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 FOR SIGMAPHARM LABORATORIES, LLC, AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Sigmapharm Laboratories, LLC, is a manufacturer of generic pharmaceutical products. Sigmapharm was founded in 2005 as a small, specialty formulation house conducting only pilot-scale development of unique, difficult-to-formulate products using proprietary drug-delivery systems. For over a decade, however, Sigmapharm has developed, manufactured, and marketed unique, cost-effective, high-barrier-to-entry generic drug products under its own label. The manufacture and marketing of generic pharmaceuticals are a substantial portion of Sigmapharm's business, and Sigmapharm has a particular interest in the development of the law concerning pharmaceutical patents.

Generic manufacturers can operate only if they have an accurate understanding of the scope of brand manufacturers' patent rights. Like other generic manufacturers, the viability of Sigmapharm's business depends on steering clear of brand manufacturers' patents and predicting the likely outcome of patent-infringement suits brought by brand manufacturers. Without a clear and predictable understanding of the scope of brand manufacturers' patents, generic manufacturers like Sigmapharm cannot make informed business decisions about product development or the timing of market entry.

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[1] Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel of record for the parties received timely notice of the intent to file this brief pursuant to this Court's Rule 37.2.

Generic manufacturers must make enormous upfront investments for generic formulations of branded drugs—developing manufacturing processes and facilities, obtaining regulatory approval, and performing bioequivalence studies—long before the generic drugs generate any revenue. Key to this long-term strategic planning is an assessment of the validity and scope of brand manufacturers' patents.

This case demonstrates the dire unpredictability surrounding a recurring and important question of patent law: the role of after-arising technology in a court's analysis of whether a patent's specification properly describes and enables the full scope of the patent, as required by 35 U.S.C. § 112(a). In Sigmapharm's view, the decision below reflects—and exacerbates—the lack of clarity as to the validity and scope of a patent that fails to enable or describe embodiments utilizing technology nonexistent at the time of the patent application. Unpredictability as to the scope and validity of brand manufacturers' patents makes it difficult for generic manufacturers to do business. And outcomes like the ones in this case provide a undue windfall to brand manufacturers—rewarding broadly construed claims without imposing the Patent Act's requirements that the full scope of a claim be enabled and described.

Sigmapharm thus has a compelling interest in ensuring that the question presented here, which applies across patent law but has outsize importance in the pharmaceutical industry, is resolved. This Court recently granted certiorari to clear up uncertainty as to the enablement requirement with respect to patents that claim entire genuses. *See Amgen Inc. v. Sanofi*, 598 U.S. 594,

603-04 (2023). The question presented here is related, but distinct, to the one addressed in *Amgen*. This Court should likewise grant certiorari to continue to bring much-needed clarity to the Patent Act's written-description and enablement requirements.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

In *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023), this Court held that to satisfy 35 U.S.C. § 112(a)'s enablement requirement, a patent's specification "must enable the full scope of the invention as defined by its claims." *Amgen*, 598 U.S. at 610. In that case, Amgen had sought to patent the entire genus of antibodies that bind to a particular protein and accomplish a particular function. *Id.* at 602. The patent's specification identified 26 such antibodies but claimed *all* antibodies with similar behavior—potentially millions more. *Id.* at 602-03, 613. The patentee did not purport to have discovered each such antibody, but it argued that it had properly enabled their discovery nonetheless. *Id.* at 613-14. The question presented thus related to the scope of the enablement requirement when a patentee claims more than it has actually discovered.

Amgen added clarity to the Patent Act's enablement requirement in the case of patents that claim entire genuses but identify and enable only specific species. *Amgen*, however, did not address or resolve a related question: what happens when a patent, as construed, covers embodiments utilizing technology that was not specifically described because it did not exist at the time of the patent application? This Court's holding in *Amgen* was that a specification does not enable claimed subject

matter if it would take a person having ordinary skill in the art (or PHOSITA) more than a "reasonable amount of experimentation to make and use" what is claimed. 598 U.S. at 612. But of course, if an embodiment involves technology that did not exist at the time of the patent application, then it follows that a PHOSITA would need to undertake undue experimentation to implement that embodiment—after all, he would have to *invent* something novel in order to make and use it. At the same time, perhaps the patentee ought not be faulted for claiming too much, as it may not have even known that future advances would mean there were unenabled and undescribed embodiments. *Amgen* did not speak to whether or how the enablement and the related written-description requirements apply in this scenario.

