to provide a disclosure that enables a person in the field to make and use the invention. The Federal Circuit's approach has thus created costly uncertainty about what content a patent applicant must include in a patent document, and, for some types of inventions in the life sciences, may make it nearly impossible to secure meaningful patent protection. This Court's intervention is critical.

ARGUMENT

I. This Court Has Underscored the Patent System's Delicate Balance of Interests, and the Federal Circuit's Adoption of a Written Description Requirement Puts that Balance at Risk.

This Court has emphasized that "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." *Pfaff v.*

Wells Elecs., Inc., 525 U.S. 55, 63 (1998). At the heart of this balance is the quid-pro-quo of the patent system: in exchange for the patent, an inventor must sufficiently disclose the invention within the patent document itself. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and *disclosure* of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." (emphasis added)). This disclosure obligation is codified in 35 U.S.C. § 112(a).[2]

As demonstrated in this case, however, the Federal Circuit has disrupted this carefully tailored balance by embracing a disclosure obligation unsupported by the text of the statute. Here, the Federal Circuit declared a patent invalid on the basis that the patent did not comply with the "written description" requirement, overturning a contrary jury verdict. *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1337-38 (Fed. Cir. 2021). The en banc Federal Circuit adopted the written description requirement in 2010, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), building on its prior cases. The Federal Circuit ruled that the test for compliance with this

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[2] Prior to the adoption of the Leahy-Smith America Invents Act of 2011, Pub. L. 112-29, 125 Stat. 284 (2011) (AIA), convention was to refer to the paragraphs of § 112, such as § 112, ¶ 1. For convenience, this brief uses the current format of § 112. The AIA did not alter the substance of 35 U.S.C. § 112(a).

so-called written description requirement is whether the patent's disclosure "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date," while at the same time admitting that the possession test "has never been very enlightening." *Ariad*, 598 F.3d at 1351. The court invoked § 112(a) as the statutory basis for its requirement.

This Court has never reviewed the Federal Circuit's questionable approach to the text of Section 112(a), its possession test, or its aggressive, seemingly standardless application of that test in a variety of cases involving innovation in pharmaceuticals and the life sciences. Given the serious consequences for innovation incentives, the Court should do so now.

A. Patent Statutes Must Balance the Public Benefits of Thorough Disclosure Against the Private Costs of Providing It.

The patent laws grant exclusive rights to inventors, but also "impose upon the inventor a requirement of disclosure" of the patented invention. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). This Court has explained how patent disclosures benefit the public: "When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing

to pay the high price of [exclusive use during the patent term] for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art." *Id.* at 481. Without an incentive to disclose, an inventor might "keep [the] invention secret and reap its fruits indefinitely." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186-87 (1933). Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 Wis. L. Rev. 81, 105-06.

The patent statute includes several provisions designed to balance the public benefits of patent disclosures against the costs of providing those disclosures. *See infra* I.B. On the one hand, these provisions must induce inventors to provide high-quality, rigorous, detailed disclosures to serve the patent system's public interest goals. On the other hand, they must recognize that providing such disclosures entails significant costs—not merely drafting costs, but potentially the costs of extensive testing, clinical evaluations, and the like. Left unchecked, such costs could rise to a level at which they impede the very innovation that the patent system seeks to encourage. These costs can be exacerbated if there is no clear standard for what is a sufficient disclosure.

The Federal Circuit's written description requirement, relied upon in the present case, adds profoundly to the cost of complying with the system's disclosure obligations without concomitant benefits to the public. Accordingly, the requirement warrants this Court's attention.

B. The U.S. Patent Statute Includes Several Provisions that Together Set the Cost/ Benefit Balance Regarding Disclosure.

Recognizing the public benefit of disclosure and its attendant costs, the modern statutory scheme includes several provisions intended to strike an optimal balance. The most prominent of these is the enablement requirement. 35 U.S.C. § 112(a) (requiring that the patent document "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 . . . "). This Court has noted that the requirement that the inventor supply an enabling description of the invention, and receive time-limited patent rights in exchange, is central to the quid-pro-quo that animates the patent bargain. *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944) ("[T]he quid-pro-quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired. . . ."). A patent that is shown to fail the enablement requirement will be ruled invalid.

