No. 2023-2218, -2220, -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*

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*

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

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DEFENDANTS-APPELLEES' PETITION FOR PANEL REHEARING OR REHEARING EN BANC

Dated: February 10, 2025

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CERTIFICATE OF INTEREST FOR DEFENDANTS-APPELLEES

Pursuant to Federal Circuit Rules 27(a)(7) and 47.4, counsel for Defendants-Appellees certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Ltd.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

N/A

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). 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.

N/A

4. Legal Representatives. List all law firms, partners, and 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. Fed. Cir. R. 47.4(a)(4).

Stamatios Stamoulis, Stamoulis & Weinblatt

5. Related Cases. Whether there are any related or prior cases, other than the originating case number(s), that meet the criteria under Federal Circuit Rule 47.5. Fed. Cir. R. 47.4(a)(5).

Yes, see separately filed notice

6. Required disclosure of information under Fed. R. App. P. 26.1(b) and 26.1(c). Fed. Cir. R. 47.4(a)(6).

N/A

Dated: February 10, 2025

Respectfully submitted,

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision reversing the district court and finding U.S. Patent No. 8,101,659 ("the '659 patent") not invalid is contrary to this Court's precedent with respect to the "written description" requirement of 35 U.S.C. § 112, including as set forth in:

- *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc);
- *Juno Therapeutics, Inc. v. Kite Pharma*, Inc., 10 F.4th 1330 (Fed. Cir. 2021);
- *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019);
- *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004); and
- *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002).

Based on my professional judgment, I further believe the panel decision is contrary to the Supreme Court and this Court's precedent with respect to the "enablement" requirement of 35 U.S.C. § 112, including as set forth in:

- *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023);
- *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003); and
- *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019).

Based on my professional judgment, I further believe this appeal requires an answer to a precedent-setting question of exceptional importance: Whether, if patent

claims are construed to cover (or embrace, include, encompass, *etc*.) later-arising technology—as Novartis argued below and the district court adopted—the patent must describe and enable such later-arising technology under 35 U.S.C. § 112(a) (35 U.S.C. § 112 ¶ 1 (pre-AIA)).

Dated: February 10, 2025 /s/ William A. Rakoczy

INTRODUCTION

A patent's specification must both describe and enable the *entire or full scope* of what is claimed. *See* 35 U.S.C. § 112(a); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1337 (Fed. Cir. 2021) ("[T]he written description must lead a [POSA] to understand that the inventors possessed the entire scope of the claimed invention."); *Amgen*, *Inc. v. Sanofi*, 598 U.S. 594, 610 (2023) ("If a patent claims an entire class of . . . compositions of matter, the patent's specification must enable a [POSA] to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims.").

It is not enough to describe and enable only examples expressly disclosed in the written specification. *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019) (Prost, C.J.) ("The question . . . is whether the [patent] demonstrates that the inventor was in possession of those [compounds] that fall within the boundaries of the claim . . . but are not encompassed by the explicit formulas or examples provided in the specification."). The panel's decision ignored the full scope requirement of Section 112(a), and should be reversed.

The critical written description and enablement issues here both emerged directly from the district court's construction of the term "wherein [valsartan and sacubitril] are administered in combination." MSN argued this term was limited to the administration of valsartan and sacubitril "as two separate components."

Novartis disagreed and argued that the plain and ordinary meaning was broad and included, for example, valsartan-sacubitril *complexes*. The district court sided with Novartis, holding "the patent is not limited to separate compounds" or "physical mixtures" but also extends to "combinations of valsartan and sacubitril in the form of a complex." Appx2104; Appx27. Because the district court adopted Novartis's broad plain meaning construction, MSN—whose product contains *complexed* valsartan and sacubitril—stipulated to infringement.

Having secured a broad construction for infringement (to its benefit), Novartis must live with that same broad construction for invalidity (to its detriment). Because all parties agreed that "valsartan-sacubitril complexes were undisputedly unknown at the time of the invention" (Op.14 n.5), and thus were not disclosed at all in the specification, the broadly construed claims were neither adequately described nor enabled. Indeed, the district court (then Chief Judge Stark) issued the following warning during claim construction:

> Novartis admits that its two patents 'do not disclose or suggest' [complexed valsartan and sacubitril]. This seems to be an admission by Novartis that, at the very least, there will be a non-frivolous issue of written description and/or lack of enablement.

