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 THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines, bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Its members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. Its core mission is to improve the lives of patients by providing timely access to these safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 20% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

AAM and its members have an interest in bringing attention to patent infringement judgments like this one that bar prompt patient access to less-expensive generic versions of life-saving medicines in contravention of the patent laws and public policy. AAM and its members require clear notice of the scope of patent coverage so they can make business decisions and investments in new life-saving medicines. They have an interest in ensuring that, as the district court held here, patent holders cannot use old, overbroad patents to enjoin sales of

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[1] Pursuant to Rule 37.2, this brief is being filed more than 10 days before the deadline, so that its filing constitutes the notice required to the parties. Pursuant to Rule 37.6, this brief was not authored in whole or in part by counsel for any party, and no person or entity other than *amicus*, its members, or its counsel made a monetary contribution to fund the preparation or submission of this brief.

pharmaceutical technologies that had not been invented at the time they were filed, and which the patents do not describe or enable.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case involves three important issues for the Court's review: (1) the written description requirement of Section 112 of the Patent Act and its application to claims that cover technology that was not known or possessed by the inventor at the time of patent filing; (2) the proper role of appellate courts in reviewing district court decisions, including whether the Federal Circuit should *sua sponte* change claim construction decisions that were not appealed; and (3) the notice function of patents and their role in fostering competition and innovation.

Here, the district court, at Novartis's urging, broadly construed the term "combination" in the claims of U.S. Patent No. 8,101,659 ("the '659 patent") to cover Novartis's drug product ENTRESTO, which contains a valsartan-sacubitril "complex," as well as petitioner MSN's generic version of the same. After this construction, MSN stipulated to infringement of those claims and focused on proving patent invalidity. Because the complex was not described in the specification—and could not have been described since it was unknown even to Novartis at the time of filing—the district court found that the claims were invalid under Section 112 for lack of written description. The district court properly held that the claims covered a genus of drug combinations, including but not limited to the complex at issue, but did not describe the full scope of that genus.

On appeal, however, a panel of the United States Court of Appeals for the Federal Circuit applied a narrower construction that excluded such complexes as a matter of law, even though *no party had appealed the district court's claim construction*. On that shaky foundation, the Federal Circuit reversed the district court's judgment that the claims were invalid for lack of adequate written description.

Even more worrying, the Federal Circuit appears to have fashioned this narrower construction after applying case law that, in the panel's view, requires that claims be interpreted to "carve out" subject matter unknown to the field at the time of filing, *but only for purposes of adjudicating invalidity under Section 112*. This decision allowed Novartis to claim "after-arising technology" (*i.e.*, a drug complex) without having to describe or enable it. The Federal Circuit then denied requests for rehearing and rehearing *en banc*.

It is settled law that a patent claim is not "like a nose of wax." It cannot be twisted one way to find infringement and then another way to avoid invalidity. *See, e.g., Amazon.com, Inc. v. Barnesandnoble.com, Inc.,* 239 F.3d 1343, 1351 (Fed. Cir. 2001); *White v. Dunbar*, 119 U.S. 47, 51 (1886). The purpose of this law is to prevent a patentee from using over-broad claims to control the making, using, selling or offering for sale of subject matter beyond what it actually invented and disclosed to the public in its patent application, as Novartis has used its claims here. There is no exception to this principle for "after-arising technology," and the public hazards of this newly created loophole are on display here.

When Novartis filed the '659 patent directed to combinations of valsartan and sacubitril, it had not discovered, invented, or described the "complex" embodied in ENTRESTO or its generic equivalents. That is not disputed. After the patent granted, however, Novartis represented to the U.S. Food & Drug Administration ("FDA") that the '659 patent claims cover ENTRESTO, obtaining a patent term extension ("PTE") and pediatric exclusivity for the patent and listing it in the Orange Book. Novartis then used the Orange Book status of the '659 patent to delay generic competition, arguing in litigation that although the '659 patent claims cover the complexes embodied in generic equivalents, Novartis was not required to disclose or enable that technology in the '659 patent. But Novartis cannot have it both ways—either the '659 patent claims cover ENTRESTO and must satisfy the dictates of Section 112 for that embodiment, or they do not, and Novartis cannot use them to block generic equivalents of ENTRESTO.

