No. 25-225

In the Supreme Court of the United States

MSN PHARMACEUTICALS, INC., ET AL., PETITIONERS

v.

NOVARTIS PHARMACEUTICALS CORPORATION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether a patent that claims as its invention a pharmaceutical composition of two specific compounds administered together, and precisely describes the chemical name and structure of those two compounds and how to make and use them, satisfies the requirement in 35 U.S.C. §112 for an enabling written description of "the invention."

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, counsel for respondent Novartis Pharmaceuticals Corporation state that (1) Novartis Pharmaceuticals Corporation is a wholly owned, indirect subsidiary of Novartis AG; and (2) no publicly traded company owns more than 10% of its stock.

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INTRODUCTION

The petition seeks review of questions that are not presented here and not the subject of any legal conflict. This Court long ago resolved the issues actually presented here, and the court of appeals' decision is correct under that settled precedent. The petition should be denied.

Novartis scientists invented a life-saving heart-failure treatment by putting together two pharmaceutical compounds—valsartan and sacubitril—in a single, novel composition. Novartis's patent described the scientists' finding that administering those drugs together had a surprisingly greater therapeutic effect than either drug alone, and claimed that exact two-drug composition. Unlike the broad patent claims this Court held invalid in *Amgen v. Sanofi*, the claims in the patent at issue here precisely recite valsartan and sacubitril by name and specify the ratio in which they should be administered. *See Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023). As the court of appeals correctly concluded, the patent is replete with information expressly describing and teaching how to use this invention, thus satisfying the requirements of 35 U.S.C. §112.

Years after this invention, a different group of Novartis scientists improved on the original invention by adding new features, such as noncovalent bonds to join valsartan and sacubitril to form a new solid-state form of the original invention, called a complex. Novartis also patented that complex, which has certain improvements over the original invention, such as for manufacturability. Novartis commercialized its inventions under the brand name ENTRESTO®, which

has become the preferred initial therapy for certain forms of heart failure.

The court of appeals' decision upholding Novartis's patent on its original invention reflects the straightforward application of well-settled law from this Court and the circuit courts. It has long been established that a patent claiming a combination of A + B, such as the one here claiming the combination of the active pharmaceutical ingredients valsartan and sacubitril, need adequately describe and enable only *that* invention—and need not describe or enable later improvements that add to it, such as A + B + C, as in the later-patented complex of valsartan and sacubitril joined by noncovalent bonds. That is true even though the A + B + C improvement infringes the original patent because the improvement includes the original invention A + B.

Infringement and validity are distinct statutory issues. Courts, including this Court, have long recognized that an original patent may cover for infringement purposes a later improvement that is itself a new invention not claimed in the original patent, and that both inventions can be validly patented. Indeed, promoting future improvements to an earlier invention is a key purpose of requiring patents to describe and enable inventions: the required description and teachings help others build on the original inventors' work. Yet later improvements that add to a claimed invention have never been a basis for reaching back and invalidating the original patent, even though they infringe the original patent.

The petition's arguments about so-called after-arising technology involve fundamentally different

situations not presented here: patents that claim as their invention technology that was developed only later, such as the patent this Court addressed in *Amgen*, which claimed "an entire class of things defined by their function." 598 U.S. at 613. This Court held that such a patent must enable the "full scope" of the claimed invention, which is the same legal rule the court of appeals applied in this case. *Id.* at 610. The patent here complies with that rule because it claims compositions with the specifically recited and described drugs valsartan and sacubitril, without any attempt to claim compositions with other drugs identified by a desired result or functional property.

This Court's review is unwarranted for at least four reasons:

First, as the court of appeals expressly concluded, the patent at issue here does not claim after-arising technology, a fatal fact petitioners (collectively, MSN) and amici ignore. This case thus presents no question about when such claims should be valid.

Second, even if this case involved that question, there is no conflict about the answer. This Court in *Amgen* recently affirmed the court of appeals' "full scope" interpretation of §112, which is the legal standard lower courts have consistently applied. What the petition tries to pass off as "four lines" of supposedly conflicting legal authorities are just different outcomes on different facts under uniform legal rules.

Third, this Court long ago resolved that those who include an original invention within their own product cannot escape liability for infringement of the original patent, or invalidate the original patent, by

arguing that their infringement involves a later improvement. There is thus no unanswered question for this Court to resolve, and the court of appeals correctly applied that settled understanding in upholding validity.

Fourth, even if there were unresolved issues about after-arising technology and even if this case implicated those issues, this would be an exceptionally poor vehicle for addressing them because of MSN's own litigation choices. MSN and its amici assert that granting review would require this Court to wade into a morass of academic questions on purportedly overlapping issues of infringement, claim construction, and invalidity, among others. Yet MSN stipulated to infringement, waiving any challenge to it. Similarly, MSN never challenged claim construction on appeal, so that issue would not be before this Court either. And contrary to MSN's narrative, Novartis neither sought nor obtained a broad claim construction. The district court's claim construction under which MSN stipulated to infringement was the very same, plain-language construction the court of appeals used in upholding the validity of these now-expired patent claims.

The petition should be denied.

STATUTORY PROVISIONS INVOLVED

The petition includes and cites the incorrect version of 35 U.S.C. §112. Although largely the same, the petition's version reflects amendments Congress made in 2011 after Novartis filed its application for the patent at issue here. C.A. App. 56; Leahy-Smith America Invents Act, Pub. L. No. 112-29, §4(c), 125 Stat. 284 (2011).[1] Congress expressly made these 2011 amendments applicable to only new patent applications. Leahy-Smith America Invents Act §4(e). Novartis thus reproduces the portions of the version of §112 that apply here:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. §112, ¶¶1-2 (2006).

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[1] Citations to "C.A. App." are to the joint appendix filed in the court of appeals, citations to "C.A. Dkt." are to the appellate docket at No. 2023-2218 (Fed. Cir.), and citations to "D.C. Dkt." are to the district court docket at No. 20-md-2930 (D. Del.).