Appx2105.

This was exactly right. To satisfy written description, Novartis must describe the "entire scope" of its claims. *Juno*, 10 F.4th at 1337. As the district court correctly found, Novartis *cannot* do that. *First*, where the construed claims include technology

that did not exist at the time of invention, the patentee "axiomatically" cannot satisfy the written description requirement. *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004); *see also Idenix*, 941 F.3d at 1164 (holding patent invalid for lack of written description when the inventors "only came up with [an undescribed] embodiment a year or so after the application was filed") (quotation omitted). Second, for genus claims, the disclosure must allow a POSA to "visualize or recognize the members of the genus" to be adequately described. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc) (quotation omitted). Novartis could not satisfy that test because the POSA could not have contemplated, much less visualized, complexes that were "undisputedly unknown" at the time of the invention. Op.14 n.5.

Nothing about that analysis should have changed on appeal. Neither party appealed the district court's claim construction. Thus, the only question before the panel was whether the '659 patent described and enabled "the full scope of its claims under the district court's broad construction," including both physical mixures and unknown complexes. *Idenix*, 941 F.3d at 1156 n.3. The panel *agreed* "the '659 patent does not describe a complexed form of valsartan and sacubitril" and that such a complex was "not discovered until four years after the priority date." Op.13. But rather than apply long-standing precedent, the panel reversed. In doing so, the panel

strayed from the unappealed claim construction before it, and confused and upended long-established patent law:

First, the panel said the district court "erroneously conflated" patentability and infringement. Op.13. The district court, however, did no such thing, and the *SRI* case on which the panel relies is inapposite. The panel compounded its error by creating an artificial distinction between what patent claims "claim" and what they "cover" for Section 112 purposes. Op.11-12. That only one claim construction applies to both validity and infringement is fundamental patent law. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement . . . . A patent may not, like a nose of wax, be twisted one way to avoid [invalidity] and another to find infringement.") (quotations and citations omitted).

Second, because the "combination" term appears in the specification, the panel thought written description was satisfied. But that *in ipsis verbis* rationale does not, and cannot, describe or show possession of the *entire* scope of the construed claims.

Third, the panel effectively changed the district court's claim construction that no one appealed. That was improper. *Idenix*, 941 F.3d at 1156 n.3. Novartis was

bound by its construction and estopped from asserting that complexes are outside the scope of the claims.

Novartis must also enable the "full scope" of its claims. *Amgen*, 598 U.S. at 610. Because valsartan-sacubitril complexes were undisputedly unknown at the time of the invention, the patent cannot possibly be enabled. To the extent the panel's decision rested on cases suggesting "later-existing state of the art" cannot be considered in enablement (Op.15-16; *see also In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977)), those cases squarely conflict with the Supreme Court's *Amgen* decision and should be overruled. Indeed, the undisputed facts and claim construction make this case the perfect vehicle for clarifying once and for all that, if claims are admittedly construed broadly enough for infringement to embrace or capture later-arising technology, the patent must, without exception, enable the full scope of that subject matter. The time for the panel's double standard is over.

The '659 patent is invalid for lack of written description and lack of enablement, and the panel's decision should be revised accordingly.

REASONS FOR GRANTING REHEARING

I. BACKGROUND

A. Entresto.®

The valsartan and sacubitril in Novartis's Entresto® product are present in a form known as a "complex" (two drugs linked by non-covalent bonds that form a

single compound). Op.4. Because its valsartan/sacubitril API is a complex, Novartis listed the '659 patent in the Orange Book. Op.4.

B. District Court Proceedings.

Claim 1 of the patent recites a pharmaceutical composition comprising (i) valsartan, (ii) sacubitril, and (iii) a pharmaceutically acceptable carrier, (iv) where the valsartan and sacubitril are administered in combination in a 1:1 ratio. Op.5-6. During claim construction, the district court rejected MSN's request to limit the claims to administration of valsartan and sacubitril as separate components (*i.e.*, in a non-complexed form, such as physical mixtures). Op.7; Appx2103-2104. Novartis insisted it did not "define or disclaim" the breadth and plain meaning of the claimed "combination" so that "sacubitril and valsartan must be separate (and not complexed)." Appx2104. Novartis argued that it expressly represented to the PTO[1] that the patent "cover[s] Entresto, a drug consisting solely of non-separate, complexed valsartan and sacubitril." Appx2104; *see also* Appx1995-1996, 15:17-16:3; Appx2008-2009, 28:17-29:13; Appx2015-2016, 35:2-36:2. The district court adopted "[Novartis's] preferred construction"—*i.e.*, wherein "the claims of the '659 Patent are not limited to physical mixtures of valsartan and sacubitril, and do not