To understand when and why the question presented here—how Section 112(a)'s twin requirements apply in the context of after-arising technology—arises, consider the following hypothetical. Suppose a patent claims a method of using a "transistor" to perform some novel computing task. The patent's specification properly discloses how to use a transistor to perform the task in a way that a PHOSITA would be able to apply to all transistors available as of the time of the patent application.[2] Suppose further, however, that years after the patent is

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[2] The *Amgen* question presented would arise if not all types of transistor would work for the task, but the patentee claimed all those that do without specifying exactly which are viable options and which are not. So long as a PHOSITA could distinguish between viable and inviable species of transistor with a "reasonable amount of experimentation," such a specification would satisfy the enablement requirement. *Amgen*, 598 U.S. at 612.

issued, someone invents a new and improved variety of transistor. And suppose the new transistor performs the patented task more efficiently.[3]

Does it infringe the patent to use the new type of transistor to perform the task? As a matter of claim construction, the answer is likely yes. The new variety of transistor is likely a "transistor" as claimed by the patent and thus using it to perform the task literally infringes the patent's claims—just as in this case, a complex of valsartan and sacubitril was deemed a "combination" as construed in the patent and thus indisputably literally infringes. Pet. App. 7a-9a; *see id.* at 88a-91a. The critical question, instead, is whether the patent can be said to satisfy Section 112(a)'s written-description and enablement requirements. If the after-arising technology should be disregarded for purposes of this inquiry (as the Federal Circuit sometimes holds, and as it held below), the patent is perfectly valid. But if the after-arising technology is considered, it is difficult to see how the patent's specification could either properly describe or enable using the newly invented transistor. The written-description requirement is meant to "convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date," *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc), but obviously the patentee did not have the capacity to perform the claimed task using the as-yet-nonexistent transistor

[3] One can also suppose that the new transistor does a worse job at the task—or maybe performs the same. The variety of possibilities underscores the need for a comprehensive framework to govern this scenario.

when it applied for the patent. Nor could the patentee have possibly enabled the task using the new transistor, which had not yet been invented. Does that make the patent invalid under Section 112(a)? Does it require narrowing the scope of the patent? Some other result?

Certiorari is warranted to resolve that question here. The Federal Circuit's precedents addressing Section 112(a)'s requirements in the case of after-arising technology are inconsistent and confusing. And the decisions in this case only add to the confusion—the district court applied a precedent under which after-arising technology is seemingly irrelevant for purposes of Section 112(a)'s enablement requirement but seemingly fatal to the patent for purposes of Section 112(a)'s related written-description requirement. That is a confusing result in its own right. The Federal Circuit reversed that determination without acknowledging that it was departing from its clear precedent applied by the district court, only exacerbating the chaos.

The upshot is not just a judgment of infringement in this suit: it is a pall of confusion hovering over patent law in a way that causes particular concern to manufacturers of generic pharmaceuticals. Generic manufacturers' entire business is based on developing and marketing products that avoid infringing brand manufacturers' patents. That business cannot operate without the ability to predict with high confidence what those patents actually cover. The more unpredictable the result in a patent-infringement lawsuit, the more reluctant generic manufacturers will be to bring new generic drugs to market at all. And the main losers are ultimately American patients, who rely heavily on high-quality and affordable

generic medicines. The American taxpayer loses as well, as the availability of generic medications saves the Medicare and Medicaid programs countless billions each year.

The facts giving rise to this case are not unusual. Respondent Novartis Pharmaceuticals Corporation owns a patent (the '659 patent) on the use of a "combination" of two drugs (valsartan and sacubitril) when used in a 1:1 ratio to treat heart failure. Pet. App. 4a-7a. After the patent issued, however, a new method of combining these two drugs was developed—it was discovered that they could be combined as a "complex." *Id.* at 15a. Petitioners developed a generic drug combining valsartan and sacubitril in complex form. *Id.* at 9a, 23a-24a. The patent was construed to cover petitioners' method of combining the drugs, even though that method did not exist at the time of the patent application. The question is whether the patent is invalid for failure to enable or describe combining the two drugs as a complex.

