**Nos. 2023-2218, 2023-2220, 2023-2221**

# UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff-Appellant*
v.
TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., *Defendants-Appellees*

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff-Appellant*
v.
ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC PHARMACEUTICALS INC., *Defendants*

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff-Appellant*
v.
MSN PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LTD.
MSN LIFE SCIENCES PRIVATE LTD., *Defendants-Appellees*
HETERO USA, INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-III, *Defendants*

Appeal from the United States District Court for the District of Delaware, Nos. 1:19-cv-01979, 1:19-cv-02021, 1:19-cv-02053, and 1:20-md-02930, Judge Richard G. Andrews

## NOVARTIS PHARMACEUTICALS CORPORATION'S OPPOSITION TO MSN'S PETITION FOR REHEARING OR REHEARING EN BANC

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MARCH 5, 2025

# CERTIFICATE OF INTEREST

Counsel for Novartis Pharmaceuticals Corp. certify under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

1. **Represented Entities**. Provide the full names of all entities represented by the undersigned counsel in this case.

Novartis Pharmaceuticals Corp.

2. **Real Parties in Interest.** Provide the full names of all real parties in interest for the entities. Do not list real parties if they are the same as the entities.

None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Novartis AG

4. **Legal Representatives.** List all law firms, partners, or associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court.

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5. **Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes, see separately filed notice.

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees).

Not applicable.

Dated: March 5, 2025

/s/ Deanne E. Maynard
Deanne E. Maynard

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| | |
|---|---|
| ’659 patent | U.S. Patent No. 8,101,659 |
| ACE | Angiotensin converting enzyme |
| ANDA | Abbreviated new drug application |
| FDA | United States Food and Drug Administration |
| NEP | Neutral endopeptidase |

## INTRODUCTION

MSN's petition identifies no legal conflict warranting en banc review, does not attempt to show importance beyond the particular facts here, and does not point to anything the Court's unanimous decision misapprehended or overlooked. Instead, MSN simply rehashes the arguments from its merits brief, based on the same flawed reasoning the Court already corrected: MSN conflates the invention that is claimed with what may infringe comprising claims like those here. In so doing, MSN asks the Court to undo decades of settled law about the relationship between foundational patents and subsequent improvements.

This case involves Novartis's foundational patent for the combination therapy included in its blockbuster heart-failure treatment ENTRESTO®. Novartis's invention was a significant, unexpected advance over then-prevailing heart-failure therapies. The claims precisely recite the exact combination therapy that Novartis's scientists invented: a pharmaceutical composition "comprising" the expressly identified drugs valsartan and sacubitril "administered in combination in about a 1:1 ratio." Appx65(col.16:17-34). The claims use structural terms, without claiming functions or desired results, and the patent describes those same structures and how combining valsartan with sacubitril improves heart-failure treatment.

In alleging a purported conflict, MSN makes arguments based on decisions presenting a different issue: the requirements for describing and enabling claims

that recite a broad genus distinguished not by structure but by function, such as drugs or antibodies that achieve a desired result. MSN continues to ignore the structural nature of the claims here in mischaracterizing the claim construction, which MSN did not appeal. The district court adopted as its construction the plain claim text—rejecting MSN's attempt to rewrite the claims to exclude from infringement a specific chemical form called a complex, in which valsartan and sacubitril are joined through weak, non-covalent bonds. A valsartan-sacubitril complex infringes because it includes the claimed invention plus unclaimed features—weak, non-covalent bonds joining valsartan and sacubitril.

This Court correctly recognized that such unclaimed features cannot support invalidity because they need not be described or enabled, and thus broke no new ground in upholding this patent's validity. Section 112 requires describing and enabling only the claimed invention. It has long been settled that a patent claiming a combination of A + B + C 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 + D—even though a combination with those improvements may infringe. Contrary to MSN's position, that conclusion treats the claims the same for both invalidity and infringement. Indeed, one purpose of the written-description and enablement requirements is to foster such later improvements.

MSN's petition should be denied.

