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 AMICUS CURIAE PUBLIC INTEREST PATENT LAW INSTITUTE IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Constitutional Provision

Statutes

Other Authorities

INTEREST OF THE AMICUS CURIAE[1]

Amicus Public Interest Patent Law Institute ("PIPLI") is a nonprofit, nonpartisan organization dedicated to ensuring the patent system promotes innovation and access for the public's benefit. PIPLI conducts and publishes research, provides pro bono assistance to people seeking to create and access technology, and shares the perspective of innovators and consumers with policymakers.

Many Americans contribute to and depend on advances in science and technology but do not participate directly in the patent system. These constituencies include consumers, patients, research scientists, small business owners, farmers, and health care providers, all of whom are not parties to this case but whose lives and livelihoods are at stake.

If patents confer exclusive rights that go beyond what they teach, patent owners will reap more rewards, but everyone else will have less freedom to innovate, compete, and thrive. Amicus has a strong interest in this case because its outcome will affect the creative freedom, economic opportunity, and health care available to countless creators, entrepreneurs, and consumers.

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[1] Counsel of record for all parties received notice at least 10 days prior to the due date of amicus curiae's intention to file this brief. Amicus states that no counsel for any party authored this brief in whole or in part. No entity or person, aside from amicus curiae, their members, or their counsel made any monetary contribution intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The Patent Act reflects a carefully crafted bargain between patent holders and the public. In exchange for describing the full scope of the claimed invention, a patent owner obtains the right to exclude others from practicing the claimed invention. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-1 (1989). This deal is fair only if there is symmetry between both sides of the bargain: the right to exclude must be commensurate in scope with what has been described in the patent. If a patent excludes the public from doing what it does not teach, the public pays too high a price while the patent owner receives a windfall. This Court has repeatedly recognized "the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 584 U.S. 325, 336-37 (2018) (quotes and citations omitted).

The question presented goes to the heart of the Patent Act's bargain between patent holders and the public when it asks "Whether, in a patent-infringement suit, a court may consider after-arising technology to hold that the patent is invalid under § 112(a) of the Patent Act." Those disclosure obligations, which include both the written description and enablement requirements, play a critical role in protecting the public's interest because exclusive rights can impede rather than achieve the patent system's constitutional mandate to promote scientific progress. Striking an appropriate balance between a patent owner's exclusive rights and the public's freedom to innovate, compete, and access

knowledge is critical to the patent system's ability to function effectively.

The written description and enablement requirements are essential to maintaining an appropriate balance because they help ensure that a patent provides exclusive rights only to the invention that is claimed and publicly disclosed. The longstanding written description and enablement disclosure obligations reflect this foundational principle of the patent system: patent owners must describe and enable the same invention to which they claim exclusive rights. When this balance falters, the public pays the price. That price is especially onerous in the context of pharmaceutical patents: too much exclusivity prevents the development of safe and effective treatments as well as the reductions in price and increases in access that competition allows.

The Federal Circuit's decision upsets the balance between a patent owner's exclusive rights and disclosure obligations because it allows claims to have one scope for infringement (i.e. claims may cover after-arising technology) and another scope for invalidity (i.e. after-arising technology may not be considered). The result is that, under the Federal Circuit's decision, patent owners may exclude others from making, using, and developing technology that the patent owner never invented or disclosed to the public. This throttles competition and discourages future innovation to the detriment of the public's interest. Nothing in the Patent Act or this Court's precedents supports, let alone requires, a result that treats after-arising technology different for invalidity than it does for infringement.

ARGUMENT

I. The Patent "Quid Pro Quo" Is A Foundational Principle That Serves The Public Interest

The Constitution, the Patent Act, and this Court's precedents require a fair bargain: an inventor receives limited exclusive rights in exchange for teaching the public how to make and use the invention.

The Constitution provides that Congress shall have the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries…." U.S. Const. art. I, § 8, cl. 8. The Patent Act fulfills this constitutional mandate by requiring patentees to describe how to make and use the full scope of the claimed invention. As this Court has recognized, the patent system promotes the process of science by inducing "disclosure of advances in knowledge which will be beneficial to society…." *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 331 (1945) (citation omitted).

The Patent Act's disclosure obligation is codified in Section 112, which requires a patent specification to contain a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use *the same*." 35 U.S.C. § 112(a) (emphasis added). The statute is clear. The disclosure must be commensurate in scope with what the patentee claims as the invention.

The term "invention" has a precise meaning here. The statute requires a patent to include claims, and these claims define the invention. 35 U.S.C. § 112(b) (requiring "one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor . . . regards as the invention."); *see also Universal Oil Prod. Co. v. Globe Oil & Ref. Co.,* 322 U.S. 471, 484 (1944) ("The claim is the measure of the grant.") (citation omitted).