These facts can recur because developments in physical chemistry often lead to new methods of synthesizing patented medications. Sometimes the patent may be construed not to cover the novel synthetic method, in which case the patent will not be invalidated under Section 112(a) but the infringement lawsuit will fail. But if the patentee obtains a broad claim construction that ensnares an accused product utilizing the after-arising technology, is the patent's specification immune from the ordinary enablement and written-description requirements?

This case presents a clean opportunity for this Court to clear up the doctrine and provide desperately needed

guidance on how to apply Section 112(a)'s requirements in the case of after-arising technology. The petition should be granted.

ARGUMENT

I. THE FEDERAL CIRCUIT'S PRECEDENTS ON THE ENABLEMENT AND WRITTEN-DESCRIPTION REQUIREMENTS FOR AFTER-ARISING TECHNOLOGY ARE IN DISARRAY.

The Federal Circuit's precedents on the question presented are self-contradictory and unclear. The decision below only makes things worse. Without this Court's intervention, clarity is unlikely to come.

A. The Case Law on Section 112(a) and After-Arising Technology Is Incoherent.

As the petition chronicles (at 15-26), different strands of the Federal Circuit's case law take different approaches to the question presented here.

For instance, in *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003), the Federal Circuit seemed to hold that after-arising technology poses an enablement problem if a patent's claims are construed to cover embodiments utilizing that new technology. Certain claims of the patent at issue were construed to cover all plant cells, both monocotyledons (or "monocots," meaning a type of flowering plant in which "the initial development of the seed produces one leaf") and dicotyledons (or "dicots," with two leaves in the initial development). *Id.* at 1338. All the examples disclosed in the patent's specification were dicots, but

the allegedly infringing product was a monocot. *Id.* As of the relevant priority date, the relevant technology as concerned monocots did not yet exist. *Id.*

The Federal Circuit held that the patent failed the enablement requirement because it claimed uses relating to monocots without enabling those uses. *Plant Genetic Sys.*, 315 F.3d at 1339-41. The court noted that had the patentee argued that the claims "were not understood by those skilled in the art as encompassing monocots when the [patent] was filed," it could have avoided invalidation of the claims. *Id.* at 1341. But the patentee had insisted that its claims covered monocots, because that was the only way to sue the defendant for infringement. *Id.* The court held that, having made that choice as to a broad claim construction, the scope of the Patent Act's enablement requirement expanded correspondingly, and the patentee had an obligation to enable those uses relating to monocots as well. *See id.* That is, the court rejected the notion that the patentee was at once "entitled to both a broad scope of coverage and a lower standard of enablement." *Id.* The specification having failed to enable this as-yet-nonexistent technology, the patent was invalid.

The next year, the Federal Circuit decided *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004). The patent at issue in *Chiron* claimed certain monoclonal antibodies and disclosed a method of making the antibodies using mouse cells. *Id.* at 1250-51. The antibodies could also be created using chimeric antibody technology, but that technology was not first disclosed until several months after the relevant application date. *Id.* at 1251. The claims at issue were "broadly construed" to

encompass both the disclosed murine antibodies and the undisclosed, unenabled, after-arising chimeric antibodies. *Id.* at 1252. The defendant's chimeric antibodies were therefore deemed infringing. *Id.*

The Federal Circuit held that the failure to enable chimeric antibodies did not render the patent invalid. *Chiron*, 363 F.3d at 1253-55. The court recited that ordinarily a patent specification must enable the full scope of the claims as construed. *See id.* at 1253. But relying on *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977), the court stated that this requirement could be overlooked in the case of "technology that arises after the date of application" because "[s]uch disclosure would be impossible." *Chiron*, 363 F.3d at 1254 (citing *Hogan*, 559 F.2d at 605-06). The chimeric antibodies, though within the patent's scope as its claims were construed, were deemed "outside the bounds of the enablement requirement." *Id.*