The enablement requirement has been the subject of scores of cases, including many cases from this Court, tracing back to the earliest days of the US patent system. *See* Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*,

2 Wash. U. J.L. & Pol'y 55, 55 n. 3-4 (2000). It remains today the international benchmark for correlating claim scope with the scope of the inventor's contribution. *See* GATT-WTO Agreement on the Trade Related Aspects of Intellectual Property TRIPS art. 29(1) (designating enablement as a minimum standard for TRIPS-compliant patent systems but not mandating a written description requirement). It is explicit in modern Section 112(a), and its existence has never been disputed.

In the modern statutory scheme, the enablement requirement does not operate alone to ensure adequate disclosure. The invention disclosed in a patent also must have utility. 35 U.S.C. § 101; *Brenner v. Manson*, 383 U.S. 519 (1966) (ruling that utility must be specific and substantial). After the application is filed, it may not be amended in any way that introduces "new matter." 35 U.S.C. § 132(a). *But cf. In re Rasmussen*, 650 F.2d 1212, 1214-15 (C.C.P.A. 1981) (interpreting Section 132 to prohibit only additions to the disclosure portion of the patent document, not additions to the claims); *Ariad*, 598 F.3d at 1348 (dismissing Section 132 as a mere "examiner's instruction"). Proscribing new matter is important to prevent inventors from continually updating their disclosures to reflect post-filing advances in the technology, to the detriment of competitors. The statute includes still other requirements that complement the foregoing, such as the definiteness requirement of Section 112(b). *Nautilus, Inc. v. Biosig Instr., Inc.*, 572 U.S. 898 (2014).

To this mix of explicit statutory safeguards, the Federal Circuit (and its predecessor tribunal) added a "written description" requirement, purporting to find it in the text of 35 U.S.C. § 112(a). In doing so, the court fundamentally altered the balance that the statute established. This Court should review the Federal Circuit's decision to create a written description requirement separate from enablement, and should scrutinize the methodology by which the court arrived at such a requirement.

II. Neither the Text of the Patent Statute nor this Court's Jurisprudence Supports the Federal Circuit's Independent Written Description Requirement.

To arrive at its conclusion that Section 112(a) imposes an independent written description requirement, the Federal Circuit in *Ariad* rejected a straightforward reading of the plain text of the statute. It also asserted that scattered cases from this Court implicitly recognized such a requirement or remarked on it in dicta. Neither the statutory text nor this Court's cases establish an independent written description requirement.

A. The Text of Section 112 Establishes an Enablement Requirement but not a Written Description Requirement.

The relevant language from Section 112 bears reiterating: the patent document "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. . . ." 35 U.S.C. § 112(a). The text is plain and its structure straightforward. The first two clauses, ending with the term "it," specify what the patent document must contain: a written description (1) "of the invention" and (2) "of the manner and process of making and using it." The remaining clauses, which follow a comma after the term "it," specify how those contents are to be evaluated: they must be rendered "in such full, clear, concise, and exact terms as to enable. . . ." By its plain terms, Section 112(a) declares that the patent document must comply with an enablement requirement.

To conjure up an additional written description requirement, the Federal Circuit has ignored the structure of Section 112(a). *Ariad*, 598 F.3d at 1343-45 (court's textual analysis). The Federal Circuit's construction requires the reader to erase the comma after "it" but retain the one after "invention," setting off the phrase "written description of the invention" as if it might be a requirement independent from enablement. But even that does not plainly yield an independent written description requirement. Instead, it yields an ungrammatical mishmash, such as "the specification shall contain (1) a written description of the invention, and (2) *of* the manner and process of making and using it[ ] in such full, clear, concise, and exact terms as to

enable. . . ." (numerals and emphasis added; comma omitted).