The disclosure obligations in the Patent Act play a critical role in guaranteeing the public's access to knowledge during and after a patent's term. As this Court has explained, one of the specification's objectives "is to make known the manner of constructing the [invention] . . . so as to enable artisans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent." *Evans v. Eaton*, 20 U.S. 356, 433–34 (1822). If a patent specification discloses only part of the claimed invention, the public receives only part of the benefit to which it is entitled.

While the Patent Act requires claims, it gives a patentee substantial freedom in drafting them. The patentee's choice of claim terminology defines the invention to which it holds exclusive rights as well as the invention that must be described and enabled so that others can make and use it. When a patentee chooses to define an invention in broad terms and claim a broad right to exclude, the invention that must be described and enabled is equally expansive.

The need to balance the right to exclude with the scope of the patent's disclosure has been part of this Court's jurisprudence for almost 150 years. In *White v. Dunbar*, the Court ruled that a patentee cannot

twist its claims to cover new inventions that were not part of the original patent application. 119 U.S. 47, 51-52 (1886). The patent claim was directed to a method for preserving shrimp by placing them in a bag made of "textile fabric" before sealing them in a metal can and boiling. *Id.* at 47. The purpose was to prevent discoloration from the shrimp's contact with the metal. *Id.* Subsequently, the patentees sought a reissue of their patent with a much broader claim that would cover a competitor's "improvements and inventions, made after the issue of [the patent]," specifically, using coatings of asphaltum cement and paraffine on the inside of a can, rather than "textile fabric." *Id.* at 48, 52. The Court invalidated the reissued patent as an unlawful attempt to cover an invention that the inventor did not create, cautioning that a patent claim cannot be treated like a "nose of wax":

> Some persons seem to suppose that a claim in a patent is like a nose of wax which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express. The context may, undoubtedly, be resorted to, and often is resorted to, for the purpose of better understanding the meaning of the claim; but not for the purpose of changing it, and making it different from what it is. The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an

> evasion of the law, to construe it in a manner different from the plain import of its terms.

Id. at 51–52.

The Court's "nose of wax" metaphor emphasizes the importance of applying a consistent scope of the claims that does not vary to suit the patent owner's interests. For this reason, "[i]t is axiomatic that claims are construed the same way for both invalidity and infringement." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (citation omitted).

Yet, this is precisely the inconsistency that is supported – even encouraged – by the Federal Circuit's decision in *In re: Entresto*, 125 F.4th 1090 (Fed. Cir. 2025). The court applied a broad construction of the claims for purposes of finding infringement and concluded that the claims cover after-arising technology. App. 14a. But when it came to assessing validity, the court applied a narrow construction and concluded that the patent did not need to describe or enable that very same after-arising technology that the claims purportedly cover. App. 16a-17a. That inconsistency upsets the carefully balanced quid pro quo upon which the patent system is grounded.

The U.S. patent system is premised on a patent owner receiving something (exclusivity) in exchange for giving something (disclosure of new and useful technology). The scope of the government-granted exclusivity needs to be coextensive with the scope of the patentee's disclosure, or else the bargain between the patentee and the public becomes asymmetrical –

the public gives up far more than it gets in return. As this Court noted in *Amgen v. Sanofi*, "if an inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain." 598 U.S. 594, 616 (2023).

II. Allowing Patents To Monopolize More Than They Disclose Stifles Innovation And Harms The Public.

A. Patents That Claim But Do Not Disclose After-Arising Technology Block Follow-On Innovation

This Court has long recognized the threat to innovation posed by broad claims that cover subject matter that is not described or enabled in the specification. In *Holland Furniture Co.* v. *Perkins Glue Co.*, this Court invalidated broad claims that extended beyond the scope enabled by the disclosure, warning that "[a] claim so broad, if allowed, would operate to enable the inventor, who has discovered that a defined type of starch answers the required purpose, to exclude others from all other types of starch, and so foreclose efforts to discover other and better types." 277 U.S. 245, 257 (1928).

The *Entresto* decision further crystallizes the importance of preventing overreach. The claims of Novartis's patent have been enforced as covering all combinations of valsartan and sacubitril, even after-arising complexes. App. 7a-9a. If Novartis's broad claims are allowed to stand without requiring a commensurately broad description of the claimed invention in the specification, then the fears expressed by this Court in *Holland* are

realized. The claims "would operate to enable [Novartis] to exclude others from all other [combinations of valsartan and sacubitril], and so foreclose efforts to discover other and better types." *Id*. The existence of novel but undisclosed combinations is not theoretical as Novartis separately patented an allegedly novel complex of valsartan and sacubitril. App. 83a.