STATEMENT

A. Factual Background

1. Novartis's U.S. Patent No. 8,101,659 ('659 patent) claims a groundbreaking dual-drug therapy that addressed a critical need for treating heart failure. Heart failure is a common "condition in which the heart is unable to pump blood at an adequate rate or an adequate volume." Pet. App. 29a (quoting C.A. App. 3352). Before Novartis's invention, the "gold standard of heart failure therapy" was a class of drugs that left much to be desired in preventing hospitalizations and mortality for certain types of heart failure. C.A. App. 3396, 3399-3400, 3408-3409, 3424-3430. And there were no good options for treating children with heart failure. C.A. App. 3428-3429, 7492-7496, 8588-8595.

Researchers at Novartis took a different approach to address the unmet needs for an effective heart-failure treatment. Pet. App. 32a-41a. Their new composition included two active ingredients that had never been administered together: valsartan and sacubitril. Pet. App. 51a-52a; C.A. App. 3185-3186. Neither drug was from the then-prevailing "gold standard" class of drugs. C.A. 3373-3374, 3421-3423. Instead, each was from a different drug class with a different effect: valsartan is an angiotensin receptor blocker that reduces the blood-vessel-constricting effects of angiotensin II, a naturally occurring hormone; sacubitril inhibits the activity of neutral endopeptidase (NEP), which also has a blood-vessel-constricting effect but works through a different mechanism of action. Pet. App. 4a-7a. Sacubitril in particular had never been administered in humans

and was part of a class of drugs that had repeatedly failed in heart-failure studies. Pet. App. 39a-41a.

Novartis's invention was putting the specific drug valsartan together with the specific drug sacubitril to treat heart failure. Putting those two drugs together in a single composition proved to be a major breakthrough. Testing showed that administering valsartan and sacubitril together in about a 1:1 ratio had a greater effect than the sum of the effects of valsartan alone and sacubitril alone. C.A. App. 9622-9657, 3421-3423. And when a large clinical trial compared Novartis's valsartan-sacubitril composition against the then-gold standard, the interim results were so strong that the trial's executive committee ended it immediately so others could begin receiving the new treatment. C.A. App. 3400-3405. The medical community was "blown away by the results." C.A. App. 3403.

Based on the Novartis researchers' efforts and the strength of the clinical-trial results, the Food and Drug Administration (FDA) approved Novartis's New Drug Application to market ENTRESTO®, a valsartan-sacubitril composition, to treat a major form of heart failure. C.A. App. 3392. FDA later approved ENTRESTO® for treating heart failure in children and expanded ENTRESTO®'s indication to include another form of heart failure. C.A. App. 3392, 7078-7151. Since introduction, ENTRESTO® has become the preferred initial therapy for a major form of heart failure in adults. C.A. App. 3428, 8750-8758.

2. Novartis's '659 patent claims the exact two-drug composition that Novartis's researchers

invented, expressly reciting by chemical name the two active ingredients and the ratio of the two:

> A pharmaceutical composition comprising:
>
> (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof;
>
> (ii) the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or (2R,4S)-5-biphenyl-4-yl-4(3-carboxy-propionyl amino)-2-methyl-pentanoic acid [collectively, sacubitril] or a pharmaceutically acceptable salt thereof; and
>
> (iii) a pharmaceutically acceptable carrier;
>
> wherein said (i) [valsartan] and said (ii) [sacubitril], are administered in combination in about a 1:1 ratio.

C.A. App. 65 (col.16:17-34); Pet. App. 6a-7a, 14a (court of appeals similarly replacing chemical names with brackets).

Claim 1 thus claims a composition requiring three basic elements, all of which are identified by name and not by some desired result or functional property: valsartan; sacubitril; and a pharmaceutically acceptable carrier (a term of art referring to non-active ingredients used in a final drug product). C.A. App. 65 (col.16:17-34). The claim further specifies the ratio of the valsartan and sacubitril within the

composition, requiring that the two be "administered in combination in about a 1:1 ratio." C.A. App. 65 (col.16:17-34). While the claim requires these expressly recited elements, it also allows compositions that include additional, unclaimed elements by using "comprising," a long-established "term of art" in patent drafting. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (discussing "comprising"). In patent claims, "comprising" is synonymous with words like "including" or "containing"—it means the claimed composition must include the specifically identified elements but also does not exclude additional, unclaimed elements that may be present. *Ibid.*; *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373-374 & n.1 (1996) (similar).

The specification of the '659 patent describes the claimed invention in detail. The patent identifies "a strong need to evaluate" new heart-failure therapies and a particular "need for more efficacious combination therapy" with "less deleterious side effects." C.A. App. 58-59 (col.2:60-col.3:5). The patent discloses the inventors' solution, detailing that the invention is putting together "valsartan" and the "NEP inhibitor" sacubitril into a single composition for treating heart failure. C.A. App. 59 (col.3:19-25), 60 (col.6:41-52), 61 (col.7:33-41). The patent describes both valsartan and sacubitril in precise terms, giving their chemical names, providing chemical structures for valsartan and sacubitril, and identifying by incorporation methods for making each. C.A. App. 59 (col.3:29-53), 60 (col.5:55-col.6:61), 65 (col.16:12-14).

The patent further describes administering the two together, such as in "[r]epresentative studies": "It has surprisingly been found that, a combination of

valsartan and a NEP inhibitor achieves greater therapeutic effect than the administration of valsartan" or "NEP inhibitors alone." C.A. App. 60-62 (col.6:41-45, col.7:33-col.10:2). The result is a "combination therapy" that is "useful in the treatment or prevention of heart failure." C.A. App. 60-61 (col.6:65-col.7:28).

The '659 patent expired in January 2025. For the six-month period following patent expiration, FDA granted Novartis an additional statutory period of marketing exclusivity in exchange for Novartis's performance of FDA-requested studies on using the invention to treat children. *See* 21 U.S.C. §355a(c). That period, often called pediatric exclusivity, expired in July 2025. Shortly thereafter, competitors, including MSN, began selling generic versions of ENTRESTO®. Thus, regardless of the outcome of MSN's certiorari petition, the patent at issue here no longer protects the claimed invention from generic or other uses.