## BACKGROUND

### A. Factual Background

#### *1. '659 patent*

Novartis owns the '659 patent, which is listed in the Orange Book for Novartis's FDA-approved drug ENTRESTO®. Op.4-6. ENTRESTO® is a combination therapy of valsartan and sacubitril. *Id.* Valsartan is an angiotensin receptor blocker that reduces the blood-vessel-constricting effects of angiotensin II, a naturally occurring hormone. *Id.* Sacubitril inhibits the activity of neutral endopeptidase (NEP), which also has a blood-vessel-constricting effect but works through a different mechanism of action. *Id.*[1]

It is undisputed that Novartis scientists were the first to disclose a combination therapy of valsartan and sacubitril. In the 2002 timeframe, the '659 patent addressed a "major public health problem": heart failure. Appx3425. As the district court found, heart failure is a chronic and increasingly common "condition in which the heart is unable to pump blood at an adequate rate or an adequate volume." Appx6 (citation omitted). Before Novartis's invention, "the most widely studied" drugs for

[1] Unless otherwise clear from context, this response uses the term "valsartan" to refer collectively to valsartan and its pharmaceutically acceptable salts, and the term "sacubitril" to refer collectively to sacubitril, sacubitrilat, and their pharmaceutically acceptable salts. *See* Op.6 n.2.

heart failure were angiotensin converting enzyme (ACE) inhibitors, which worked differently from either valsartan or sacubitril. Op.4-6.

Novartis scientists recognized a need for "a 'more efficacious combination therapy which has less deleterious side effects.'" Op.4-5 (quoting Appx59(col.3:3-5)). They understood through their research that "[t]he nature of hypertensive vascular diseases is multifactorial," so it could be beneficial for "drugs with different mechanisms of action" to be "combined." Appx58(col.2:65-67). After significant efforts, they "'surprisingly found that a combination of valsartan and a NEP inhibitor achieves greater therapeutic effect than the administration of valsartan, ACE inhibitors or NEP inhibitors alone.'" Op.5 (quoting Appx60(col.6:41-44); brackets omitted).

The '659 patent recites the specific combination therapy that Novartis's scientists developed:

> 1. A pharmaceutical composition comprising:
>
> (i) the AT 1-antagonist [valsartan];
>
> (ii) the NEP inhibitor [sacubitril]; and
>
> (iii) a pharmaceutically acceptable carrier;
>
> wherein said (i) AT 1-antagonist [valsartan] and said (ii) NEP inhibitor [sacubitril], are administered in combination in about a 1:1 ratio.

Appx65(col.16:17-34); Op.5-6, 12 (Court using similar brackets).

### *2. ENTRESTO®*

ENTRESTO® includes valsartan and sacubitril in the form of a complex. A complex is a type of solid-state chemical form in which different atoms or molecules are joined using weak, non-covalent bonds. Appx26-27. When so joined, the individual components remain distinct and readily identifiable, and they separate from each other in water or when ingested. Appx3473-3474. Years after the '659 patent's 2002 priority date, a different team of Novartis researchers—led by solid-state chemists—developed and patented sacubitril and valsartan (along with water and sodium ions) in a "complex" form. Appx3085; Appx7138; Appx7131-7151.

Because a valsartan-sacubitril complex includes the composition claimed in the '659 patent plus other unclaimed features, Novartis listed the '659 patent in the Orange Book for ENTRESTO® and the PTO granted a patent term extension. Appx2104-2105; Appx5043-5048. Consistent with Novartis's positions in this litigation, Novartis told FDA that the '659 patent's claims "read on the approved product" ENTRESTO®. Appx4961-4964.

MSN asserts its generic versions of ENTRESTO® contain a valsartan-sacubitril complex. Op.4, 7.

## B. Procedural Background

### *1. Claim construction and trial*

After MSN submitted an ANDA seeking to market and sell generic ENTRESTO®, Novartis sued for infringement under 35 U.S.C. §271(e)(2). Op.6-7.

During claim construction, MSN sought to exclude from infringement complexes of valsartan and sacubitril by arguing that the '659 patent had redefined the phrase "administered in combination in about a 1:1 ratio" to require administering valsartan and sacubitril as physically separate components. Op.7; Appx2032; Appx2103-2104. Novartis contended there was no basis for adding new limitations and that the plain text needed no further construction. Appx2103-2104.

As it has throughout this litigation, Novartis asserted that MSN's arguments were confusing the issues of claim construction, infringement, and invalidity. Appx1999; Appx2005-2006. Novartis explained at the claim-construction hearing that the valsartan-sacubitril complex "is literally covered by the claims of the '659 … patent[] because it *comprises* a combination of valsartan and sacubitril, but that compound included additional features"—"[n]amely, the noncovalent interaction[s] between valsartan and sacubitril." Appx2006 (emphasis added). Those "non-covalent interactions between valsartan and sacubitril[] are not elements of the claimed combination, and thus do not need to be described" or "enable[d]." Appx2006-2008.