[1] Novartis's representation had significant, financially lucrative consequences—it resulted in a *two-year extension* of the '659 patent term, until January 2025. Op.4.

exclude combinations of valsartan and sacubitril in the form of a complex." Appx27; *see also* Appx2103-2105.

Following claim construction, there was "no[] dispute" the claims were "directed to a genus of 'combinations' of sacubitril and valsartan, which includes complexes of sacubitril and valsartan." Appx27; *see also* Appx44 ("[Novartis] points out that physical mixtures of valsartan and sacubitril, and complexes of valsartan and sacubitril, are mere subsets of the claimed genus."); Appx2152 (Uncontested Facts: "The Court's construction . . . encompasses non-covalently bonded complexes of [valsartan and sacubitril]."); Appx3109 (Novartis's Opening Statement: "As [Novartis] will explain, valsartan and sacubitril are the structural features common to the claimed genus."). In short, as construed, the plain meaning of the claims included complexes as specific embodiments in the genus of the claimed invention.

After trial, in view of the full scope of the construed claims, the district court (now Judge Andrews) concluded Novartis "axiomatically" could not satisfy written description. Appx44 (quoting *Chiron*, 363 F.3d at 1255). For enablement, however, the court reached the opposite conclusion, determining this Court's case law meant that "later-existing state of the art may not be properly considered in the enablement analysis." Appx38. But the district court expressed concerns with the consequences of this case law. Appx39, n.15.

C. The Panel Decision.

The panel reversed on written description and affirmed on enablement. Op.11-16. For written description, the panel began correctly, recognizing: "The issue on appeal is whether the '659 patent describes what is claimed, viz., a pharmaceutical composition comprising valsartan and sacubitril administered 'in combination.'" Op.11-12. But the panel quickly went wrong, stating: "The issue is *not* whether the '659 patent describes valsartan-sacubitril complexes. Because the '659 patent does not claim valsartan-sacubitril complexes, those complexes need not have been described." Op.12. But the '659 patent *does claim* valsartan-sacubitril complexes (and every other combination of those two components), and thus must show possession of that *entire scope*. That is precisely the construction the district court adopted at Novartis's urging, and the only one the panel had before it. In view of this broad construction, the panel's recognition that "valsartan-sacubitril complexes were undisputedly unknown at the time of the invention" (Op.14 n.5) required affirmance for inadequate written description.

For enablement, the panel's decision was based on "reasons similar" to written description: "a specification must only enable the *claimed* invention." Op.15. But again, the '659 patent *does claim* valsartan-sacubitril complexes (and every other combination of those components), and thus must enable that *full scope*. The

panel improperly cast that aside. The admitted failure to enable "later-discovered valsartan-sacubitril complexes" (Op.16) required reversal and a finding of invalidity.

II. THE CLAIMS ARE NOT ADEQUATELY DESCRIBED

A. The '659 Patent Claims a Genus of Valsartan-Sacubitril Combinations.

Written description begins with claim construction. *Atl. Rsch. Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1354 (Fed. Cir. 2011) ("[C]laim construction is inherent in any written description analysis.") (quotation and citation omitted). The panel acknowledged this basic proposition: "The scope of what is claimed (and must be adequately described) is, in turn, determined through claim construction." Op.12.

The claims were broadly construed as a genus of all valsartan-sacubitril "combinations," whether a physical mixture, a complex, or otherwise. This construction governs written description. *See VR Optics, LLC v. Peloton Interactive, Inc.*, No. 2021-1900, 2023 WL 2031213, at *7 (Fed. Cir. Feb. 16, 2023) (rejecting patentee's "attempt to reinterpret the claim" where the district court "adopted [patentee's] proposed construction verbatim"); *see also Idenix*, 941 F.3d at 1156 n.3 ("[U]nder a narrower construction, the claims of the [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. 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.") (citation omitted).