3. As is common for a commercial drug, Novartis's commercial product ENTRESTO® includes the invention claimed in the '659 patent plus more. It is undisputed that ENTRESTO® includes valsartan and sacubitril in the specified ratio, i.e., it includes the claimed composition. Pet. App. 4a; C.A. App. 2142. ENTRESTO® also includes additional, unclaimed elements, such as noncovalent bonds joining the valsartan and sacubitril molecules together in a solid-state form known as a complex. C.A. App. 3085, 7131-7151. Noncovalent bonds are weak bonds, such as ionic interactions between molecules. Pet. App. 55a; C.A. App. 3473-3474. This way of joining the molecules into a new solid-state complex form was an improvement developed by a different team of

Novartis researchers, led by solid-state chemists, years after the '659 patent's invention priority date. This improvement was itself an invention—and Novartis separately patented valsartan-sacubitril complexes. C.A. App. 5064-5083.

B. Procedural Background

1. District court proceedings

MSN and other generic manufacturers filed applications with FDA seeking to market valsartan-sacubitril compositions before Novartis's patent expired. Pet. App. 23a-24a. Novartis sued under 35 U.S.C. §271(e). Pet. App. 23a-24a.

a. After claim construction, MSN stipulated to infringement

During the claim-construction phase of the litigation, MSN asked the district court to construe the claims to add an atextual limitation. Pet. App. 7a-8a; C.A. App. 2103-2105. MSN argued that the claim phrase "wherein said [valsartan and sacubitril] are administered in combination" should be rewritten to require that valsartan and sacubitril be "administered in concert as two separate components." C.A. App. 2103-2105. In so arguing, MSN sought to exclude a valsartan-sacubitril complex from infringing the claims. Pet. App. 7a-8a.

Contrary to MSN's repeated assertions in its certiorari petition, Novartis did not seek or obtain a broad claim construction that included complexes as part of the '659 patent's claimed invention. Instead, Novartis contended that the claims' plain text needed no further construction and that there was no basis for adding MSN's atextual limitation to the claims.

C.A. App. 2103-2104. Novartis explained the relationship between valsartan-sacubitril complexes and the invention under the claims' plain text: while a complex includes "a combination of valsartan and sacubitril," a complex also "include[s] additional features"—like "the noncovalent interaction[s] between valsartan and sacubitril"—that "are not elements of the claimed combination." C.A. App. 2006-2008. That is, the invention claimed by the '659 patent does not itself include complexes, but valsartan-sacubitril complexes include the claimed invention.

The district court agreed with Novartis that the plain claim text needed no further interpretation, declining to adopt any construction of the claims beyond the claim text itself. C.A. App. 2103-2105. And contrary to MSN's suggestion, the district court rejected MSN's insistence that adding an atextual limitation to the claims was needed to avoid invalidity: the district court found "'no basis to believe'" that it "'was necessarily consigning the asserted claims to a judgment of invalidity.'" Pet. App. 9a (quoting district court; brackets omitted). *Contra* Pet. 11.

Nearly 10 months later and as the case neared trial, MSN stipulated to infringement. Pet. App. 9a-13a; D.C. Dkt. 540 (public version of stipulation at Dkt. 524). Nothing in that stipulation was conditioned on the claim-construction order, which the stipulation did not mention. D.C. Dkt. 540; C.A. Oral Arg. Audio 21:25-35 (MSN: "I don't believe that stipulation was limited" based on the construction).[2] The stipulation stated that "MSN wishes to avoid

[2] Available at https://www.cafc.uscourts.gov/oral-arguments/23-2218_11132024.mp3.

significant discovery as to the infringement of the Asserted Claims" and "to limit the action to the issue of whether the Asserted Claims" are "invalid." D.C. Dkt. 540 at 2. The district court accepted MSN's unequivocal stipulation. D.C. Dkt. 526. Thus, although MSN asserts its generic is a complex, there is no evidence here showing whether that is so.

b. After trial, the district court rejected all but one of MSN's invalidity challenges

The parties proceeded to trial solely on MSN's invalidity challenges. As relevant here, MSN argued Novartis's patent was invalid under 35 U.S.C. §112. Section 112 requires "a written description of the invention, and of the manner and process of making and using it" sufficient to "enable" others to "make and use" the invention. 35 U.S.C. §112, ¶1.

MSN argued Novartis's patent was invalid because it lacked details about adding noncovalent bonds to valsartan and sacubitril to form them into a complex, which Novartis invented only later. Pet. App. 9a-13a. Novartis responded that MSN was demanding description and enablement of matter "not recited in the claims." C.A. App. 3107-3108. The claims "simply recite the combination of the two drugs," valsartan and sacubitril; "[t]hey do not recite any linkage between the two." C.A. App. 3107. Novartis also explained that MSN was confusing the issues of (1) what the patent claims as the invention, which must be described and enabled, and (2) what may infringe the claims, which may include other matter beyond the invention that need not be described or enabled. C.A. 3107-3108.

The district court rejected all but one of MSN's invalidity challenges. Pet. App. 9a-13a. It adopted MSN's view that because Novartis's claims "cover" the later-developed valsartan-sacubitril complexes for infringement, the patent had to include a written description of those complexes to be valid. Pet. App. 12a-13a.

2. Court of appeals proceedings

A unanimous panel of the Federal Circuit reversed the one invalidity ground the district court had adopted and affirmed the district court's rejection of MSN's other invalidity arguments. Pet. App. 13a-21a. The court of appeals agreed with Novartis that the district court, by focusing on "whether the '659 patent describes valsartan-sacubitril complexes," had "erroneously conflated the distinct issues of patentability and infringement." Pet. App. 13a-17a.