Innovators will not spend the time and money to develop technology if they are precluded from commercializing that technology by overbroad patents, i.e. patents that are broader than their disclosures. Patents have the potential to encourage innovation because they reward the discovery of new technology with exclusivity that allows the patentee to reap the commercial benefits of that innovation. However, patents also have the power to *discourage* innovation by blocking would-be innovators from commercializing their inventions.

The key to balancing the simultaneous encouraging and discouraging effects of patents is to enforce the quid pro quo of the patent system and require patent claims to be supported by a coextensive patent disclosure. *The Incandescent Lamp Patent*, 159 U.S. 465, 475-76 (1895). Patents that claim subject matter that the patentee did not invent reward the first inventor for claiming a broad but undefined concept and punishes subsequent innovators who create technology that the first inventor never even contemplated. Allowing patents to cover after-arising technology, while refusing to consider that same after-arising technology in the invalidity analysis, discourages

the very creation of such technology, to the detriment of the public-at-large.

B. Legal Uncertainty Discourages Innovation And Investments In Technology

The conflicting lines of Federal Circuit case law regarding the treatment of after-arising technology create doctrinal chaos that makes it difficult for innovators and investors to know what technology is available to use and improve upon. As this Court and other tribunals have observed, especially with respect to patents and patent law, "clarity is essential to promote progress.' *Bilski v. Kappos*, 561 U.S. 593, 655 (2010) (Stevens, J., concurring) (citation omitted); 561 U.S. at 613 (Stevens, J., concurring) ("In the area of patents, it is especially important that the law remain stable and clear."). Indeed, Congress created the Federal Circuit to address a serious problem: the lack of uniformity and consistency in patent law. As Judge Newman noted on the 25th Anniversary of the Federal Circuit, a lack of consistency is harmful to innovation:

> Review of the Federal Circuit, after twenty-five years, starts with a reminder of the economic recession and industrial stagnation that led to the formation of this court. Its charge, the expectation and hope of its creators, was that uniform national law, administered by judges who understand the law and its purposes, would help to revitalize

> industrial innovation through a strengthened economic incentive.[2]

Yet, the Federal Circuit has been remarkably *inconsistent* in how it treats after-arising technology. As explained in the Petition, there are no fewer than four divergent approaches to how the Federal Circuit has treated after-arising technology. Petition, at 15-22. This lack of consistency and certainty places a fundamental aspect of the U.S. patent system at risk. Patent owners, alleged infringers, and innovators are currently unable to assess risks, evaluate investments, and make decisions based on a useful, understandable and consistently applied test regarding the treatment of after-arising technology. Such confusion threatens both the economy-boosting effects of maintaining a functional patent system and faith in the judiciary to produce reliable, consistent outcomes.

It is important for the Supreme Court to address the role of after-arising technology because courts need consistent precedent to provide reliable, consistent judgments and patent owners, alleged infringers and innovators need clarity regarding the scope and validity of patents that claim after-arising technology. Unpredictability in the patent system is harmful to the economy, the patent system as a whole, and to inventors, business entities, investors, potential infringers, and other interested parties who need to understand what can and cannot be patented and what can and cannot be commercialized without threat of infringement. This uncertainty puts a

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[2] Hon. Pauline Newman, After Twenty-Five Years, 17 FED. CIR. B.J. 123, 123 (2007).

significant strain on the incentives for innovation that the Patent Act attempts to promote.

C. Enforcing Patents Against After-Arising Innovation Without A Corresponding Disclosure In The Patent Harms Public Access To That Innovation

If Novartis prevails, the *Entresto* case will not be the first instance of public access to innovation being reduced by enforcement of a patent against after-arising innovation. Those harms date back to the origin of the Federal Circuit's exception to the disclosure rules for after-arising technology – *In re Hogan*, 559 F.2d 595 (CCPA 1977). *Entresto*, 125 F.4th at 1097 (citing *Hogan*). In *Hogan*, the Federal Circuit's predecessor, the Court of Customs and Patent Appeals,[3] held patent claims that covered all solid polymers of 4-methyl-1-pentene, including those "not having been . . . in existence" at the time of the patent application, met the disclosure requirements of § 112. *Id.* at 605-07. Hogan then obtained allowance of the patent along with a second, related patent for polypropylene claiming priority to the same parent patent application, U.S. Patent No. 4,376,851 ("'851 patent").