Estoppel also bars a contrary construction. Novartis successfully obtained that construction for infringement purposes, and must live with it for validity as well. What is more, to secure a two-year patent term extension, Novartis represented to the PTO that the '659 patent covers Entresto,® which contains "complexed valsartan and sacubitril." Appx2104. The PTO approved the extension based on this representation. Op.4; Appx2104. Novartis also benefitted from a 30-month stay of generic approvals because of its Orange-Book-listed '659 patent. *See* 21 U.S.C. §355(j)(5)(B)(iii). Having repeatedly represented that the full scope of the patent includes Entresto,® Novartis is bound by the district court's plain meaning construction.

B. Under *Ariad* and *Chiron*, the Claims Are Not Described.

The test for written description is whether the disclosure "reasonably conveys to [a POSA] that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351 (citations omitted). To satisfy written description, the '659 patent must describe the "entire scope" of what is claimed. *Juno*, 10 F.4th at 1337; *Idenix*, 941 F.3d at 1163 (holding the question is "whether the [patent] demonstrates that the inventor was in possession of [compounds] that fall within the boundaries of the claim . . . but are not encompassed by the explicit

formulas or examples provided in the specification"). Here, the patent fails these requirements.

First, the claims are invalid under *Chiron*, a precedential decision the district court relied on but the panel did not even address. In *Chiron*, "the district court broadly construed the claims of the [patent] to embrace chimeric and humanized antibodies." 363 F.3d at 1252. But because chimeric antibodies did not exist on the priority date, the Court found the claims "axiomatically" invalid for lack of written description. *Id.* at 1255 ("[T]he Chiron scientists, by definition, could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist [yet]. Thus, axiomatically, Chiron cannot satisfy the written description requirement for . . . chimeric antibodies.").

Chiron (and its logic) controls the outcome here. The claims were construed to embrace *all* valsartan-sacubitril combinations, including both physical mixtures and complexes. *Supra* § I.B. But "valsartan-sacubitril complexes were undisputedly unknown at the time of the invention." Op.14 n.5. Thus, the claims of the '659 patent are "axiomatically" invalid for lack of written description. *Chiron*, 363 F.3d at 1255.

Second, as genus claims, the claims are also invalid under *Ariad*—another precedential decision the panel did not address. "[A]n adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries," and "instead requires the disclosure of 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 [a POSA] can visualize or recognize the members of the genus." *Ariad*, 598 F.3d at 1349-50 (quotation omitted). Novartis did not even try to identify "representative species"—and for good reason: there are none described. And the only "common features" that Novartis did rely on—*i.e.*, valsartan and sacubitril—merely "draw a fence around a genus that includes both complexes and physical mixtures of valsartan and sacubitril." Appx45. Moreover, it is undisputed "the '659 patent does not describe a complexed form of valsartan and sacubitril" (Op.13), and that such complexes were "unknown at the time of the invention" (Op.14 n.5). As such, the '659 patent cannot satisfy the written description requirement for genus claims. A POSA could not possibly "visualize or recognize" valsartan-sacubitril complexes when they were not known until years after the date of the invention. *Ariad*, 598 F.3d at 1350.

C. The Decision Contradicts Bedrock Patent Law.

When the claims are evaluated under the district court's construction—*i.e.*, as genus claims embracing all valsartan-sacubitril combinations in a 1:1 ratio, including complexes—at least *Chiron*, *Ariad*, *Juno*, and *Idenix* all dictate the same outcome: the claims fail to meet the written description requirement. But the panel's opinion went in the opposite direction and fundamentally erred for several reasons.

First, the panel found "[b]y stating that the claims were '*construed to cover* complexes of valsartan and sacubitril,' the district court erroneously conflated the distinct issues of patentability and infringement, which led it astray in evaluating written description." Op.13. This contradicts fundamental patent law. Claim construction determines the full scope of the claims, which must be construed the same for patentability and infringement. *See Amazon.com*, 239 F.3d at 1351. To support its holding, the panel relied on *SRI International v. Matsushita Electric Corp. of America*, 775 F.2d 1107 (Fed. Cir. 1985). Op.14. But *SRI* merely held that "[a] claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, *not* in light of the accused device." *SRI*, 775 F.2d at 1118. *SRI* brooks no distinction between patentability and infringement when it comes to claim construction, as the panel believed. Op.13-14. The district court did not run afoul of this precedent.