Although valsartan-sacubitril complexes "include the claimed invention along with additional unclaimed features," complexes with those additional features are "not what is claimed." Pet. App. 15a, 18a. Because complexes merely include the claimed invention but are not themselves the claimed invention, "[t]he issue is *not* whether the '659 patent describes valsartan-sacubitril complexes." Pet. App. 13a (Circuit's emphasis). Instead, the issue is whether the patent describes the "claimed" invention. Pet. App. 13a-17a.

Addressing that issue, the court of appeals expressly applied the district court's interpretation of the claims, which no party challenged on appeal: "[t]he invention of the '659 patent, *as construed by the district court*, is a composition in which valsartan and

sacubitril are administered 'in combination.'" Pet. App. 17a (emphasis added). "That invention is plainly described throughout the specification." Pet. App. 13a-17a. "[E]ven MSN's expert conceded that the '659 patent adequately discloses" valsartan and sacubitril administered in combination, absent MSN's flawed focus on unclaimed complexes. Pet. App. 15a.

The court of appeals held that MSN's challenge that the patent fails to enable one of skill in the art to make and use the invention failed for "similar" reasons: "a specification must only enable the *claimed* invention." Pet. App. 17a-19a (Circuit's emphasis). MSN's arguments contradicted settled precedent about patent law's "'encouragement of improvements on prior inventions.'" Pet. App. 18a-19a (quoting *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977)). Under settled precedent, "[t]he later-discovered valsartan-sacubitril complexes, which arguably may have improved upon the 'basic' or 'underlying' invention claimed in the '659 patent, cannot be used to 'reach back' and invalidate the asserted claims." *Ibid.*

MSN sought rehearing en banc, arguing that the panel had *sua sponte* changed the district court's claim construction. MSN based that assertion on a footnote in the court of appeals' decision that simply noted that the district court had not construed the claims as claiming complexes as the invention and that such a construction "would have been error." Pet. App. 15a-16a & n.5; *see* C.A. Dkt. 136 at 6-7, 16-18. The court of appeals denied rehearing without recorded dissent. Pet. App. 98a-100a.

3. Further proceedings after remand

On remand, the district court entered judgment for Novartis, enjoined MSN from commercial marketing, and ordered that the effective date of MSN's FDA approval to market generic versions of ENTRESTO® be reset until July 16, 2025, after Novartis's pediatric-exclusivity period ended. D.C. Dkt. 1824; *see* 35 U.S.C. §271(e)(4)(A) (requiring reset of FDA approval in these circumstances).

MSN then moved under Federal Rules of Civil Procedure 59 and 60 for relief from that final judgment. D.C. Dkt. 1830, 1831. MSN again argued that the court of appeals had purportedly adopted a new claim construction, which MSN insisted warranted vacating the final judgment and reopening MSN's infringement stipulation. D.C. Dkt. 1831. The district court denied those requests, finding that MSN was making arguments that were "meritless," "pretty close" to "frivolous," "too late," and "rewriting history": "[t]he Federal Circuit d[id] not change the claim construction" or "the scope of the patent" on appeal. *Novartis Pharms. Corp. v. MSN Pharms., Inc.*, No. 2025-1722, Dkt. 5-2 at Add162, Add168 (Fed. Cir. May 2, 2025) (transcript of April 29, 2025 district court hearing on MSN's Rule 59 and 60 motions, included in MSN's addendum to its motion for a stay pending appeal).

MSN appealed that denial and sought a stay of the district court's final judgment pending appeal. The court of appeals denied the stay. *Id.*, Dkt. 19 (Fed. Cir. May 23, 2025) (Federal Circuit's stay denial order). Noting the district court's conclusion that the court of appeals "did not alter the claim construction

on appeal" or "change the scope of the patent," the court of appeals concluded that MSN was unlikely to succeed on appeal of the denial of its post-remand Rule 59 and 60 motions. *Id.*, Dkt. 19 at 5-6. MSN then voluntarily dismissed that appeal. *Id.*, Dkt. 20 (Fed. Cir. June 10, 2025) (dismissal stipulation).

REASONS FOR DENYING THE PETITION

I. THERE IS NO CONFLICT BETWEEN THE DECISION HERE AND OTHER CIRCUIT PRECEDENT

Contrary to MSN's attempt to cobble together four supposedly divergent "lines" of precedent applying §112 to "after-arising technology" (Pet. 15-26), the Federal Circuit applies the same legal rule in all cases: 35 U.S.C. §112 requires a patent's specification to describe and enable "the full scope of the invention as defined by its claims." *Amgen*, 598 U.S. at 610 (affirming Federal Circuit's correct application of this standard). To the extent the outcomes differ in MSN's cited decisions, they merely reflect the differences in the facts and issues of each case. And even were there any legal differences, this Court should allow the lower courts to consider its recent guidance in *Amgen* before wading back into these issues.

A. *Idenix* and Similar Decisions Apply the Same Legal Rule as Here to a Situation Not Presented by this Case—Functionally Defined Claims

Many of MSN's cited decisions turned on an issue this Court already resolved in *Amgen*, which is not present here: applying §112 to a patent claim that "seeks to monopolize an entire class of things defined by their function." 598 U.S. at 613. Both this Court and the Federal Circuit have recognized the "problem" that may arise when a patent tries to claim "all means of achieving" some desirable result yet fails to "describe[] how to make and use them all." *Id.* at 607; *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1853); *Incandescent Lamp Pat.*, 159 U.S. 465, 472 (1895);

Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc) (explaining that such claims present "especially acute" §112 problems).