The pharmaceutical industry is watching this case closely. If Novartis succeeds in using this improper after-arising technology loophole, others will see a new strategy they can employ to fashion over-broad claims to delay generic competition and yet evade the requirements of Section 112 that protect the public's interests in ensuring that patents do not let inventors control more than they invented. Considering the importance of these issues to AAM's mission, AAM submits this brief as *amicus curiae* in support of granting MSN's petition for certiorari.

ARGUMENT

Certiorari is warranted here. As explained in MSN's petition for *certiorari*, the Federal Circuit's decision conflicts with its own precedents and the precedents of this Court regarding the requirements for patentability under Section 112 of the Patent Act. The Federal Circuit's decision allowed Novartis to interpret its claims broadly to block generic competitors' products, but then narrowly to avoid invalidity under Section 112, in contravention of settled law that requires claims to be construed the same way for both infringement and validity. AAM wishes to call this Court's attention to at least the following three bases for granting *certiorari*: (1) the Federal Circuit applied an incorrect legal standard in evaluating written description; (2) the Federal Circuit should not have *sua sponte* changed a claim construction that no party appealed; and (3) the decision undermines the notice function of patents and hinders competition in contravention of the public policies embedded in the Patent Act.

I. The Panel's Reversal of the District Court's Holding that the Claims of the '659 Patent Lack Written Description Support Was Founded on the Wrong Legal Test and Is Contrary to Supreme Court and Federal Circuit Precedent.

It is undisputed that Novartis had not invented valsartan-sacubitril complexes at the time of filing the '659 patent and had not described or enabled them. Indeed, Novartis filed separate patents to such complexes several years later. *See In re Entresto*, 125 F.4th 1090, 1099 (Fed. Cir. 2025). Once the '659

patent claims were construed to cover such complexes, it logically followed that the claims were invalid, as the district court held.

Indeed, in adopting the broad construction urged by Novartis, the district court warned that, because Novartis had admitted that the patent did not disclose the complex, "at the very least, there [is] a non-frivolous issue of written description and/or lack of enablement as this case proceeds on Novartis's preferred construction." *See In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-MD-2930-LPS, 2021 WL 2856683, at *4 (D. Del. July 8, 2021). With no triable issue of infringement remaining after this construction became law of the case, MSN stipulated to infringement but pressed for a judgment of invalidity for lack of written description and enablement of the complex. MSN prevailed on the question of written description.

The district court found that, because a formulation containing the valsartan-sacubitril complex was unknown at the time of filing and the structural features disclosed in the patent specification could not help a skilled artisan visualize such a complex, the claims were invalid for failing to meet the written description requirements of Section 112. *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. CV 19-1979-RGA, 2023 WL 4405464, at *22 (D. Del. July 7, 2023). The district court's decision correctly treated Novartis's claims as "genus" claims, which covered the full scope of "combinations," including "complexes."

For genus claims, "merely drawing a fence around a perceived genus" and "leaving it to others to

explore the unknown contours of the claimed genus" is inadequate to show written support. *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014). Rather, when a patent claims a genus, its specification must disclose "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 Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (*en banc*) (internal citations and quotes omitted); *see also, e.g., Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011), *cert. denied*, 565 U.S. 1196 (2012); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F. 4th 1330, 1335 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (Mem) (2022). Here, the district court followed this precedent when it ruled that the asserted claims lack written support. *In re Entresto*, No. CV 19-1979-RGA, 2023 WL 4405464 at *21 (citing *Ariad*).

The Federal Circuit, however, in violation of its own precedent, treated the asserted claims as species claims that cover only combinations and not complexes. *In re Entresto*, 125 F.4th at 1100. The panel held that the patent's disclosure showed that "the inventors had possession of *a pharmaceutical composition* comprising valsartan and sacubitril administered 'in combination'" and thus "the claims are supported by an adequate written description." *Id.* at 1098 (emphasis added). But saying that the inventors possessed "a" combination does not mean they possessed all of the "combinations" covered by the full scope of these genus claims. *Id.* Under this

Court's precedent in *Amgen v. Sanofi* (which addresses enablement), if Novartis wanted to claim for itself "the entire genus of" combinations (just as Amgen sought to claim "the entire genus" of antibodies) it needed to provide Section 112 support. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 602 (2023). If it could not, Novartis had the reasonable and fair option to seek more limited claims to cover only what it had actually invented. As this Court explained in *Amgen*, "Section 112 of the Patent Act reflects Congress's judgment that if an inventor claims a lot, but enables only a little, the public does not receive the benefit of its bargain." *Id.* at 616. That same logic applies to written description—if an inventor claims a lot, but describes only a little, the public does not receive the benefit of its bargain.