Not surprisingly, this convoluted approach to the text has long had its detractors. *See Ariad*, 598 F.3d at 1363-64 (Rader, J., concurring in part); *id.* at 1367-68 (Linn, J., concurring in part); *In re Barker*, 559 F.2d 588, 594-95 (C.C.P.A. 1977) (Markey, J., dissenting). *Cf. Ariad*, 598 F.3d at 1360 (Gajarsa, J., concurring) (asserting that Section 112 is a "model of legislative ambiguity"; joining the majority but doubting whether an independent written description requirement should be viewed as a "necessity of patent law"). Nonetheless, the Federal Circuit has shown no willingness to reconsider its approach to the text. This Court should intervene for purposes of reviewing the Circuit's suspect statutory interpretation.

B. This Court Has Not Adopted an Independent Written Description Requirement.

In addition to its textual analysis, the Federal Circuit has attempted to justify its creation of an independent written description requirement by gesturing towards scattered statements in this Court's jurisprudence. But this Court has never announced the adoption of a separate written description requirement resembling what the Federal Circuit has applied in this and several prior cases.

In *Ariad*, the Federal Circuit invoked this Court's remarks in *Festo Corp. v. Shoketsu Kinzoku Kogyo*

Kabushiki Co., 535 U.S. 722, 736 (2002), that the patent document "must describe, enable, and set forth the best mode of carrying out the invention." But *Festo* was addressing a patent infringement doctrine. The quoted remarks are dicta, notwithstanding the Federal Circuit's profession of subservience to them. *See Ariad*, 598 F.3d at 1347 ("As a subordinate federal court, we may not so easily dismiss such statements as dicta but are bound to follow them.").

The Federal Circuit in *Ariad* also rested on a few other cases from this Court decided before 1952, the year when Congress enacted the patent statute in its modern form. These cases are of dubious relevance to the proposition that the post-1952 statutory scheme allows for a separate written description requirement, and none of them announce the adoption of a separate written description requirement. For example, in *Schriber-Schroth Co. v. Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938), this Court asserted that a patent application "cannot be broadened by amendment so as to embrace an invention not described in the application as filed"—an enunciation of the new matter prohibition. At that time, however, the new matter prohibition was not separately codified, as it is today in 35 U.S.C. § 132. *See also Ariad*, 598 F.3d at 1363 (Rader, J., dissenting in part) (agreeing that *Schriber-Schroth* stands only for "the unremarkable proposition that an applicant cannot add new matter to an original disclosure.").

In addition, in *Evans v. Eaton*, 20 U.S. 356, 433-34 (1822), this Court referred to "two objects" of the

patent's disclosure: first, "to make known the manner of constructing the machine . . . so as to enable artizans to make and use it," and, second, "to put the public in possession of what the party claims as his own invention" so as to distinguish the invention from what was known and to put others on notice as to what would constitute infringement. However, the Court was construing the 1793 Patent Act, Patent Act of 1793, Ch. 11, 1 Stat. 318-23 (Feb. 21, 1793), which included no separate requirement for including patent claims in the patent document. In the modern statute, the claims perform this second "object," *Markman v. Westview Inst., Inc.*, 517 U.S. 370, 372 (1996). This Court has confirmed as much, noting that "the focus of patent construction has shifted" to the claims. *Nautilus, Inc.*, 572 U.S. at 902. It is a fallacy, therefore, to suggest that this Court's 1822 *Evans* decision implies that the modern statutory scheme includes a separate written description requirement.

The most that these cases can demonstrate is that this Court has *not* addressed the Federal Circuit's written description requirement in the post-1952 statutory scheme. Indeed, the Federal Circuit's imaginative reconstruction of this Court's cases belies the Circuit's assertion that a separate written description requirement is "basic to patent law." *Ariad*, 598 F.3d at 1345. It is not basic; it is a recent creation supported by neither the modern statutory text nor this Court's cases.

