No. 25-225

IN THE
Supreme Court of the United States

MSN PHARMACEUTICALS, INC., *et al.*,

Petitioners,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Respondent.

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

BRIEF OF PROFESSORS JONATHAN MASUR AND LISA OUELLETTE AS AMICI CURIAE IN SUPPORT OF THE PETITION

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October 8, 2025

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INTEREST OF AMICI CURIAE[1]

Amici are two professors who have written extensively on the questions presented in this case regarding the impact of after-arising technology on the enablement and written description requirements of 35 U.S.C. § 112.

Jonathan Masur is the John P. Wilson Professor of Law at the University of Chicago Law School. He is also the Director of the Wachtell, Lipton, Rosen & Katz Program in Behavioral Law, Finance and Economics and the David and Celia Hilliard Research Scholar.

Lisa Larrimore Ouellette is the Deane F. Johnson Professor of Law at Stanford Law School and a Senior Fellow at the Stanford Institute for Economic Policy Research.

Professors Masur and Ouellette are among the leading scholars in the field of patent law. They are co-authors of *Patent Law: Cases, Problems, and Materials* (4th ed. 2025), the leading patent casebook, which has been adopted by over seventy law schools. They have also written extensively on the application of enablement and written description in the context of after-arising technology. Most importantly, they are the authors of *Disclosure Puzzles in Patent Law*, 92 U. Chi. L. Rev. 1609 (2025).

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[1] Counsel for amici curiae notified counsel for all parties at least 10 days prior to the due date of amici's intention to file this brief. Amici certify that no counsel for a party authored this brief in whole or in part and no person or entity, other than amici or their counsel, has made a monetary contribution to the preparation or submission of this brief.

Amici have no financial interest in the outcome of this case; they share a professional interest in ensuring that patent law develops in a way that serves the public interest.

INTRODUCTION

Imagine a patent that claims a machine that includes a "metal gear." The patent's specification describes gears made from every then-known metal. The specification also discloses how to make gears from those metals and use those gears in the claimed machine. At the time the patent was issued, the patent thus satisfied the two key disclosure requirements of 35 U.S.C. § 112. It satisfied the "enablement" requirement because it taught how to make and use machines with metal gears. And it satisfied the "written description" requirement because it described all such machines.

Now imagine that, several years after the patent issued, a new metal is invented—call it mithril—that is much softer than any metal known at the time of the patent. What does that after-arising technology do to the claim? The claim on its face covers a machine with gears made from mithril. But the specification neither describes nor explains how to make and use gears made from that new metal—because the metal did not exist when the specification was written.

The Federal Circuit has proven unable to coherently resolve these important questions relating to after-arising technology—urgently calling for this Court's intervention. As to enablement, the Federal Circuit has held that so long as the specification enables the full scope of the claim when the patent is issued, the patentee can claim after-arising technology

that falls within the scope of the claim without any need to show that the specification teaches how to implement the claim with the after-arising technology. *E.g.*, *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254-55 (Fed. Cir. 2004). This blows a giant hole in the enablement requirement. Imagine, for instance, that mithril is so soft that it requires special techniques to mold into functioning gears—techniques that were not known when the patent was issued. Allowing the patentee to claim the machine with mithril gears without teaching how to make such a machine gives the patentee a windfall, extending its monopoly to cover machines with metal gears that the patentee undisputedly did not enable.

As to written description, the Federal Circuit initially seemed to take exactly the opposite approach, holding that a patent is invalid for lack of written description if it does not adequately describe after-arising technology that falls within the scope of the claims. *Chiron*, 363 F.3d at 1255. This creates exactly the opposite problem: It risks invalidating claims that were valid when issued for failing to describe examples of the claimed invention that did not exist at the time of the patent. The Federal Circuit in this case seems to have backtracked from that approach—without acknowledging its prior decisions. But, as explained below, it did so for bizarre reasons that compound rather than resolve the confusion.

As discussed below, the correct approach to these questions is relatively straightforward and flows naturally from basic principles of patent law. In short, after-arising technology should never invalidate a claim that was valid when issued. But neither should

a patentee be able to assert a claim against a product that a skilled artisan could not have made and used with access to both the specification's disclosures and knowledge of the new technology. To take the mithril example above, the invention of mithril should not invalidate a claim to a machine with "metal gears" that was valid when issued. And if mithril could be substituted one-to-one for the other metals described in the specification, then the patentee should be able to cover a machine with mithril gears. But the patentee should *not* be able to assert the claim against a machine with mithril gears if mithril had unusual properties such that a skilled artisan would not have been able to make and use the machine with mithril gears based on the specification's disclosures and knowledge of mithril. As amici explain, a correct application of existing patent doctrine leads to that logical result.