The Federal Circuit also should not have found written description support merely because the specification literally referred to "combinations" of valsartan and sacubitril. *See In re Entresto*, 125 F.4th at 1098. The Federal Circuit has repeatedly rejected the argument that "the written description requirement . . . is necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification." *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002); *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs Inc.*, 923 F.3d 1368, 1380 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 902 (Mem) (2020).

The Federal Circuit's approach also threatens to erode the written description test set forth in *Ariad* and *Amgen* that protects the public against patent claims that seek to capture more than what the inventor contributed to the field. The Court should

grant *certiorari* to clarify that the lower court, and not the Federal Circuit, applied the correct standard for the genus claims at issue here.

II. The Federal Circuit Violated Appellate Procedure by *Sua Sponte* Changing a Claim Construction that No Party Appealed and After the Parties Stipulated Regarding Infringement.

While claim construction is an issue of law that the Federal Circuit approaches *de novo*, the Federal Circuit has cautioned against changing a district court's claim construction where, as here, the parties stipulated to infringement based on that construction and no party appealed it, specifically saying "that is no way to conduct an appeal." *Idenix Pharms. LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1156 n.3 (Fed. Cir. 2019). Similarly, Justices of this Court have long recognized that appellate courts should only address the matters before them. *See, e.g.*, *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.,* 511 U.S. 164, 194–95 n.4 (1994) (Stevens, J., dissenting) ("As I have said before, 'the adversary process functions most effectively when we rely on the initiative of lawyers, rather than the activism of judges, to fashion the questions for review.'"); *United States v. Burke*, 504 U.S. 229, 246 (1992) (Scalia, J., concurring) ("The rule that points not argued will not be considered is more than just a prudential rule of convenience; its observance, at least in the vast majority of cases, distinguishes our adversary system of justice from the inquisitorial one."); *City of Memphis v. Greene*, 451 U.S. 100, 130 (1981) (White, J., concurring) ("I much prefer as a matter of policy

and common sense to answer the question for which we took the case.").

The *Idenix* case is strikingly similar to this one. There, as here, the defendant stipulated to infringement under the court's claim construction, the defendant proved that the patent lacked Section 112 support (enablement) under that claim construction, and the patent owner appealed the invalidity ruling. *Idenix*, 941 F.3d at 1153. As in this case, "[n]either party challenge[d] the district court's claim construction [on] appeal." *Id.* at 1155. The panel majority not only affirmed the lack of enablement but also found the claims invalid for lack of written description. *Id.* at 1162, 1164.

The dissenting judge would have found the claims valid, but "only by disregarding the district court's binding claim construction, ignoring the resulting stipulation of infringement, and analyzing a case that is not the one presented to us." *Id.* at 1156 n.3. As in this case, the defendant had proposed a narrow construction that was not adopted by the district court and then stipulated to infringement. *Id.* The majority then examined whether the district court's "broad construction" was enabled, which it was not. *Id.*

The majority explained the same tension that applies in this case:

> We agree with the dissent that, under a narrower construction, the claims of the '597 patent might well be enabled, and the accused product would not infringe. But that is not the case before us. We are

> tasked with deciding whether the claims, as construed, are enabled. The dissent appears to agree with us that they are not. Dissent at 12 ("the '597 specification did not describe and enable products other than . . . the narrow formulas of three OH groups"). But rather than answer that question, the dissent has applied its newly invented claim construction to find a hypothetical narrower claim valid but not infringed. Respectfully, that is no way to conduct an appeal.

Id.