The *Chiron* court distinguished *Plant Genetic Systems* on the basis that the unenabled monocots there had been "nascent technology when the application was filed," unlike the chimeric antibodies in *Chiron* (or the amorphous propylene at issue in *Hogan*). *Chiron*, 363 F.3d at 1257. The Federal Circuit thus appeared to adopt a rule that if some aspects of the technology had begun to emerge as of the date of the patent application, then the usual rule applied: the specification "must enable one of ordinary skill in the art to practice 'the full scope of the claimed invention,'" and "'[t]he enabling disclosure of the specification [must] be commensurate in scope with the claim under consideration." *Id.* at 1253 (alterations in original) (first quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); and then quoting *In re*

Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983)). But if that technology did not exist *at all*, then (for some unspecified reason) the enablement requirement apparently did not apply with its usual force, and the patentee was entitled to a broad monopoly even as to embodiments that it had failed to enable. *See id.* at 1254 ("The law does not expect an applicant to disclose knowledge invented or developed after the filing date. . . . The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction.").

Despite this relaxation of the enablement requirement, the *Chiron* court proceeded to invalidate the patent on written-description grounds. 363 F.3d at 1255-56. In fact, the analysis was quite straightforward: the court explained that "the Chiron scientists, by definition, could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist at the time of the . . . application." *Id.* at 1255. The court did not grapple with why this holding made sense in light of its enablement holding—or what good the principle that after-arising technology need not be enabled would be if that technology must still be disclosed to satisfy the Patent Act's written-description requirement.

B. The Decision Below Casts This Important Area of Patent Law into Further Chaos.

Indeed, the proceedings in this case are indicative of the hopelessness of predicting how the question presented might be resolved in any particular case. The district court here followed an approach it believed was dictated by the Federal Circuit's decision in *Chiron*. *See*

Pet. App. 67a-75a (declining to invalidate the '659 patent on enablement grounds under *Chiron*); *id.* at 77a-80a (invalidating the patent on written-description grounds under *Chiron*). Correct or not, that at least appears to be the path dictated by one on-point Federal Circuit precedent.

In reversing the district court with respect to written description, the court of appeals did not comment on the trial court's application of *Chiron*, or even mention *Chiron* at all in its analysis. *See* Pet. App. 13a-17a. Instead, the court concluded that Novartis's invention "is plainly described throughout the specification." *Id.* at 14a; *see id.* at 14a-15a. The *Chiron* court had considered it "axiomatic[]" that a patentee "cannot satisfy the written description requirement for . . . new matter" claimed by the patent but embodied by after-arising technology. 363 F.3d at 1255. Yet in the decision below, that axiomatic principle fell by the wayside. It is anyone's guess what the law of written description actually is moving forward, or which version of that law will be applied in any particular case.[4]

Not only did the Federal Circuit depart from its precedent with no explanation, the analysis it did offer is difficult to understand. With respect to the written-description requirement, the court of appeals held that "complexes need not have been described" in the '659

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[4] *See* Jonathan S. Masur & Lisa Larrimore Ouellette, *Disclosure Puzzles in Patent Law*, 92 U. Chi. L. Rev. (forthcoming 2025) (manuscript at 42-43), https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=2376&context=public_law_and_legal_theory (noting the inconsistency between *Chiron* and the decision below).

patent because the patent "does not claim . . . complexes." Pet. App. 13a. In the court's view, though the '659 patent *covers* complexes, it does not *claim* them. *Id.* at 15a-16a. The court stated that to mesh these two inquiries is to "conflate[] the distinct issues of patentability and infringement." *Id.* at 16a. This suggestion is not consistent with well-established patent principles.