At this stage, though, the important point is not that amici's proposed solution is the correct one but that, despite multiple opportunities, the Federal Circuit has proven unable to develop a coherent approach to addressing the impact of after-arising technology on section 112's disclosure requirements. The only way to clear up the jumble the Federal Circuit has created in this crucial area of patent law is for this Court to intervene.

This case presents an unusually clean vehicle for this Court to address these issues. Novartis claimed a "combination" of two pharmaceutical compounds and enabled and described the only then-known way of combining them. But scientists discovered that these compounds can be combined as a "complex," with superior pharmaceutical properties. The parties stipulated that the claim covers such a complex, but it

was not enabled or described in the specification (because it did not exist when the specification was written). This case is thus very close to the mithril hypothetical described above and provides an ideal case to address the complicated and important issues that the Federal Circuit has failed to coherently resolve.

This Court should grant the petition for a writ of certiorari.

ARGUMENT

The patent system rests on a fundamental quid pro quo: In exchange for "public disclosure of new and useful advances in technology," the inventor is given a limited monopoly over those advances. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998); *see also, e.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) ("[E]xclusive patent rights are given in exchange for disclosing the invention to the public.").

Two disclosure requirements in 35 U.S.C. § 112 play a key role in aligning patent law with that underlying bargain. Section 112's "enablement" requirement ensures that the disclosures in the patent's specification teach a skilled artisan how to make and use the claimed invention. And section 112's "written description" requirement ensures that the patent describes the invention, giving the public notice of the scope of the claimed patent monopoly and preventing the patentee from drafting claims, years after the initial patent, that expand the scope of the invention.

Applying the enablement and written-description requirements can be complicated when the patent's disclosures enable and describe the full scope of the invention *at the time of the patent*, but do not enable

and/or describe post-patent inventions that are covered by the patents' claims. The Federal Circuit has failed to coherently apply section 112's disclosure requirements in this context, adopting rules that divorce the disclosure requirements from their role in aligning the scope of the patent monopoly to the scope of the disclosed invention. This Court's intervention is urgently needed.

I. The Federal Circuit has failed to coherently apply section 112's disclosure requirements in the context of after-arising technology, calling for this Court's intervention.

As amici explain in their article, the Federal Circuit has had multiple opportunities to apply section 112's enablement and written-description requirements to after-arising technology—including in this case. *See* Jonathan S. Masur & Lisa Larrimore Ouellette, *Disclosure Puzzles in Patent Law*, 92 U. Chi. L. Rev. 1609, 1636-62 (2025). Yet the Federal Circuit has failed to develop a coherent approach to applying either doctrine to such technology. It has thus become clear that this Court's intervention is needed.

To explain these issues, the brief uses the mithril hypothetical described above, in which an inventor named Aleida invents a machine that uses a "metal gear." One year after she files for her patent, someone else invents a new type of metal called mithril that falls within the literal scope of the claims even though

no one foresaw mithril's existence when the claim was drafted.[2]

A. Enablement

Section 112 states that a patent's specification must "enable any person skilled in the art ... to make and use" the patented invention. 35 U.S.C. § 112(a). To satisfy this requirement, a skilled artisan must be able to "make and use a patented invention" with only a "reasonable amount of experimentation." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 612 (2023). The amount of experimentation that is permissible "will depend on the nature of the invention and the underlying art." *Id.* The Federal Circuit has long held that, as a general matter, enablement is judged at the time of filing—an inventor cannot file for a patent and then figure out how to construct or use the invention later. *Hogan*, 559 F.2d at 605-06.

As applied to after-arising technology, one might imagine this means that Aleida's claim to a gear made with *any* metal, if understood to encompass mithril, is not enabled. At the time of filing, Aleida did not know how to make (or obtain) mithril for use in her invention—nobody did.