Instead, the district court construed the claims not with reference to MSN's product, but based on the "intrinsic record" and Novartis's "represent[ation] to the [PTO] that the ['659 patent] cover[s] Entresto, a drug consisting solely of non-separate, complexed valsartan and sacubitril." Appx2103-2105. The district court then properly relied on that construction to find the claims invalid for lack of written description. Appx27-28; Appx43-45. Consistent with *Markman*, the district court simply recognized the claims had been *construed to cover* valsartan-sacubitril

complexes. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim covers the alleged infringer's product or process, which in turn necessitates a determination of what words in the claim mean.") (quotations omitted).

Second, the panel found the claims adequately described because they are directed to valsartan and sacubitril "administered in combination," and that such "combinations" are described in the specification. Op.12-13. But this surface-level, *in ipsis verbis* analysis does not satisfy written description. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968-69 (Fed. Cir. 2002) ("The appearance of mere indistinct words in a specification . . . does not necessarily satisfy [the written description] requirement."); *Ariad*, 598 F.3d at 1350 ("[G]eneric claim language appearing *in ipsis verbis* in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed."). Observing that the "combination" claim term is present in the specification (Op.12-13) does *not* mean the entire claim scope is adequately described. Indeed, the panel acknowledged the '659 patent says nothing about complexes because they were "undisputedly unknown" until years after the priority date. Op.14 n.5.

Third, to justify its decision, the panel effectively narrowed the plain meaning construction of valsartan and sacubitril administered "in combination." It stated that if "the claims were construed to *claim* valsartan-sacubitril complexes," this

"construction would have been error" because "the '659 patent could not have been construed as claiming those complexes as a matter of law." Op.14 n.5. But the claims *were* construed to claim complexes. The plain and ordinary meaning of valsartan and sacubitril administered in combination was broad and was *not* an issue on appeal. Indeed, as mentioned above, Novartis would have been estopped from appealing and disavowing the claim construction it sought and won for infringement purposes. The only issue before the panel was whether the specification adequately described the entire (or full) scope of the claims as construed. *Idenix*, 941 F.3d at 1156 n.3.

The plain meaning of valsartan and sacubitril "in combination" is very broad, and Novartis embraced that breadth by securing its preferred construction for infringement purposes, obtaining a patent term extension, and listing the '659 patent in the Orange Book for Entresto.® Unlike the district court's analysis that did *not* stray from the construction, the panel simply disregarded it (and bedrock patent law) to exclude complexes from the scope of the claims—the opposite of what Novartis sought below.

Finding "the '659 patent could not have been construed as claiming [valsartan-sacubitril] complexes as a matter of law" (Op.14 n.5) means MSN's infringement stipulation (predicated on its product containing a valsartan-sacubitril complex) should be vacated by the district court on remand. It also means the '659

patent should be delisted from the Orange Book. But in its recent briefs (ECF110; ECF115), Novartis claims the '659 patent is now valid and infringed, and that Novartis is entitled to pediatric exclusivity even though the claims do not claim complexes. Novartis cannot have it both ways, twisting the claims like a nose of wax. By analyzing Novartis's plain meaning construction, the panel should have affirmed for lack of written description.

III. THE CLAIMS ARE NOT ENABLED

A patentee must also enable the "full scope" of what is claimed. *Amgen*, 598 U.S. at 610; *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Again, the claimed invention includes all valsartan-sacubitril combinations, including complexes (*supra* § I.B), which were "undisputedly unknown at the time of the invention" (Op.14 n.5). Thus, the '659 patent does not enable the *full scope* of the claims and is invalid. *Amgen*, 598 U.S. at 610.

The panel's decision was premised on the proposition that valsartan-sacubitril complexes are "later-existing" art that cannot be used to judge enablement. Op.15-16 (citing *Hogan*, 559 F.2d at 606). But *Hogan* cannot be read so broadly, and certainly does not discard the fundamental proposition that where, as here, claims are construed to encompass later-arising technology for infringement purposes, the full scope of the claims, including such later-arising technology, must be enabled. *See Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1341 (Fed.