III. This Court's Intervention Is Critical to Restore the Appropriate Balance within the Patent System.

The written description requirement has now ossified at the Federal Circuit. *See*, *e.g.*, *Ariad*, 598 F.3d at 1347 (invoking stare decisis to justify its separate written description requirement); *Biogen Int'l GmbH v. Mylan Pharms., Inc.*, 18 F.4th 1333, 1341 (Fed. Cir. 2021) (insisting that "[t]he statutory mandate for a written description as a prerequisite for patenting an invention has been a fixture of our laws for more than two centuries"); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991) (suggesting that only the "uninitiated" would question the existence of a separate written description requirement). No further productive percolation at the circuit can be expected.

But the story of the written description requirement is more than just a remarkable instance of Federal Circuit intransigence. In recent years, the Federal Circuit has allowed the doctrine to expand without discernible limits and has largely abandoned any pretense of explaining how the doctrine fits into the modern statutory scheme.

A. The Federal Circuit Is Applying Its Written Description Requirement Aggressively to Strike Down Patents.

The written description requirement now plays a substantial role in modern patent cases involving pharmaceuticals and the life sciences. In part this is

because the Federal Circuit has expanded the doctrine's reach, often reviewing supposedly factual written description determinations without meaningful deference.

1. The Federal Circuit Has Extended the Reach of the Written Description Requirement.

The Federal Circuit has steadily extended the reach of its written description requirement far beyond even what its predecessor court had done. This case well illustrates the trend.

When the Court of Customs and Patent Appeals (C.C.P.A.) first devised the written description requirement, the court confined it to cases where a patent applicant had amended an application during prosecution to claim subject matter that had not been contained in the disclosure of the patent application as filed. *See*, *e.g.*, *In re Ruschig*, 379 F.2d 990, 995-96 (C.C.P.A. 1967). The Federal Circuit continued this practice in its early cases. *See*, *e.g.*, *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991). The court could have used existing statutory tools—the Section 112 enablement requirement or the Section 132 new matter prohibition—to handle these cases, but it embraced the written description requirement instead. Regarding the new matter prohibition, which prohibits amendments that add new matter into the "disclosure of the invention," the C.C.P.A. had

already hamstrung itself by interpreting the term "disclosure" strictly to exclude amendments to the claims, in sharp contrast to its freewheeling interpretation of Section 112. *In re Rasmussen*, 650 F.2d 1212, 1214-15 (C.C.P.A. 1981); *see also TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (treating Section 132 as subsumed within the written description requirement).

In time, the Federal Circuit expanded the reach of the written description requirement considerably, applying it to claims that were included in the original patent application, but which recited therapeutic outcomes or functional attributes. *Ariad*, 598 F.3d at 1349-51; *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997). As a result, even though the disclosure in the patent document may have fully taught a person of ordinary skill in the art how to make and use the invention, the Federal Circuit empowered judges to second-guess whether the inventor had full "possession" of the chemical or biological entities that would generate those therapeutic outcomes or functional benefits.

In recent years, culminating in the present case, the written description requirement has crept even further outward. Under the Federal Circuit's current caselaw, where a claim is directed to a "genus" (a label that could describe most claims), the written description requirement is satisfied only if the patent document discloses "either a representative number of species falling within the scope of the genus or structural

features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350. According to the Federal Circuit's decision below, the disclosure here could qualify as "representative" only if it demonstrates that Juno possessed *all* species of the invention "known and unknown." *Juno*, 10 F.4th at 1335. This reflects another considerable expansion and establishes a disclosure obligation that is all but impossible to satisfy. *See* Dmitry Karshtedt, Mark A. Lemley, and Sean B. Seymore, *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 4 (2021).

2. The Federal Circuit Has Aggrandized the Power to Invalidate Patents at the Appellate Level through the Written Description Requirement.

The Federal Circuit has declared that compliance with its written description requirement is a question of fact. *Ariad*, 598 F.3d at 1351. It has also made a point of saying that the analysis for compliance with the written description requirement "is highly dependent on the facts of each case." *Biogen*, 18 F.4th at 1341. But to the extent that these pronouncements might connote customary constraints on the exercise of appellate oversight, they are simply illusory, as the present case illustrates.