Yet the law as it currently stands is directly to the contrary. For the Federal Circuit, evaluating enablement at the time of filing means evaluating whether the claim is enabled *for whatever technology existed*

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[2] Amici assume, consistent with the facts of this case, that the claim itself covers the after-arising technology. Additional issues arise where the claim might not cover the after-arising technology. *See* Masur & Ouellette, 92 U. Chi. L. Rev. at 1636-48.

and was encompassed by the claim at the time of filing, not for any after-arising technology that falls within the claim scope. The seminal case is *In re Hogan*, decided by the Court of Customs and Patent Appeals (the predecessor to the Federal Circuit) in 1977. In *Hogan*, the patentee claimed an entire genus of polymers and disclosed a method for making them. *Id.* at 597-98. The patentee argued that at the time of filing, only "crystalline" polymers were known in the art, and it was not disputed that the specification fully enabled the production of crystalline polymers. *Id.* at 605-06. However, at some later point, a different inventor discovered another species of polymer, the "amorphous" polymer. *Id.* The court held that amorphous polymers fell within the literal scope of the claim, which was not limited to only crystalline polymers. *Id.* But it did not invalidate the claim on this basis. Rather, the court held the claim was enabled as of the time of filing because the specification properly enabled crystalline polymers, the only species of polymers known at that moment. *Id.* Because amorphous polymers were unknown, they were irrelevant to the enablement determination. And because the claim was enabled as of the moment of filing, it was enabled forever, full stop. *Id.* at 605. Later Federal Circuit cases have adopted the same logic and reached the same result. *E.g.*, *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254-55 (Fed. Cir. 2004).

Under this approach, the patentee often will get to have it both ways. Per the above example, if Aleida can convince the court to interpret her claim broadly

enough to literally encompass the after-arising technology, she can sue another party for making a variant with mithril. It does not matter to the Federal Circuit whether a person with skill in the art who read Aleida's specification could actually produce the variant of the invention with mithril. So long as her claim is enabled based on the metals that existed when she filed for a patent, it is forever enabled. Aleida gets the sweet (mithril infringes) without the bitter (testing whether mithril is enabled).

The *Hogan* approach violates the principle that a patent right should be commensurate with its disclosure. Suppose Aleida's disclosure would not have enabled a variant of her invention that used mithril at the time she filed her patent. That is, imagine that, at the time Aleida filed for the patent, a skilled artisan who had access to Aleida's patent specification and access to mithril still could not make a version of her invention using mithril. Perhaps mithril is softer than other metals, and thus it would not function properly as a material for gears. Or perhaps it is harder than other metals and could not be molded into a gear using known methods. Mithril could not simply be plugged into the rest of her invention, as one might plug in gears made of steel or iron. Some additional step is required—the mithril would have to be combined with some other type of metal, or the invention would need to be adjusted to account for the difference between mithril gears and other metal gears.

Under these circumstances, Aleida should not be able to capture variants of her invention that use

mithril. The common property she identified that applies to all other metals does not apply one-to-one to mithril. Someone else must do work to fill in the gap between what Aleida's specification discloses and a variant of her gears that employs mithril. That additional work is what renders her patent insufficient to warrant stretching her claim to include mithril within its scope. She has not provided the necessary quid and does not deserve the quo.

Or to offer another hypothetical, suppose Aleida drafted a claim in 1997 involving a software algorithm on a "computer" that was enabled for all computers existing in 1997. If it would be easy to implement that invention with the iMac computer introduced in 1998, then the claim should validly cover that after-arising technology. But if it takes more than a reasonable amount of experimentation to implement Aleida's invention with a quantum computer after they were first created in 1998, then Aleida should not be allowed to capture that variant of her invention.

Amici discuss a proposed solution to this problem below. But the key point for purposes of the petition is that the Federal Circuit has consistently failed to apply the enablement requirement in this context in a way that complies with the bargain that justifies the patent monopoly. Instead, the court has given patentees a windfall, allowing them to extend their patent monopoly to cover inventions that they did not teach the public how to make and use—and likely did not even know how to make or use themselves.

B. Written Description

Section 112 also requires that the patent's "specification shall contain a written description of the invention." 35 U.S.C. § 112(a). "That requirement is satisfied only if the inventor conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrates that by disclosure in the specification of the patent." *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1376 (Fed. Cir. 2019) (quotation marks, brackets, and alterations omitted). One of the primary purposes of written description is to ensure that the patentee does not seek to claim more than she invented, especially by amending her claims, after the specification was drafted, to encompass new inventions or target competitors' products.