> Once the patents were allowed, Phillips Petroleum Company promptly asserted the '851 patent against its competitors in the market for

[3] Shortly after its inception in 1982, the Federal Circuit "deem[ed] it fitting, necessary, and proper to adopt an established body of law as precedent," specifically, the "body of law represented by the holdings of the Court of Claims and the Court of Customs and Patent Appeals . . . ." *South Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982).

polypropylene, a widely-used plastic. *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1249 (1989); Hisham A. Maddah, *Polypropylene as a Promising Plastic: a Review*, Am. Journal of Polymer Science 2016, 6(1):1-11 at 2 ("PP is the most widely used thermoplastic . . . ."). The Federal Circuit rejected the competitors' challenge to the sufficiency of the parent application, reasoning that their "misdirected approach here is the same as that improperly relied upon by the PTO in *Hogan*" and that the claim's coverage of after-arising technology does not impact compliance with the disclosure requirement of section 112. *Id.* at 1250-51. As a result, the competitors faced a $300 million damages judgment. Charles W. Adams, *Blocking Patents and the Scope of Claims* 54 (2008), *available at* https://web.stanford.edu/dept/law/ipsc/pdf/adams-charles.pdf. The public also lost out – the polypropylene produced by the process described in the Hogan patents was "brittle and has never been a successful commercial product." *Id.*; Frank M. McMillan, *The Chain Straighteners* 70 (1st ed. 1979) ("[I]n Hogan's words, the project 'had to fight its way from a beginning that could be described as a few grammes of a brittle plastic made in a hopelessly inefficient process to its present status as the leading process for the production of linear polyethylene."). The '851 patent compromised the ability of competitors to sell the public better catalysts, developed by others over years of work.

In another example a decade later, Amgen alleged patent infringement against a competitor that sought regulatory approval to sell HMR4396, a form of recombinant erythropoietin ("EPO")

useful for treating anemia. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 98 (D. Mass. 2001). The accused infringer made HMR4396 by artificially activating the human EPO gene "where it naturally resides" and thus made the product using *endo*genous DNA. *Id.* at 102. By contrast, Amgen's patents described methods of using *exo*genous DNA to make EPO by inserting human DNA into a hamster cell via a vector. *Id.* "Experts called by both parties agreed . . . that the Amgen specification did not explicitly show any examples of human EPO production whereby the endogenous EPO DNA was expressed" – the use of endogenous DNA was after-arising innovation. *Id.* at 150 n.50; *Kirin Amgen v. Hoeschst Marion Roussel Ltd.*, [2004] UKHL 46, [2005] 1 All ER 667, [8]-[11] (appeal taken from Eng.) (summarizing differences between the patent's exogenous DNA and competitor's endogenous DNA methods for making EPO).

The District of Massachusetts nonetheless rejected the accused infringer's challenge to the sufficiency of Amgen's patents' disclosure, noting that "the written description requirement does not demand that the specification describe technological developments in the way in which the claimed composition is made that may arise after the patent application is filed." *Id.* at 150 (citing *U.S. Steel*, 865 F.2d at 1251; *In re Koller*, 613 F.2d 819, 824-25 (Fed. Cir. 1980); *Hogan*, 559 F.2d at 606, *analysis incorporated for the '349 patent at id.* at 153-54 & n.51. The accused infringer appealed the written description holding with respect to one of Amgen's patents (U.S. Patent No. 5,756,349), but the Federal Circuit summarily affirmed, finding

simply that "we see no error" in the district court's holdings. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1317 (Fed. Cir. 2006), *questioned on other grounds*, 469 F.3d 1039 (Fed. Cir. 2006).

Notably, the British courts reached the opposite conclusion when considering a European equivalent that Amgen sought to enforce against the same after-arising endogenous EPO product in the United Kingdom. *Kirin Amgen*, [2004] UKHL 46, [2005] 1 All ER 667. The House of Lords held that the accused infringer "did not infringe any of the claims" of the European patent, reasoning that a "man skilled in the art would not have understood the claim as sufficiently general to include gene activation. He would have understood it to be limited to the expression of an exogenous DNA sequence which coded for EPO." *Id.* at [80]-[85]. With respect to the sufficiency of the disclosure, the House of Lords stated, "Assuming the claims can be read, as the judge thought, to include any way of making EPO by recombinant DNA technology, the specification does not disclose a way of making it in sufficiently general terms to include the [accused infringer's] process." *Id.* at [114].

While HMR4396 was subsequently approved and launched for use in Europe "at a 30% discount to rival products,"[4] its makers never brought it to the U.S. market due to Amgen's patents. Andrew Pollack, *British Company to Buy U.S. Maker of*

[4] *Shire launches Dynepo in Germany*, Pharmaceutical Business Review (Mar. 16, 2007), *available at* https://www.pharmaceutical-business-review.com/news/434bfshire_launches_dynepo_in_ge#start.