Rejecting MSN's rewrite, the district court kept the original language of the claims without addition: "'wherein said valsartan and sacubitril are administered in combination.'" Op.7 (quoting Appx2103-2104; brackets omitted). The district court, then Judge Stark, also rejected MSN's view that reading in a limitation was needed to avoid Section 112 concerns: the district court found "'no basis to believe that the construction the court adopted was necessarily consigning the asserted claims to a judgment of invalidity.'" Op.8 (quoting district court; brackets omitted).

Nearly 10 months later and as the case neared trial, MSN stipulated to infringement. Op.8-11; D.Ct.Dkt.540. Nothing in that stipulation was conditioned on the claim-construction order, which the stipulation did not mention. D.Ct.Dkt.540. The stipulation stated that "MSN wishes 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." *Id.* The district court accepted that unequivocal stipulation. *Id.*

The parties proceeded to trial on MSN's invalidity challenges. Novartis again explained that MSN was demanding enablement and a written description of matter "not recited in the claims" and rebutted MSN's reliance on the fact that valsartan-sacubitril complexes infringe these comprising claims. Appx3107-3108. The claims "simply recite the combination of the two drugs," valsartan and sacubitril; "[t]hey do not recite any linkage between the two." Appx3107 (Novartis's opening

statement); Appx3582-3583. Infringement of the '659 patent's claims thus "can be asserted against a non-covalent complex, but there's no requirement to enable the additional features of the complex" that are not claimed; and MSN's written-description argument "fails, too, for the same reasons." Appx3107-3108.

The district court, now Judge Andrews, rejected MSN's enablement, obviousness, and indefiniteness challenges. Op.8-11. The district court concluded that the claims lacked adequate written description, however, by adopting MSN's view that because Novartis's claims "cover" the later-developed valsartan-sacubitril complexes for infringement, the patent had to describe them. Op.11 (discussing the district court's reliance on *Chiron v. Genentech*, 363 F.3d 1247 (Fed. Cir. 2004)).

***2. This Court's unanimous decision***

Novartis appealed the written-description invalidity judgment, while MSN raised non-enablement and obviousness as alternative grounds without challenging claim construction. Op.11; MSN.Pet.5-6. This Court reversed on written description and otherwise affirmed, upholding the patent's validity. The Court agreed with Novartis that, by focusing on "whether the '659 patent describes valsartan-sacubitril complexes," the district court had "erroneously conflated the distinct issues of patentability and infringement." Op.11-14. The written-description question is whether the patent describes "*whatever is now claimed*." Op.12 (Court's emphasis; citation omitted). Although valsartan-sacubitril

complexes "include the claimed invention along with additional unclaimed features," complexes with those additional features are "not what is claimed." Op.13, 15. The claimed invention—a pharmaceutical composition comprising valsartan and sacubitril "administered in combination"—"is plainly described throughout the specification." Op.12-14. "[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. Op.13.

The Court held that MSN's enablement arguments failed for "similar" reasons: "a specification must only enable the *claimed* invention." Op.15-16 (Court's emphasis). MSN's arguments contradicted settled precedent about patent law's "'encouragement of improvements on prior inventions.'" Op.15-16 (quoting *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977)). Under that 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." *Id.*

In its second post-judgment petition, MSN seeks rehearing of these rulings. MSN no longer challenges the district court's finding that the claimed invention would not have been obvious.

## REASONS TO DENY REHEARING

### A. MSN Presents No Proper Basis for Panel or En Banc Rehearing, Instead Merely Rearguing the Merits

The rehearing criteria are long settled: panel rehearing requires identifying "with particularity" a point of law or fact the Court "overlooked or misapprehended"; and en banc rehearing requires identifying a conflict with precedent or a question of "exceptional importance." Fed. R. App. P. 40(b). This Court expressly instructs that "[p]etitions for rehearing should not be used to reargue issues previously presented that were not accepted by the merits panel during initial consideration of the appeal."[2]

Yet MSN's petition merely rehashes the same arguments previously presented and rejected. MSN identifies no legal or factual point the Court misapprehended or overlooked. And MSN's supposed "conflict" just repeats MSN's arguments about how it believes precedent should be applied to this case's facts. *Compare* MSN.Response.Br.vii-xi, 1-2, 16-34 (arguing the '659 patent's claims fail under *Ariad* and full-scope written description and enablement decisions because of the purportedly "broad claim construction"), *with* MSN.Pet.iii-v, 1-7, 11-20 (arguing same). MSN does not even attempt to show importance beyond the '659 patent,

[2] https://www.cafc.uscourts.gov/home/case-information/case-filings/petitions-for-rehearing-rehearing-en-banc/.

instead expressly addressing its petition only to whether this particular patent's claims are "adequately described" and "enabled." MSN.Pet.iii (capitalization altered).