The Federal Circuit's key precedent applying the written-description requirement in the context of after-arising technology is its decision in *Chiron v. Genentech*. That case involved a claim for a type of "monoclonal antibody." 363 F.3d at 1250. There are several ways of creating monoclonal antibodies: they can be made within humans, within animals, or as "chimeric" antibodies that incorporate both human and animal genetic material. *Id.* When the patent was filed, chimeric antibodies had not yet been discovered and thus were not described in the specification—they were after-arising technology. *Id.* at 1251. But the court construed "antibody" in the claim to include chimeric antibodies and adopted the *Hogan* position that enablement is judged at the time of filing.

The court thus concluded that the claim was enabled and was infringed by chimeric antibodies because it taught how to make all types of antibodies that existed at that moment. *Id.* at 1254-55. The fact that it did not and could not enable chimeric antibodies was viewed as irrelevant to whether the claim could capture these after-arising variants. This was already a misstep. As explained in the previous section, the *Hogan* approach is misguided.

The *Chiron* court then went on to hold the claim invalid for lack of written description on the theory that the claim encompassed chimeric antibodies, but the relevant specification offered no indication that the inventor had possession of chimeric antibodies at the time of the effective filing date. *Id.* at 1255. Of course, the inventor could not possibly have possessed chimeric antibodies—chimeric antibodies did not yet exist. There is an obvious tension between the court's approaches to written description and enablement: the latter is judged as of the time of filing, while the former is (apparently) judged at the time of litigation, with reference to after-arising technology. Yet that tension goes unremarked upon in the opinion.

The Federal Circuit's approach to written description applied in *Chiron* also departs from the basic patent bargain—though for the opposite reason as the Federal Circuit's approach to enablement. If the approach outlined in *Chiron* were taken seriously, it would mean that *every* claim that captures after-arising technology is invalid for lack of written description, even if a skilled artisan with access to the specification and knowledge of the after-arising technology

could easily practice the patent. Only in the rare instance where the applicant was immensely prescient (or lucky) to foresee the arrival of new technology would she escape this doctrinal vise grip.

The Federal Circuit in this case seemed to walk back its holding in *Chiron*. Here, the patent claimed two hypertension drugs "in combination," and it disclosed the only known combination method at the time of filing: a physical mixture. Pet. App. 15a. Later researchers discovered a method of combining the drugs in a "complex," in which they were connected by weak chemical bonds. Pet. App. 15a. The district court construed the claim to cover this after-arising type of combination, but based on *Chiron*, it held the claims invalid for lack of written description. Pet. App. 11a-13a.

The Federal Circuit reversed, but for a bizarre reason: even though the parties stipulated that the version of the invention made with a complex infringed the claims, the Federal Circuit asserted that this after-arising technology "is not what is claimed." Pet. App. 15a-17a. The Federal Circuit thus arrived at the right answer for the wrong reasons, and it failed to explain why this result is consistent with *Chiron*. Indeed, it did not discuss *Chiron* at all.

The net result is that, as with enablement, the Federal Circuit has proven unable to develop a coherent approach to written description in the context of after-arising technology. Only this Court's intervention can correct these intractable errors.

II. This case presents an ideal vehicle for addressing these issues.

As the petition and the above discussion make clear, this case presents an ideal vehicle to address the correct application of enablement and written description in the context of after-arising technology. In short, Novartis's patent claimed a pharmaceutical composition of two hypertension drugs, valsartan and sacubitril, "in combination." Pet. App. 7a. When the patent was filed, the only known method of combining these chemicals was in a physical mixture, and that is the only combination method disclosed in the specification. Pet. App. 15a. In the intervening years, however, scientists discovered a means of combining the two chemicals in a "complex," an arrangement in which they are connected by weak chemical bonds. Pet. App. 89a. This is the method used to make the accused infringing drug. Pet. App. 15a. The district court, applying *Chiron*, held that the patent satisfies the enablement requirement even though it does not teach how to use the newly invented "complex," but that the patent is invalid for lack of written description because it does not describe the complex. Pet. App. 11a-13a. And, as discussed, the Federal Circuit then reversed the court's finding of lack of written description on the theory that the "complex" "is not what is claimed"—even though it was undisputedly covered by the claims. Pet. App. 15a-17a.