In this case, the Federal Circuit panel should have exercised its proper appellate role and "decided the case before it": whether, based on the district court's undisputed and un-appealed claim construction, the district court's judgment of invalidity for lack of written description should be affirmed, reversed, or remanded. *Id.* Instead, the panel's decision to depart from its role allowed Novartis to use the district court's broader claim construction to block generic competition for ENTRESTO while at the same time using the Federal Circuit's narrower construction to avoid Section 112 scrutiny. To prevent this unjust and untenable outcome, the Court should grant *certiorari*.

III. The Decision Below Undermines the Notice Function of Patents and Stifles Competition.

It is a long-established tenet of patent law that the specification must describe and enable what is

claimed and thereby apprise the public of what is still open to them. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) ("It has long been understood that a patent must describe the exact scope of an invention and its manufacture to 'secure to the patentee all to which he is entitled, and to apprise the public of what is still open to them.'") (citing *McClain* v. *Ortmayer,* 141 U.S. 419, 424 (1891) (internal brackets removed)). Such disclosure is core to the bargain made with the public in return for a limited monopoly. *See Amgen*, 598 U.S. at 605 ("So today, just as in 1790, the law secures for the public its benefit of the patent bargain by ensuring that, "upon the expiration of the patent, the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it.") (citing *United States* v. *Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933)) (internal brackets removed).

Full disclosure is also crucial for competitors to understand the metes and bounds of patents that may be relevant to their products. This is of particular concern to AAM and its members now that the U.S. Patent Office is turning away petitions for *inter partes* review based on the "settled expectations" of the patent owner if its patent persists for a number of years without being challenged. *See* Dani Kass, *Patent Office Leader Rejects IPRs Based On 12-Year Wait*, LAW360 (June 6, 2025), https://www.law360.com/articles/2350693/patent-office-leader-rejects-iprs-based-on-12-year-wait; Ryan Davis, *Stewart Issues Dozens More Discretionary Denial Decisions*, LAW360 (Aug. 15, 2025), https://www.law360.com/articles/2375631/stewart-issues-dozens-more-discretionary-denial-decisions.

If a company cannot determine whether a patent will be asserted against its after-arising technology, there is no reason for that company to challenge that patent's validity until the patent is (1) asserted in court, (2) disclosed during the "patent dance" pursuant to the Biologics Price Competition and Innovation Section, 42 U.S.C. § 262(*l*)(3)(A), or (3) listed in the Orange Book. At any of these points in time, it may be too late to institute review under the Patent Office's new discretionary denial rules.

This Court has long protected companies from patent owners that seek to use overbroad claims to ensnare after-arising technology without risking invalidity. Take for example the *Incandescent Lamp* case, on which this Court relied in *Amgen*. *The Incandescent Lamp Patent,* 159 U.S. 465 (1895). In considering this precedent in *Amgen*, the Court aptly stated: "For more than 150 years, this Court has enforced the statutory enablement requirement according to its terms. If the Court had not done so in *Incandescent Lamp*, it might have been writing decisions like *Holland Furniture* in the dark. Today's case may involve a new technology, but the legal principle is the same." *Amgen*, 598 U.S. at 616.

As MSN properly noted in its petition, *Incandescent Lamp* is about after-arising technology in the field of lightbulbs. If the Court had not limited the patent claims to exclude Thomas Edison's bamboo conductors, which were not explicitly claimed or described, the public may not have had the benefit of Edison's inventions. *Amgen*, 598 U.S. at 609.

The same is true with *O'Reilly v. Morse*, yet another case relied on by this Court in *Amgen*.

O'Reilly v. *Morse,* 15 How. 62 (1853). The problem here is the same as in *Morse*. There, "the problem was that the claim covered *all* means of achieving telegraphic communication, yet Morse's specification did not describe how to make or use them all." *Amgen*, 598 U.S. 594. Here, the problem is that the claim covers *all* combinations of valsartan and sacubitril, yet Novartis's specification did not describe how to make or use them all. This Court did not allow Morse to use a broad claim to cover after-arising technology, and it should not allow Novartis to do so, either.

This case presents the perfect vehicle for the Court to confirm the principles set forth above by granting MSN's petition for *certiorari*.

CONCLUSION

For the foregoing reasons, amicus curiae AAM respectfully submits that certiorari is warranted to rectify the Federal Circuit's reversal of the district court's judgment of invalidity for lack of written description, its breach of appellate procedure, and its undermining of the notice function and competitive benefits of the Patent Act.

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