That was the issue in all the decisions in MSN's so-called "*Idenix* line." Pet. 15-18 (citing *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019); *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004)). In *Idenix* itself, the court of appeals' analysis about whether the patent enabled persons of skill in the art to make and use the claimed invention's full scope did not involve any question about after-arising technology. 941 F.3d at 1154-1163. Rather, the court's analysis focused throughout on the patentee's attempt to claim as the invention use of any of "'billions and billions' of compounds" that were "effective" to treat the hepatitis C virus. *Id.* at 1154-1165. Just as this Court had concluded for the functionally defined claims in *Amgen*, the Federal Circuit held that the *Idenix* patent's identification of "four examples" was insufficient to entitle the patentee to such a broad functionally defined claim. *Ibid.*

Plant Genetic and *Chiron* presented the same issue of patentees trying to claim broad classes of things defined by function. *Plant Genetic*, 315 F.3d at 1337-1338; *Chiron*, 363 F.3d at 1247. The patent in *Plant Genetic* claimed as the invention any of a class of transgenic plant cells capable of "blocking the function of glutamine synthetase." 315 F.3d at 1337-1338. The patent claims were invalid because the patent "gave no instruction how" to achieve that functional result with a substantial portion of the claimed class. *Id.* at 1340-1341. Similarly, in *Chiron*, the patent

claimed every "monoclonal antibody that binds to human [HER2] antigen," which is associated with breast cancer. 363 F.3d. at 1250. The patent was invalid because the disclosure lacked detail to support claiming every antibody that achieved the desired HER2-binding result. *Id.* at 1254-1255.[3]

B. *Hogan* and the Decision Here Apply the Same Legal Rule as Other Cases but Reach Different Results Because of Different Facts

While *Idenix*, *Plant Genetic*, and *Chiron* all turned on patents claiming entire classes defined by their functions, neither of the decisions in MSN's so-called "*Hogan-Entresto* line" involved that issue. The patent application in *Hogan* recited simply "[a] normally solid homopolymer of 4-methyl-1-pentene." 559 F.2d at 597. As the Federal Circuit's predecessor court recognized, "4-methyl-1-pentene" referred to a specific, and specifically described, chemical structure. *Id.* at 597 & n.4. The Patent and Trademark Office's examiner had rejected the claim not because the patent application failed to teach how to make and use the full scope of that narrow claim, but because the application did not teach an alternative way of making the polymer that had been discovered after the applicant's invention (but before the examiner's

[3] In relying on *Chiron*, MSN omits that invalidity there was based on 35 U.S.C. §102, not §112. The portion of *Chiron* MSN cites addressed issues related to adding new matter to a patent application and priority, issues governed by the statutory provisions in 35 U.S.C. §§120 and 132. Although closely related to §112, the analysis under those provisions is not always identical, including because the burdens can differ. *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008).

decision). *Id.* at 606. On appeal from the Office's rejection, the court of appeals reversed because the claim was to the homopolymer itself and not any particular method of making it. *Ibid.*; *see Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1374-1375 (Fed. Cir. 2017) (similarly explaining *Hogan*). And as the Office never disputed, the patent application gave an enabling disclosure of the homopolymer. *Hogan*, 559 F.2d at 606. Plus, requiring patent applicants to foresee future developments in ways of making their inventions would "impose an impossible burden on inventors and thus on the patent system." *Ibid.*

Hogan therefore applied the same full-scope legal rule as *Idenix*, *Plant Genetic*, and *Chiron* (and this Court's *Amgen* decision). It merely reached a different result because of the difference in the invention that was claimed. Indeed, in unsuccessfully trying to distinguish *Hogan* in the Federal Circuit, MSN itself described *Hogan* as "focus[ing] on 'developments in methods of making the claimed composition,'" which MSN asserted "is not the issue here." C.A. Dkt. 29 at 24-25 (MSN's appellate brief, which also similarly tried to distinguish *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989)).

For similar reasons, the decision here creates no conflict with any other decision. The court of appeals applied the same legal rule as in each of the decisions just discussed, requiring that the '659 patent describe and enable the full scope of "the *claimed* invention." Pet. App. 14a-19a (Circuit's emphasis). The court of appeals took pains to explain that the outcome of its analysis followed from the specific nature of the '659 patent's claimed invention: a composition of two precisely defined drugs, administered together. Pet.

App. 14a-15a. The court concluded: "That invention is plainly described throughout the specification." Pet. App. 14a-15a, 17a-19a.

The court of appeals' reasoning belies MSN's suggestion that the court applied some sort of categorical rule about after-arising technology, which the court's rationale does not even implicate. MSN bases its "reach back" argument on cherry-picked fragments of the court of appeals' decision stitched together with the district court's reasoning. Pet. 19 (altering quote from circuit court's note that "later-discovered valsartan-sacubitril complexes * * * cannot be used to 'reach back' and invalidate the asserted claims" (MSN's alteration; quoting Pet. App. 18a-19a)). But the court of appeals actually reasoned that, because "the '659 patent does not claim valsartan-sacubitril complexes," the later-discovered complexes could "not affect" the patent's validity. Pet. App. 15a-17a; *see* Pet. App. 15a (complex "is not what is claimed"), 17a ("patent does not claim as its invention valsartan-sacubitril complexes"). Rather, valsartan-sacubitril complexes "include the claimed invention along with additional unclaimed features." Pet. App. 18a. MSN's invalidity challenges thus failed because §112 requires a description of only the claimed invention, not unclaimed features. Pet. App. 17a-19a.

Indeed, the language MSN quotes, once the full context is included, highlights that the key fact here is that complexes need not be described because they are not the claimed invention: "The later-discovered valsartan-sacubitril complexes, which arguably may have *improved upon the 'basic' or 'underlying' invention claimed in the '659 patent*, cannot be used to 'reach back' and invalidate the asserted claims." Pet.

App. 18a-19a (emphasis added); *see Rex Med., L.P. v. Intuitive Surgical, Inc.*, --- F.4th ----, 2025 WL 2799030, at *11-12 (Fed. Cir. Oct. 2, 2025) (rejecting §112 validity challenge because "[o]ur case law is clear that an applicant is not required to describe in the specification every conceivable and possible future" product incorporating the invention; citation omitted).