Anemia Treatment, *NY Times* (Apr. 22, 2005), *available at* https://www.nytimes.com/2005/04/-22/business/worldbusiness/british-company-to-buy-us-maker-of-anemia-treatment.html ("TKT has not been able to sell Dynepo in the United States because of Amgen's patents."); thepharmaletter, *No launch yet for TKT's Dynepo, says Aventis* (Apr. 14, 2002), *available at* https://www.thepharmaletter.com/no-launch-yet-for-tkt-s-dynepo-says-aventis ("Aventis has confirmed that it will hold off on launching its new erythropoietin drug Dynepo (epoetin delta), developed in collaboration with Trankaryotic Therapies, until ongoing litigation with Amgen and its Japanese affiliate Kirin-Amgen is resolved."). The endogenous DNA technology used in HMR4396 avoided the production of a sialic acid known as Neu5Gc found in CHO-produced EPO and linked to "[i]mmunogenicity and increased clearance" and suspected to "contribute to EPO-resistence . . . ." Zahra Shahrokh et al., *Erythropoeitin Produced in a Human Cell Line (Dynepo) Has Significant Differences in Glycosylation Compared with Erythropoetins Produced in CHO Cell Lines*, 8(1) MOLECULAR PHARMACEUTICS 286, 294-95 (Dec. 7, 2010). But, thanks in part to the Federal Circuit allowing Amgen to enforce its patents against after-arising technology, the U.S. public never got to explore these potential advantages.

D. Patents That Extend Beyond Their Disclosure To Cover Undisclosed After-Arising Technology Increase Drug Costs

The impact of the Federal Circuit's approach to after-arising technology in *Entresto* will continue to harm the public in the context of drug patents. Americans pay more for prescription drugs than our counterparts in the rest of the world. One recent study of 33 countries found that U.S. prices across all drugs (including brands and generics) were nearly three times as high as prices in other countries. Andrew W. Mulcahy et al., *Int'l Prescription Drug Price Comparisons: Estimates Using 2022 Data*, HHS (Feb. 2024), available at https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf. For every dollar paid in other countries for drugs, Americans paid $2.78. *Id*. The price gap is even larger for brand-name drugs, for which Americans pay 422% more than all other comparison countries. *Id*.

One of the factors driving up U.S. drug prices is the amount of time brand-name drugs are protected from competition with generic or other brand-name drugs. A 2024 report from the Congressional Research Service noted that "some studies suggest that IP rights are among the most important factors driving high drug prices." Kevin J. Hickey & Erin H. Ward, *The Role of Patents and Regulatory Exclusivities in Drug Pricing*, *Congressional Research Service* (updated Jan. 30, 2024) at 2 (citations omitted). That report noted the various patent strategies available to, and frequently employed by, brand-name drug companies to stave off competition, including "evergreening," in which drug innovators add new patents to their portfolio as old patents expire, and patent thickets, in which drug innovators amass a

large number of patents relating to a single product. *Id.* at 6.

The Federal Circuit's rulings that after-arising technology can be held to infringe a patent gives drug innovators yet another powerful weapon to delay competition and consumer access to affordable medicines. The Federal Circuit's decision allows a drug maker to enforce its patent against a broad swath of subject matter, including after-arising technology that the maker never invented.

There is nothing inherently wrong with a drug innovator obtaining broad patent claims so long as those claims are supported by a coextensive disclosure. Innovators should be incentivized and rewarded with exclusivity for making pioneering discoveries. However, that exclusivity must fit within the carefully crafted quid pro quo of the patent system where the scope of the right to exclude must be commensurate in scope with what the patent owner disclosed and enabled in the patent specification. When this balance is upset, unsupported patents become a mechanism for strategically delaying the entry of generic competition and unnecessarily extending high drug prices for consumers.

Enforcing the quid pro quo of the patent system will not cause pharmaceutical companies any harm. Pharmaceutical companies have large portfolios of patents to protect their innovations and included within those portfolios are patents that are narrowly tailored to the actual innovations made by the pharmaceutical companies. Overbroad patents are not necessary to provide these

protections. But there is every reason to expect that leaving intact the current dichotomy in which after-arising technology is treated differently for infringement than it is for validity will continue to harm innovation and extend the period in which the U.S. public endures high drug prices.

CONCLUSION

For the foregoing reasons, we respectfully urge the Court to grant the petition.

Respectfully submitted,

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