In practice, the written description requirement has become a vehicle for appellate judges to second-guess the fact-finder de novo. In the present case, a

jury found that Kite had failed to prove its invalidity defense based on the written description requirement, and the court denied Kite's JMOL motion, but the Federal Circuit reversed and invalidated the claims, disregarding Juno's expert testimony. *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1337-38 (Fed. Cir. 2021). Likewise, in *Ariad*, after the jury found infringement and rejected the invalidity argument and the district court denied JMOL, the Federal Circuit reversed and invalidated the claims. *Ariad*, 598 F.3d at 1340; *see also Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, No. 2021-1070, 2022 WL 2204163 (Fed. Cir. Jun. 21, 2022) (invalidating a patent on written description grounds; overriding a district court determination that had been based in part on the district court's crediting of expert testimony). Results such as these call into question the Federal Circuit's fealty to the designation of the written description requirement as a question of fact.

Moreover, some Federal Circuit judges have recently advanced the view that they should have the power to ignore factual evidence on written description compliance that arises outside the text of the patent document and its record at the U.S. Patent and Trademark Office (the prosecution history), under some circumstances. *Biogen Int'l GmbH v. Mylan Pharms., Inc.*, 28 F.4th 1194 (Fed. Cir. 2022) (Lourie, J., dissenting from denial of rehearing en banc) ("Where the disclosure in a patent's specification plainly corresponds to what is claimed, extrinsic evidence should not be used to cast doubt on the meaning of what is disclosed."). If

this principle is accepted in all circumstances, it might lead Federal Circuit judges to base written description analyses solely on their own impressions of the patent document and prosecution history. A similar phenomenon played out in the Federal Circuit's claim construction jurisprudence: the court purported to review patent claim construction decisions de novo, until this Court intervened to require the Federal Circuit to abide by its obligation to apply the ordinary rules of deference when reviewing a record that contained genuinely disputed matters of underlying fact, such as those deriving from extrinsic evidence of claim construction. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015); *see also* Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 Ind. L.J. 779, 803 (2011) (discussing how the Federal Circuit has "elevated the disclosure within the patent over the knowledge of the [person having ordinary skill in the art]."). Similarly, intervention is warranted here.

B. The Federal Circuit Has Never Adequately Distinguished Its Written Description Requirement from the Statutory Enablement Requirement.

The expanding power of the written description requirement is troublesome for another reason: the Federal Circuit remains unable to explain the relationship between its written description requirement and those requirements that the statute explicitly contemplates, most notably the enablement requirement. The Federal Circuit has spent years confounding itself over

this relationship, with no discernible progress. *See*, *e.g.*, *Barker*, 559 F.2d at 594 (Rich, J., concurring) (enablement and written description requirements are distinct, but also "commingled"); *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421 (Fed. Cir. 1987) ("The purpose of the description requirement . . . is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined."); *Vas-Cath, Inc.*, 935 F.2d at 1563 (Fed. Cir. 1991) (criticizing the language in *Kennecott*); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) ("Those two requirements [enablement and written description] usually rise and fall together. That is, a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa. . . . Whether the flaw in the specification is regarded as a failure to demonstrate that the patentee possessed the full scope of the invention . . . or a failure to enable the full breadth of that claim, the specification provides inadequate support for the claim under section 112, paragraph one.").