Far from conflicting with that reasoning, MSN's so-called "*Idenix* line" affirmatively agrees with it. The court of appeals here quoted and applied *Plant Genetic*, which confirmed that "'[o]ne cannot use a later-existing state of the art to invalidate a patent that was enabled for *what it claimed* at the time of filing.'" Pet. App. 18a (quoting 315 F.3d at 1340; emphasis added and alteration omitted). Likewise, all three judges in *Chiron* agreed with and applied *Hogan*, just as the court of appeals did here. *Chiron*, 363 F.3d at 1254-1255; *id.* at 1262 (Bryson, J., concurring: "no quarrel with the holding of *Hogan*").

Before Congress vested exclusive patent jurisdiction in the Federal Circuit, other courts of appeals consistently reached similar conclusions on similar facts. For example, writing for the Second Circuit, Judge Learned Hand rejected a validity challenge to an invention for an improved spark plug. *B.G. Corp. v. Walter Kidde & Co.*, 79 F.2d 20, 22 (2d Cir. 1935). Judge Hand acknowledged that the inventor "did not foresee the particular adaptability of his plug to the airplane" and "did not even know the especial needs of its engine." *Ibid.* Yet that later adaptation of the invention did not affect the patent's validity. *Ibid.* The patent "laid down with perfect certainty" the details of what the inventor "accomplish[ed] and how."

Ibid. An inventor "is not charged with a prophetic understanding of the entire field of [the invention's] usefulness." *Ibid.*; *see Larson v. Crowther*, 26 F.2d 780, 787 (8th Cir. 1928) ("An inventor is entitled to all the uses to which his invention may be put, even if he is not aware of such uses when he secures his patent."); *Yancey v. Enright*, 230 F. 641, 647 (5th Cir. 1916) ("[A]ddition of an improving feature does not excuse the appropriation of the appellant's invention.").

C. MSN's Third and Fourth "Doctrinal Lines" About Different Issues Likewise Show No Legal Conflict and Are Not Even Implicated Here

Stretching to find a nonexistent conflict, MSN posits two additional "doctrinal lines" of supposedly conflicting precedent based on two Federal Circuit decisions. Pet. 20-22 (discussing *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347 (Fed. Cir. 2000), and *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870 (Fed. Cir. 2004)). Both decisions addressed only claim construction and infringement. *Schering*, 222 F.3d at 1349; *SuperGuide*, 358 F.3d at 873. Neither involved any question of invalidity, the sole issue presented here. Pet. i.

Nor is either decision even implicated here because MSN strategically chose to stipulate to infringement and not to raise claim construction on appeal. Thus, even if MSN were correct that *Schering* and *SuperGuide* show the Federal Circuit taking competing approaches about whether, for infringement purposes, claims may be construed to "cover" after-arising technology, there would be no conflict with the decision here. Pet. 20-22. MSN never raised any

question of claim construction on appeal, despite raising other alternative invalidity grounds. Pet. 19 (conceding same); C.A. Dkt. 29 (MSN's appellate brief, raising no claim-construction issue).

Likewise, MSN stipulated that it does "not contest infringement" of the '659 patent, without preserving its right to appeal that issue. D.C. Dkt. 540. The stipulation expressly stated its purpose, making no mention of claim construction: MSN "wish[ed] to avoid significant discovery as to the infringement of the Asserted Claims" and "to limit the action to the issue of whether the Asserted claims" are "invalid." D.C. Dkt. 540 at 2. Thus, nothing supports MSN's attempted about-face now in asserting that its stipulation was "because" of claim construction. Pet. 11, 18-19, 32; *accord* C.A. Oral Arg. Audio 21:25-35 (MSN: "I don't believe that stipulation was limited" based on the construction).

Even aside from MSN's strategic choices to stipulate to infringement and not to appeal claim construction, the petition's attempts to show a conflict related to infringement and claim construction fail because they are based on a false claim-construction narrative. MSN argues at length about whether a patentee that "secures a claim construction that captures" after-arising technology for "infringement" must be held to the "same construction" for validity. Pet. 18-26. But the court of appeals used the same claim construction for its invalidity analysis that the district court had adopted ten months before MSN's infringement stipulation. The only "claim construction" was the plain claim text, without modification. Pet. App. 14a. Rather than narrow that claim construction to decide validity (as MSN wrongly insists),

the court of appeals explicitly decided the validity of "[t]he invention of the '659 patent, as construed by the district court." Pet. App. 17a.

Under that plain-text construction, Novartis's '659 patent does not "*claim* valsartan-sacubitril complexes" as the invention, nor could it have been construed to do so. Pet. App. 16a n.5 (Circuit's emphasis). Rather, the patent specifically claims a composition comprising valsartan + sacubitril together. Valsartan-sacubitril complexes are covered by those claims for infringement purposes because those complexes *include* that invention + unclaimed features such as noncovalent bonds. As explained further in Part II, *infra*, settled law establishes that a product containing the elements "A + B + C + D" "directly infringes claims to A + B + C." *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984). MSN rightly never suggests any conflicting precedent on that issue warranting this Court's review.

II. THERE IS NO CONFLICT WITH THIS COURT'S PRECEDENT, WHICH LONG AGO RESOLVED THE ISSUES HERE, AND THE DECISION BELOW IS CORRECT UNDER THAT SETTLED PRECEDENT

This Court's review is also unwarranted because this Court has already conclusively resolved and rejected the use of "after-arising" improvements to invalidate patent claims like those here. The court of appeals correctly resolved this case under that precedent. In arguing otherwise, MSN overlooks centuries of precedent and foundational principles of patent law.

A. Statutory Text and Precedent Require Describing and Enabling Only the Claimed Invention, Not Future Improvements that May Infringe

1. MSN and its amici ignore statutory text making clear that what matters for patent validity is the scope of the claimed invention, not what may infringe the patent. As *Amgen* recognized, the Constitution "vests Congress with the power" to control patent law. 598 U.S. at 604 (citing U.S. Const., Art. I, §8, cl. 8). Congress was plain that it suffices for a patent specification to contain "a written description of *the invention*, and of the manner and process of making and using *it*." 35 U.S.C. §112, ¶1 (emphases added); *see Amgen*, 598 U.S. at 604-605 (noting requirement has remained "largely intact" since 1790). The invention, in turn, is defined by the "one or more claims particularly pointing out and distinctly claiming" it. 35 U.S.C. §112, ¶2. Thus, as *Amgen* held, "the specification must enable the full scope of the invention *as defined by its claims*." 598 U.S. at 610 (emphasis added). Nothing in §112's text refers to infringement, which is governed by a different statutory provision. *See* 35 U.S.C. §271.