MSN seeks a do-over. That is not a proper basis for panel or en banc rehearing, and the petition should be denied for this reason alone.

### B. The Court's Decision Creates No Conflict with MSN's Cited Written-Description and Enablement Decisions, Which Involve Claims Reciting Desired Results or Performance Properties

No further review is warranted for the additional reason that MSN's petition relies on precedent about an issue not presented here: Section 112's application to "claims that use functional language to define the boundaries of a claimed genus." *Ariad Pharms. v. Eli Lilly*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc). Claims of that type may present an "especially acute" problem because they "may simply claim a desired result" without sufficient written description or enablement of what achieves that result. *Id.* As the Supreme Court has explained, a "problem" may arise when a patent purports to claim as the invention "all means of achieving" some desirable result without "describ[ing] how to make and use them all." *Amgen v. Sanofi*, 598 U.S. 594, 607 (2023) (emphasis omitted).

There is no similar written-description or enablement problem here. MSN has never argued that the asserted claims recite a desired result or performance property. The claims here recite exact drugs and their required ratio: a pharmaceutical

composition "comprising" valsartan and sacubitril "administered in combination in about a 1:1 ratio." Appx65(col.16:17-34). MSN identifies no allegedly conflicting precedent addressing claims like these or even treating such claims as "genus" claims in the relevant way under Section 112. Instead, ignoring this distinction, MSN and its amicus cite decisions involving claims to molecules that achieve a specific binding result (*e.g.*, *Ariad*, *Juno*, and *Amgen*) or a specific efficacy in treating a disease (*e.g.*, *Idenix*). MSN.Pet.11-18; AAM.Amicus.Br.7-11; *Ariad*, 598 F.3d at 1341; *Juno Therapeutics v. Kite Pharma*, 10 F.4th 1330, 1335 (Fed. Cir. 2021); *Amgen*, 598 U.S. at 599; *Idenix Pharms. v. Gilead Scis.*, 941 F.3d 1149, 1155 (Fed. Cir. 2019).

But the distinction makes all the difference and refutes MSN's claimed conflict. As Novartis's merits briefing explained, "[t]he claims in this case, not involving functional claim language, do not present the fundamental difficulty presented by the claims in virtually all of the precedents on which Defendants rely." *GlaxoSmithKline v. Banner Pharmacaps*, 744 F.3d 725, 731 (Fed. Cir. 2014); Novartis.Opening.Br.35-36; Novartis.Reply.Br.9. As *Banner* made clear, compliance with Section 112 "sharply differs" depending on whether the patent recites a "claimed genus" distinguished by some "shared performance property." 744 F.3d at 731-32.

This difference also rebuts MSN's complaint that the Court "did not address" *Ariad*. MSN.Pet.13-14. MSN omits that the discussion about the "generic statement of an invention's boundaries" in *Ariad* was addressing claims that "did not distinguish the genus from other materials in any way except by function, *i.e.*, by what the genes do." 598 F.3d at 1349-50. Representative species or common structural features were needed there because those claims and the description stated only "a useful result" and not what "accomplish[es] the result." *Id.*

Yet "this [C]ourt has repeatedly 'explained that an adequate written description'" can be "'a precise definition, such as by *structure*.'" *Banner*, 744 F.3d at 730 (*Banner*'s emphasis; quoting *Ariad*, 598 F.3d at 1350). Such a precise definition "is an identification of 'structural features commonly possessed'" by the claimed matter. *Id.* (citation omitted). Here, because the '659 patent's claims and written description precisely define the claimed combination therapy by structure, the Court had no need to go further. Op.11-14.