It is a fundamental tenet of patent law that a patent's claims—as its words are construed—"define the metes and bounds of the patentee's invention." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012). Patent law does not recognize any distinction between what a patent's words are construed to cover and what the patent "claims." Here, the '659 patent was construed to cover complexes. That means the patent *claims* complexes. And it is equally fundamental that the written description required by Section 112(a) must "describe the invention set forth in the claims." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). There is no room for some sort of liminal category of subject matter that is at once sufficiently described by the patent claims' words so as to be within the scope of the patentee's monopoly, yet evade the Patent Act's written-description requirement. After all, if a patent's claims sets out its metes and bounds and precisely establishes the scope of the patentee's monopoly, what can it possibly mean to say that a patent covers something it does not claim?

To defend this novel and jarring distinction between a patent's claims and its coverage, the Federal Circuit noted that "'[c]laims are not construed "to cover" or "not to cover" the accused [product],'" and instead "'[i]t is

only *after* the claims have been *construed without reference to the accused device* that the claims, as so construed, are applied to the accused device to determine infringement.'" Pet. App. 16a (second alteration in original) (quoting *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (en banc)). But that principle, true as it may be, is irrelevant to the question at hand. The '659 patent was not construed here with reference to petitioners' generic drug; it was construed to cover complexes (manufactured by *anyone*) through its use of the word "combination." *See id.* at 88a-91a. It therefore claims complexes. Wordplay aside, this conclusion is unavoidable, and district courts are certain to struggle to apply the Federal Circuit's analysis going forward.

The court of appeals offered a slightly different, but still inscrutable, analysis with respect to enablement. The court held that the '659 patent could not be invalid for failure to enable valsartan-sacubitril complexes because the patent "does not expressly claim complexes." Pet. App. 19a; *see id.* at 17a-19a. Here, the court seemed to see as critical that the '659 patent does not *explicitly* mention complexes; if it had, it would likely be unavoidable that the enablement requirement is not met. But why should the failure to *expressly* claim complexes affect the enablement requirement given the premise that the patent *does*, in fact, claim complexes? Generally, "the specification must enable the full scope of the invention as defined by its claims." *Amgen*, 598 U.S. at 610. In *Amgen*, the claims were construed to cover the entirety of a species, so this Court held that because undue experimentation was necessary to find the elements of

that species, "Amgen ha[d] failed to enable all that it ha[d] claimed." *Id.* at 613. It is hard to see why an equivalent analysis should not hold here—if the '659 patent is construed to claim complexes, but it does not enable complexes, then how has Novartis "enable[d] all that it has claimed"? *Id.*

II. THE UNCERTAINTY AS TO THE SCOPE OF PHARMACEUTICAL PATENTS MAKES IT DIFFICULT FOR GENERIC-PHARMACEUTICAL MANUFACTURERS TO DO BUSINESS.

The state of the Federal Circuit's case law on the question presented is untenable. Generic pharmaceuticals play a critical role in providing American patients with access to life-saving medications. But the uncertainty in the patent law governing pharmaceuticals makes it difficult for the companies that manufacture those generic drugs to operate.

Generic medicines play an enormously important role in the U.S. healthcare system. Generic manufacturers like Sigmapharm develop and bring to market high-quality generic drugs that comprise the vast majority of prescriptions while costing just a fraction of the price. In 2024, for instance, generics accounted for approximately 90% of all prescriptions filled in the United States while accounting for just 12% of all prescription-drug spending.[5] The availability of generic and

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[5] Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 2 (Sept. 2025), https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf.

biosimilar medicines saved patients and taxpayers $467 billion in 2024 alone, and a total of $3.4 trillion over the last ten years.[6] In an era where inflation is a major concern to U.S. consumers, generic medications are continually subject to "severe deflation."[7] And the availability of generic medications is strongly associated with positive, cost-effective health outcomes for patients.[8] To put it simply, when generic drugs do not make it to market, patients suffer because they simply cannot afford high-priced, branded versions of the life-saving medicines they need.

The viability of the pharmaceutical-drug industry turns on a delicate dance around brand manufacturers' patent rights. Generic manufacturers need to understand the precise scope of pharmaceutical patents so that they can design around them or utilize the Hatch-Waxman "skinny label" process to carve out patented uses of compounds that are themselves no longer patented. *See Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405-07 (2012). Designing around a patent will often involve changes in the manufacturing processes or the delivery mechanisms for the drug—

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[6] *Id.* at 10.