That difference matters because, although a patent's claims "'define[] the scope of a patent grant,'" they "function[] to forbid" more than just "exact copies of an invention." *Markman*, 517 U.S. at 373-374 & n.1 (citation omitted). "[F]or example, a claim for a ceiling fan with three blades attached to a solid rod connected to a motor would not only cover fans that take precisely this form, but would also cover a similar fan that includes some additional feature, e.g., such a fan with a cord or switch for turning it on and

off." *Ibid.* What Congress required to be described was "the invention" and the "manner and process of making and using it," not everything that may infringe. 35 U.S.C. §112, ¶1; *Amgen*, 598 U.S. at 610; *see* Pet. App. 15a-16a (court of appeals explaining that it is erroneous to "conflate[] the distinct issues of patentability and infringement").

2. Cementing the difference between validity and infringement, this Court long ago recognized that a valid patent may "capture" as infringing later-developed improvements that were not disclosed in the patent. "Two patents may both be valid when the second is an improvement on the first, in which event, if the second includes the first, neither of the two patentees can lawfully use the invention of the other without the other's consent." *Cantrell v. Wallick*, 117 U.S. 689, 694 (1886) (recognizing that an infringing improvement will often involve "[c]hanges in the construction" of the original invention). Core to recognizing that the two patents—the one to the original invention and the one to the infringing improvement—"may both be valid" is that the original patent need not disclose the later improvement (because if it did, such an earlier disclosure would mean the purported improvement was not novel and thus not patentable). *Ibid.*; *see Cochrane v. Deener*, 94 U.S. 780, 787 (1876) ("One invention may include within it many others, and each and all may be valid at the same time.").

This Court has applied these principles to reject an appellate court's reliance on a later-developed improvement to conclude that an earlier patent had "no merit." *Temco Elec. Motor Co. v. Apco Mfg. Co.*, 275 U.S. 319, 324-328 (1928) (citing *Cantrell*, 117 U.S. at

694). In that case, Temco sued Apco for infringing a patented shock absorber designed by the Thompsons. *Id.* at 321-323. In defense, Apco argued that the Thompson patent's design "ha[d] been proved to be ineffective"; that only an improvement by later inventor Storrie overcame the original design's problems; and that Apco was using Storrie's later-patented design. *Id.* at 324-325. Although this Court recognized that the Storrie design improved on the Thompson design, the Thompson patent was nevertheless valid and the Storrie design was "an appropriation of the original design" that infringed the Thompson patent, despite adding to it. *Id.* at 325-328. This Court thus reversed the Fifth Circuit's use of the later "patentable improvement" against the original patent: "It is well established that an improver cannot appropriate the basic patent of another, and that the improver without a license is an infringer and may be sued as such." *Id.* at 328; *see Morley Sewing Mach. Co. v. Lancaster*, 129 U.S. 263, 289 (1889) (rejecting that an accused infringer could avoid liability because it was practicing an "improvement" that was "unknown before"; "use of [the improvement] involves the plaintiff's invention"); *Winans v. Denmead*, 56 U.S. (15 How.) 330, 342-343 (1853) (explaining that "it is not a defence" to infringement that the claimed invention is later "embodied in a form not described").[4]

[4] As these decisions show, this Court's settled recognition that a patented invention may be a valid "blocking" patent against later, undescribed improvements continued after the 1836 amendments to the Patent Act. *Contra* IP Law Professors' Amici Br. 15-16 & n.37.

B. MSN's Conflation of Invalidity and Infringement Issues Is Wrong

MSN and its amici have no answer for this settled precedent, which they ignore. They cite no precedent—from this Court or even a court of appeals—contradicting the settled understanding that §112 requires describing and enabling only the full scope of the invention defined by the claims, not every infringing future improvement that adds to the invention. MSN largely resorts to broad platitudes about patent law's quid pro quo of an enabling public disclosure in exchange for limited rights in an invention. Pet. 28-34. But that future inventors can improve on a patented invention tends to show that the original patentee fulfilled its part of the quid pro quo. And this Court has already rejected that patent law relieves from infringement liability those who incorporate others' inventions into their products (even if the product has improvements). *Temco*, 275 U.S. at 328 ("well established that an improver cannot appropriate the basic patent of another").

The court of appeals' decision also fully accords with *Incandescent Lamp*. *Incandescent Lamp* struck down Sawyer and Man's attempt to claim as their invention "every fibrous or textile material" that could be used in an electric lamp. 159 U.S. at 471-472. MSN argues *Incandescent Lamp* shows that after-arising technology must be described and enabled "if a patentee broadly claims after-arising technology." Pet. 30-33; *see* Pet. i, 2-3, 6 (repeatedly arguing same). But here, the Federal Circuit concluded that the '659 patent does not claim after-arising technology: "the '659 patent does not claim valsartan-sacubitril complexes." Pet. App. 13a, 15a (valsartan-sacubitril

complex "is not what is claimed"), 17a ("patent does not claim as its invention valsartan-sacubitril complexes"). That fact, and not any difference in the legal rule, explains the different outcomes between this case and *Incandescent Lamp*.

The facts here differ from *Incandescent Lamp* in another key way. The Court there acknowledged that Sawyer and Man's "claim might not be too broad" if they "had discovered in fibrous and textile substances a quality common to them all" that "adapted them peculiarly to incandescent conductors." *Incandescent Lamp*, 159 U.S. at 472. Here, Novartis's invention was the discovery of a common property shared by every composition of valsartan and sacubitril administered together in about a 1:1 ratio: giving a patient valsartan together with sacubitril "achieves greater therapeutic effect than the administration of valsartan" or sacubitril "alone." C.A. App. 60-62 (col.6:41-45, col.7:33-col.10:2). Contrary to MSN's unsupported assertion, the record here shows that a valsartan-sacubitril complex produces that same therapeutic effect because the valsartan and sacubitril molecules separate when the complex is swallowed. C.A. App. 3473-3474, 7084.