For similar reasons, MSN wrongly complains of an improper "*in ipsis verbis* analysis." MSN.Pet.16 (citing *Enzo Biochem v. Gen-Probe*, 323 F.3d 956, 968-69 (Fed. Cir. 2002); *Ariad*, 598 F.3d at 1350). *Enzo* and *Ariad* are both express that "claim language appear[ing] *in ipsis verbis* in the specification" is insufficient when it merely describes the invention "in terms of its function" or "activity" rather than what the invention is. *Enzo*, 323 F.3d at 968; *Ariad*, 598 F.3d at 1350. But when,

as here, the claims and the description use the same words to provide a "structural identification" of the invention, that match satisfies Section 112 because it shows "the claim is no broader in scope than the written description." *Banner*, 744 F.3d at 730-31; *see Ariad*, 598 F.3d at 1349 (recognizing that "many original claims will satisfy the written description requirement" based on similar *in ipsis verbis* matching).

Because this case presents no issue about functionally defined genus claims like those in MSN's cited decisions, this case provides no vehicle for review of the written-description or enablement requirements for such claims. Moreover, as Novartis's merits briefing explained but this Court had no need to address, even were the '659 patent claims viewed through the lens used for such genus claims, the claims are adequately described and enabled. The descriptions of valsartan and sacubitril in precise structural terms readily satisfy the common-structural-features test for written description, and the record amply supports the district court's findings establishing enablement. Novartis.Opening.Br.33-36; Novartis.Reply.Br.6-9, 17-21.

### C. The Court Correctly Applied Longstanding Written-Description and Enablement Principles to the Unappealed Plain-Text Construction of These Structurally Defined Claims

#### *1. MSN continues to conflate patentability and infringement*

With no conflict with precedent, MSN repeats its merits argument that if the claims as construed "cover (or embrace, include, encompass, *etc*.)" valsartan-sacubitril complexes for purposes of infringement, then the '659 patent must describe and enable complexes' unrecited features. MSN.Pet.2; MSN.Response. Br.1-2. This Court rightly rejected that argument as "conflat[ing] the distinct issues of patentability and infringement." Op.13; Novartis.Reply.Br.9-10 (Novartis previously explaining same). While terms like "cover, embrace, include" may sometimes be loosely used, the statutory requirements are clear: Congress required describing and enabling only "the invention," defined by "one or more claims particularly pointing out and distinctly claiming the subject matter." 35 U.S.C. §112; Op.13-16. Section 112 imposes no obligation to describe "a component that is *not* claimed." *Allergan USA v. MSN Lab'ys Priv.*, 111 F.4th 1358, 1372 (Fed. Cir. 2024) (Court's emphasis).

Here, the unappealed plain-text construction precisely recites the claimed subject matter: "wherein said [valsartan and sacubitril] are administered in combination" in about a 1:1 ratio. Op.12 (Court's alteration); Appx2103-2104. As this Court explained, "[t]hat invention is plainly described throughout the

specification." Op.12-13 (describing specification passages). In holding otherwise, the district court had been led "astray" by "erroneously conflat[ing] the distinct issues of patentability and infringement." Op.13. For "reasons similar to those" supporting adequate description, the invention is enabled because the patent teaches how to make and use "the *claimed* invention," "a composition in which valsartan and sacubitril are administered 'in combination.'" Op.15 (Court's emphasis).

This Court identified the fundamental flaws in MSN's conflation of patentability and infringement (Op.13), yet MSN persists without answering. MSN.Pet.11-18. For example, MSN misconstrues a footnote in this Court's decision, suggesting the Court "effectively changed" the claim construction. MSN.Pet.6, 16-18 (citing Op.14 n.5). But the Court assessed validity based on the claim language, applying the unappealed plain-text construction. Op.12. The cited footnote made no change to that construction; instead, it simply elaborated on the distinction the Court recognized between what a patent *claims* as its invention (and therefore must be described and enabled) and what may infringe those claims

because it *includes* the invention, like valsartan-sacubitril complexes. Op. 13-15 & n.5.[3]

### *2. This Court's decision accords with well-settled law about foundational and improvement patents, correctly recognizing* Chiron *is inapposite*

For similar reasons, this case is unlike *Chiron*, which MSN wrongly accuses the Court of not addressing. *See* MSN.Pet.13. The Court explained that the district court misread *Chiron* as requiring a focus on whether the '659 patent described valsartan-sacubitril complexes. Op.10-14. Novartis's briefing detailed that *Chiron* involved a different situation—whether Chiron had improperly added new matter, defeating an assertion of priority to an application filed 11 years earlier. Novartis.Opening.Br.37-39. Chiron's patent recited the invention functionally: "A monoclonal antibody that binds to human [HER2] antigen." *Chiron*, 363 F.3d at 1249. The patent expressly defined that invention broadly as any homogeneous population of antibodies, including chimeric antibodies, that bind to the HER2