[7] *Id.* at 13.

[8] *See generally* Becky A. Briesacher et al., *Medication Adherence and the Use of Generic Drug Therapies*, 15 Am. J. Managed Care 450 (2009); Niteesh K. Choudhry et al., *Improving Adherence to Therapy and Clinical Outcomes While Containing Costs: Opportunities from the Greater Use of Generic Medications; Best Practice Advice from the Clinical Guidelines Committee of the American College of Physicians*, Annals Internal Med. (Nov. 24, 2015), https://doi.org/10.7326/M14-2427.

perhaps, as here, utilizing some after-arising technology. Analyzing brand manufacturers' patents and developing these non-infringing manufacturing processes involves enormous investments, and generic manufacturers will not make these investments if they cannot have reasonable certainty of success in an infringement lawsuit. The decision below (like the Federal Circuit's other decisions sporadically relaxing Section 112(a)'s enablement and written-description requirements) throws a wrench in this system.

For starters, the court of appeals' approach in this case allows brand manufacturers to unduly expand the scope of their monopolies, claiming formulations and processes that were not disclosed or enabled in their patent specifications. This makes it extraordinarily difficult for generic manufacturers to design around patents and locks generics out of the market for decades. The Federal Circuit's uneven approach to the question presented thus fundamentally alters the competitive landscape of the pharmaceutical industry, systematically disadvantaging generic manufacturers and providing a windfall for brand manufacturers. The decision below provides a dangerous roadmap for brand manufacturers bringing infringement suits, as it seemingly allows—against all patent-law principles previously known—for certain subject matter to be claimed by a patent without being described or enabled by the patent's specification. Indeed, even when generic manufacturers *themselves* develop new technology to improve the manufacture or delivery of a drug, the brand manufacturer can argue that this new process is within the scope of its valid claims even though it could not possibly have described

or enabled the new technique. Generic manufacturers are left in an impossible position.

While these pernicious effects could stifle innovation in any industry, the need for predictability in the context of generic pharmaceuticals makes the state of the Federal Circuit's precedent particularly problematic. Generic manufacturers cannot make sound investment decisions without predictability as to the scope and validity of brand manufacturers' patents. Developing a generic drug requires years of investment before any revenue is generated—investment carefully tailored to complex assessments of whether brand manufacturers' patents can be invalidated or avoided. The unpredictability of how after-arising technology will be treated in a court's Section 112(a) analysis makes these assessments inherently unreliable.

The cumulative effect of these problems is to significantly increase the barriers to generic medications entering the market, reduce competition, and increase prices. Generic manufacturers faced with the unpredictable legal landscape must either accept unmanageably high litigation risks or avoid markets entirely even where there is room for beneficial competition. And smaller generic manufacturers with limited resources may be particularly disadvantaged—these companies have less capacity to accept litigation risk and are thus more likely to avoid developing drugs where the existing patents have unpredictable scope.

In the end, it is not only patients who lose when a generic manufacturer cannot bring a new generic drug to market—it is the American taxpayer who loses as well. Programs related to health care represent the largest

category of federal spending—nearly $2 trillion in fiscal year 2024, and over a quarter of all federal expenditures for that year.[9] A significant portion of that money goes toward prescription drugs in the Medicare and Medicaid programs.[10] Higher barriers to market entry for generic manufacturers means higher drug prices—leading inevitably to higher taxes, lower quality of care, or both.

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[9] *See* Juliette Cubanski et al., *What Does the Federal Government Spend on Health Care?*, KFF (Feb. 24, 2025), https://www.kff.org/medicaid/what-does-the-federal-government-spend-on-health-care.

[10] In 2023, the federal government spent nearly $200 billion on prescription drugs, and that number has grown significantly each recent year. *See Medicare and Medicaid Expenditures: Prescription Drugs; 2024 Report*, Rios Partners Health of Health Rpt., https://www.healthofhealth.org/medicare-and-medicare-expenditures-prescription-drugs (last visited Sept. 28, 2025); *see also NHE Fact Sheet*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet (last updated June 24, 2025).

CONCLUSION

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

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OCTOBER 2025