A valsartan-sacubitril complex is thus not like Edison's bamboo, which had a "peculiar fitness" for use as a filament that Edison alone discovered, not Sawyer and Man. *Incandescent Lamp*, 159 U.S. at 471-472. Although MSN baldly asserts that a "complex yielded greater efficacy in treating heart failure," its record citation says no such thing. Pet. 10 (citing Pet. App. 4a). Indeed, the D.C. Circuit in parallel litigation concluded the opposite, accepting FDA's position (to MSN's benefit in that case) that the

complex's "co-crystal structure has nothing to do with" ENTRESTO®'s "pharmacological effects." *Novartis Pharms. Corp. v. Kennedy*, --- F.4th ----, 2025 WL 2737402, at *4-5 (D.C. Cir. Sept. 26, 2025) (quoting FDA's explanation that there is "no evidence 'demonstrating that the physical form of the active ingredients in Entresto is known to impact the safe or effective use of the drug'").[5]

Citing only a law review article, MSN attempts to raise an entirely new theory, arguing that although unclaimed elements need not be described or enabled, that rule should apply only to "a feature that is severable from an invention's essence." Pet. 34. Nothing about that waived argument merits review. That is especially so because the unclaimed features that distinguish the invention here from a valsartan-sacubitril complex—noncovalent bonds between molecules—are severable. C.A. App. 3473-3474, 7084 (undisputed that the noncovalent bonds forming the complex are severed when the complex is swallowed); *Novartis*, 2025 WL 2737402, at *5 (summarizing FDA's findings that the complex "'dissociates rapidly in vivo to sacubitril and valsartan,' so 'there is no exposure' to" the complex).

Even some of MSN's amici agree that MSN's merits arguments are wrong. For example, one brief argues that "after-arising technology should never

[5] To be sure, Novartis also obtained patents on its subsequent invention of a complex of valsartan and sacubitril, the solid-state form used in ENTRESTO®. C.A. App. 7138-7139. But that form improved on the '659 patent's invention in ways other than increasing its therapeutic efficacy, such as simplifying manufacturing and drug formulation through use of a single solid form rather than separate drug substances.

invalidate a claim that was valid when issued," and thus opines that the court of appeals "arrived at the right answer for the wrong reasons." Masur-Ouellette Amici Br. 3, 13. That view supports denying the petition, as this Court "review[s] judgments of the lower courts, not statements in their opinions." *Amgen*, 598 U.S. at 615.

III. EVEN WERE THERE ANY CONFLICT, MSN'S LITIGATION CHOICES MAKE THIS CASE AN EXCEPTIONALLY POOR VEHICLE FOR REVIEW

Even had MSN identified conflicting authorities or an unsettled and important issue warranting this Court's review, this case (involving a now-expired patent) would present an exceptionally poor vehicle for review.

First, MSN hinges its question presented on a patentee "ensnar[ing], as infringing, an accused device that features after-arising technology." Pet. i. But this case presents no issue about infringement because MSN stipulated to taking that issue off the table. Pet. App. 16a-17a (court of appeals relying on same).

Given that litigation choice by MSN, this Court would be unable to address what MSN says are the overlapping issues of "claim construction, infringement, and validity" that are tangled up with the question presented, let alone the five overlapping issues MSN's amici say would have to be addressed. Pet. 35-36; Pet. 31 (suggesting this Court's review would require "fashion[ing] limiting principles and refin[ing] related doctrines," including on infringement); IP Law Professors' Amici Br. 22-25 (listing five

overlapping issues and suggesting the need for a "broad enough" question presented "to obtain extensive briefing on the related issues"). Those academic questions—about which MSN's amici openly disagree with one another on the merits—are thus neither presented nor preserved here. *See* IP Law Professors' Amici Br. 7 (acknowledging amici "may present different resolutions at the merits stage" were this Court to grant review).

Second, this case would not allow the Court to address "an accused device that features after-arising technology." Pet. i. MSN stipulated to infringement to "avoid significant discovery" into the nature of its accused generic product. D.C. Dkt. 540 at 2. And the D.C. Circuit appears to have recognized that MSN's product is primarily "not a complex" of valsartan and sacubitril but a composition of separate valsartan and separate sacubitril, which is not after-arising technology. *Novartis*, 2025 WL 2737402, at *5.

Third, MSN focuses heavily on claim construction, as do its amici. But claim construction was not before the court of appeals because no party appealed it. Pet. App. 17a (court of appeals expressly applying district court's unchallenged construction). Plus, the only "construction" of the claims was the unaltered claim text, which the district court concluded required no construction and which the court of appeals did not change. *See supra* pp. 15-17, 24-26. Therefore, no question of claim construction is presented or preserved.

Finally, MSN's question presented mushes together issues that the court of appeals has long treated as distinct, leaving unclear what issue (or

issues) MSN actually seeks to have this Court review. As MSN acknowledges, the Federal Circuit has long interpreted 35 U.S.C. §112 to impose both (1) a "written description" requirement under which a patent must show that the inventor invented what is claimed, and (2) an "enablement" requirement under which the patent must teach others how to make and use the invention. *Ariad Pharms.*, 598 F.3d at 1343-1345 (explaining court of appeals' interpretation); Pet. 3 (acknowledging same). The court of appeals here applied that interpretation and addressed those issues separately. Pet. App. 13a-19a. Yet MSN's question presented refers to the requirements of §112 generally, and its discussion of the purportedly conflicting "doctrinal lines" fails to address the requirements separately. The petition thus leaves vague the issues MSN believes warrant this Court's review and fails to show any conflict on any specific issue.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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