[3] MSN suggests twisting the Court's footnote to reopen infringement or add a post-judgment delisting counterclaim. MSN.Pet.16-18 (citing Op.14 n.5). But MSN mooted any claim-construction dispute for infringement purposes by stipulating to infringement independent of claim construction. Op.14; D.Ct.Dkt.540; Oral.Arg.Audio(21:15) (MSN: "I don't believe that stipulation was limited" based on the construction). MSN likewise waived any delisting counterclaim by not pleading one. Such a counterclaim would have failed anyway because valsartan-sacubitril complexes like ENTRESTO® "include the claimed invention" as a combination drug product of these two active ingredients. Op.15; 21 U.S.C. §355(j)(5)(C)(ii)(I).

antigen. *Id.* at 1252, 1254-55, 1257-58. Because Chiron claimed as its invention HER2-binding chimeric antibodies, to obtain priority it had to show earlier possession of that later invention, which it could not do. *Id.*

That is nothing like the situation here, which involves a foundational patent followed by a subsequent improvement. Unlike the *Chiron* patent, the '659 patent does not claim as its invention "yet-unidentified ways of achieving a desired result." *Banner*, 744 F.3d at 731. Instead, as the district court's plain-text construction confirmed, the "claimed invention" here is an undisputedly novel combination therapy "comprising" two specific compounds, valsartan and sacubitril. Appx65(col.16:17-34); Appx2103-2105. That novel therapy produced an unexpected and "improved treatment for heart failure." Appx3471. As MSN has never disputed, those therapeutic benefits are independent of the solid-state form of the claimed combination therapy. Appx3473-3474 (even in complex form, valsartan and sacubitril retain "individual identities" and "separate" when ingested).

Novartis's later development of a valsartan-sacubitril complex improved on that inventive combination therapy by adding features not claimed in the '659 patent, including non-covalent bonds linking valsartan and sacubitril. Appx2005-2006 (Novartis explaining same at claim-construction hearing); Op.16. But unlike in *Chiron*, Novartis never sought priority for that improvement back to the '659 patent,

instead consistently maintaining that valsartan-sacubitril complexes were a separate, later invention. Novartis.Opening.Br.16.

As this Court correctly concluded (Op.15), such "later existing improvements" are part of a later-existing state of the art and cannot be used "to 'reach back' and preclude or invalidate a patent on the underlying invention." *Hogan*, 559 F.2d at 606 (addressing enablement); *U.S. Steel v. Phillips Petroleum*, 865 F.2d 1247, 1251-52 (Fed. Cir. 1989) (addressing written description and enablement). Requiring an enabling description of future ways an invention might be added to or improved "'would invalidate all claims (even some "picture claims").'" Op.15 (quoting *Hogan*, 559 F.2d at 606); *see SRI Int'l v. Matsushita Elec.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc) (similarly rejecting that "impossible" requirement in infringement context). It also would nullify a key part of the "*quid-pro-quo* premise of patent law": securing an inventor's rights to its invention in exchange for an enabling description that promotes future improvements. *Amgen*, 598 U.S. at 604-05. Because *Hogan* accords with this settled understanding—consistently recognized by this Court and the Supreme Court—there is no justification for MSN's passing request to overrule *Hogan* and any unspecified "progeny." MSN.Pet.19.

At bottom, MSN's arguments about the later-developed valsartan-sacubitril complex contravene "'[o]ne of the simplest, clearest, soundest, and most essential

principles of patent law'": both a foundational invention and a later improvement "'may be validly patented,'" even when the improvement "cannot be practiced without infringing" the foundational patent's claims. *In re Kaplan*, 789 F.2d 1574, 1577-78 (Fed. Cir. 1986) (Rich, J.; citation omitted); *see Cantrell v. Wallick,* 117 U.S. 689, 694 (1886) ("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."). The Court's decision here correctly preserves this longstanding principle.

## CONCLUSION

MSN's petition should be denied.

Dated: March 5, 2025

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the relevant type-volume limitations of the Federal Rules of Appellate Procedure and Federal Circuit Rules because the filing has been prepared using a proportionally spaced typeface and includes 3,889 words, excluding the parts of the brief exempted by the Rules.

Dated: March 5, 2025

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ny-2903991