This case thus presents an ideal opportunity for this Court to reconsider both (1) the Federal Circuit's categorical *Hogan*/*Chiron* rule that allows a patentee to assert its monopoly over after-arising technology

that is not enabled by the specification and (2) the Federal Circuit's incoherent approach to applying the written-description requirement in this context, which requires that the patentee describe not-yet-invented examples of the invention.

III. Though less relevant at the certiorari stage, amici's proposed approach correctly resolves these issues based on foundational patent principles.

The Federal Circuit's inability to develop a coherent approach to section 112's disclosure rules in the context of after-arising technology calls out for this Court's intervention regardless of how best to correct the Federal Circuit's errors. Amici therefore only briefly summarize their proposed approach, which is described in more detail in their article. Masur & Ouellette, 92 U. Chi. L. Rev. at 1650-56, 1658.

Amici believe that, under basic patent law principles, the crucial question for purposes of after-arising technology should be whether the version of the claim using after-arising technology is enabled based on the information provided in the specification *plus* the after-arising technology. To return to the mithril example, if mithril would have worked perfectly well as a material for the claimed gears based purely on the disclosures in the patent, then the patent should both satisfy the written description and enablement requirements and be read to cover mithril gears. If, by contrast, it would have taken some special, unknown and undisclosed technique to make or use mithril gears in the claimed machine, then the patentee should not be able to obtain a windfall by obtaining a

monopoly over the machine with mithril gears. But, in amici's view, this should not mean the claim is *invalid*—just that it doesn't reach the non-enabled after-arising technology as a matter of *infringement*.

That result is easier to reach as a matter of fundamental patent law principles than as a matter of doctrine. Reaching that result doctrinally is tricky because claims are generally read to have their ordinary meaning and one of the assumptions in these after-arising technology cases is that the claim, on its face, *does* cover the after-arising technology—for instance, "metal gears" includes mithril gears and valsartan and sacubitril "in combination" includes a complex of the two compounds.

Amici believe the best solution lies in the reverse doctrine of equivalents.[3] Under the reverse doctrine of equivalents, which this Court has applied for more than a century, a device that would ordinarily literally infringe a patent claim will be held not to infringe that claim if it operates on a wholly different "principle" from the principle described in the patent. *E.g.*, *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608-09 (1950); *Boyden Power-Brake Co. v. Westinghouse*, 170 U.S. 537, 568 (1898). To be sure, that doctrine has not often been invoked in recent

[3] Alternatively, non-enabled after-arising technology could be categorically excluded from literal claim scope as a matter of claim construction. In addition, ensnarement doctrine should be used to prevent patentees from asserting claims against non-enabled after-arising technology through nonliteral infringement under the doctrine of equivalents. *See* Masur & Ouellette, 92 U. Chi. L. Rev. at 1639-41, 1651.

years, and there is an unanswered question as to whether it survived the Patent Act of 1952. *See Steuben Foods, Inc. v. Shibuya Hoppmann Corp.*, 127 F.4th 348, 357 (Fed. Cir. 2025) (acknowledging but not deciding this issue). But the doctrine is an excellent fit for the problem created by non-enabled after-arising technology: a later-arising device falls within the literal scope of the patent claim, but because of the new technology it employs—technology that the patent does not enable—it operates by a different principle and hence falls outside the bounds of what the patent should be able to capture.

Amici therefore propose that a court engage in a three-step inquiry. First, it should evaluate whether the claim as written was fully enabled and described at the time of filing, with respect only to the technology and knowledge available at the time of filing. If it was not, the claim is invalid for lack of enablement and/or written description. Next, the court should determine if the after-arising technology at suit infringes the claim. If it does not (or if it is an unclaimed element that is not connected to the claim limitation itself), the inquiry is over. If it does infringe via an express claim element, then the court should proceed to the third step: determine whether the version of the claim using after-arising technology is enabled based on the information provided in the specification plus the after-arising technology. This last step is where the Court should depart from *Hogan*—if this third step is not satisfied, the version of the invention that incorporates after-arising technology does not infringe the claim.

Ultimately, though, these merits questions are for another day. What matters for present purposes is that the Federal Circuit's precedents in this area have radically departed from patent law's basic bargain, and the Federal Circuit has shown no indication that it can right the ship. The time has come for this Court to intervene.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

Respectfully submitted.

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