For example, the Federal Circuit has denied that the written description requirement is a phantom "super enablement" requirement, *Ariad*, 598 F.3d at 1352, yet in the same breath has advocated a test that is practically indistinguishable from its enablement test. Specifically, in *Ariad*, the en banc court asserted that "the level of detail required to satisfy the written description requirement varies depending on the nature

and scope of the claims and on the complexity and predictability of the relevant technology," *Ariad*, 598 F.3d at 1351, and that compliance may sometimes be evaluated based on factors "including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" *Id.*, *quoting Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

The circuit reiterated those factors in the case below. *Juno*, 10 F.4th at 1335. But this is largely just a rehash of the enablement test—specifically, the test for evaluating whether one of ordinary skill in the art would need to undertake "undue experimentation" to make and use the invention based on the disclosure in the patent document. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (ruling that undue experimentation is tested based on factors including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

Similarly, in characterizing the purpose of the written description requirement, the Federal Circuit has asserted that "[t]he 'written description' requirement serves a teaching function, as '*quid-pro-quo*' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" *Univ. of Rochester v.*

G.D. Searle & Co., 358 F.3d 916, 922 (Fed. Cir. 2004) (*quoting Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002)). But the Federal Circuit has also routinely stated that "[t]he requirement of enablement, stated in 35 U.S.C. § 112, enforces the essential '*quid-pro-quo* of the patent bargain' by requiring a patentee to teach the public how 'to practice the full scope of the claimed invention.'" *Pacific Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, 996 F.3d 1342, 1350 (Fed. Cir. 2021) (*quoting McRO, Inc. v. Bandai Namco Games Am., Inc.*, 959 F.3d 1091, 1099-1100 (Fed. Cir. 2020)); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

The Federal Circuit has generally deflected these concerns by suggesting that while there may be "little difference in some fields between describing an invention and enabling one to make and use it," *Ariad*, 598 F.3d at 1352, the difference is profound for "chemical and chemical-like inventions." *Id.* But the statute draws no such distinction, and, in any event, the Federal Circuit's efforts to explain the distinction amount to little more than fragile tautology.

Specifically, the court has invoked the following hypothetical: "consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described." *Ariad*, 598 F.3d at 1352, *quoting In re DiLeone*, 436 F.2d 1404, 1405 n. 1 (C.C.P.A. 1971). But this does nothing to explain *why* a document that fully

teaches those in the field how to make and use the entire A, B, C class should be deemed not to have "described" that class. Indeed, given the conditions that the document "contains no broadening language of any kind," but still satisfies the enablement requirement, the document's "discussion" of compound A must necessarily convey a great deal (expressly or implicitly) when read by those in the field. What the hypothetical actually shows is that by "discussing" compound A, the inventor has done what the statute asks, and there should be no need to force the inventor to go through the costly exercise of also "describing" (whatever that may mean) compounds B and C. Indeed, what better way is there to show "possession" of an invention than by providing enough information to allow one of skill in the art to make and use it? Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. Rev. 123, 162 (2006).

At its best, the written description requirement is redundant of the enablement requirement; at its worst, by design, it is a one-way ratchet against the patentability of pharmaceutical and biotechnological inventions. Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 Berkeley Tech. L.J. 615, 617 (1998).

The Federal Circuit's reliance on the written description requirement fosters uncertainty and imposes substantial costs, as this case illustrates. The use of dual doctrines of enablement and written description does not provide double assurance that the disclosure

is adequate. Instead, it results in a net loss, undercutting the development of the statutory enablement requirement and diverting resources towards an extra-statutory written description requirement which continues to defy ready explanation.

C. This Case Is an Appropriate Vehicle for Review.

This case squarely presents the issue of whether the Federal Circuit erred in recognizing an independent written description requirement. It illustrates all of the problematic aspects of that requirement.

Where the Federal Circuit relies on an extra-statutory patentability doctrine, this Court should intervene. Likewise, where the Federal Circuit seeks to rewrite the scope of its own powers relative to other actors in the patent system, the case for this Court to intervene is compelling.

Moreover, the Court also has before it petitions for certiorari on fundamental questions pertaining to the enablement requirement, *Amgen Inc. v. Sanofi*, No. 21-757, and another regarding the written description requirement, *Biogen Int'l GmbH v. Mylan Pharms., Inc.*, No. 21-1567, presenting the Court with an unusual opportunity to review the Federal Circuit's approach to Section 112(a) comprehensively. The Court should take up the opportunity.

CONCLUSION

This Court should grant the petition for writ of certiorari.

Respectfully submitted,

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