Cir. 2003) (holding claims invalid as not enabled, notwithstanding *Hogan*, where "[patentee] concedes that the cell claims cover [later-developing] monocot cells" because "[o]nly by doing so can [patentee] sue [defendant], which makes monocot products, for infringement"); *Chiron*, 363 F.3d at 1263 (Bryson, J., concurring) ("[W]here the claims are accorded a scope that exceeds the scope of the enablement, I would hold that the claims are . . . not enable[d]."); *Idenix*, 941 F.3d at 1164 (finding no enablement where inventors "only came up with [an undescribed] embodiment a year or so after the application was filed") (quotation omitted). Reading these cases otherwise creates "an uneasy discrepancy between the scope of infringement and the scope of enablement." Appx39, n.15.

Novartis had to enable valsartan-sacubitril complexes here because the claims were construed to encompass those complexes at its request and to its benefit for infringement. *Supra* § I.B. To the extent *Hogan* and its progeny hold that later-arising technology is *per se* irrelevant to enablement, even if the claims are construed to encompass such technology for infringement—those cases should, and indeed must, be overruled as directly contrary to Supreme Court precedent that "the specification must enable the full scope of the invention as defined by its claims." *Amgen*, 598 U.S. at 610. *Amgen* creates no exception for later-arising technology. Quite the contrary, "the more a party claims, the broader the monopoly it demands, the more it must enable." *Id*. at 613. The claims here—broadly construed to cover

all combinations for infringement without exception—cannot withstand that scrutiny, let alone avoid enabling that broad scope.

CONCLUSION

For the foregoing reasons, panel or en banc rehearing should be granted.

Dated: February 10, 2025

Respectfully submitted,

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Dated: February 10, 2025

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Statutory Addendum

35 U.S.C. § 112 ¶ 1 (pre-AIA)

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.

35 U.S.C. § 112(a) (AIA)

In General.--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 or joint inventor of carrying out the invention.

Panel Opinion

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

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

2023-2218, 2023-2220, 2023-2221

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

Decided: January 10, 2025

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for plaintiff-appellant. Also represented by SETH W. LLOYD; NICHOLAS NICK KALLAS, CHRISTINA A. L. SCHWARZ, Venable LLP, New York, NY.

WILLIAM A. RAKOCZY, Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL, argued for defendants-appellees. Also represented by KEVIN E. WARNER; RONALD M. DAIGNAULT, RICHARD JUANG, Daignault Iyer LLP, Vienna, VA.

Before LOURIE, PROST, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Following a three-day bench trial, the United States District Court for the District of Delaware determined that

claims 1–4 of U.S. Patent 8,101,659 ("the '659 patent") were not shown to be invalid for obviousness, lack of enablement, or indefiniteness, but were shown to be invalid for lack of written description. *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-md-2930, 2023 WL 4405464, at *13, *21, *22 (D. Del. July 7, 2023) ("*Decision*"). Judgment was entered on those grounds. Appellant Novartis Pharmaceuticals Corporation ("Novartis") challenges the district court's written description determination. Appellees MSN Pharmaceuticals, Inc., MSN Laboratories Private Ltd., and MSN Life Sciences Private Ltd. (collectively, "MSN")[1] argue that the judgment of invalidity should be affirmed, either by affirming the district court's written description determination or, alternatively, by reversing the district court's obviousness or enablement determinations.

For the following reasons, we reverse the district court's determination that the claims lack an adequate written description, and we affirm its determinations that the claims were not shown to be invalid as either non-enabled or obvious.

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[1] Of the presently named defendants, only MSN participates in this appeal. Each of Hetero USA Inc., Hetero Labs Limited, Hetero Labs Limited Unit-III (collectively, "Hetero"), Torrent Pharma Inc., Torrent Pharmaceuticals Ltd. (collectively, "Torrent") have since settled their disputes with Novartis. *See* ECF Nos. 57, 58, 61, 78. Moreover, Novartis indicated that it noted an appeal in its case against Alembic Pharmaceuticals, Ltd. and Alembic Pharmaceuticals, Inc. (collectively, "Alembic") only "[o]ut of an abundance of caution." ECF No. 15 at 2 n.1. But because the case against Alembic is stayed and because Alembic did not participate in the trial on the merits, "Alembic is not an appellee here." *Id.*

BACKGROUND

I

In 2015, the U.S. Food and Drug Administration ("FDA") approved the New Drug Application ("NDA") for a combination therapy of valsartan and sacubitril, which Novartis markets and sells under the brand name Entresto®. Entresto includes valsartan and sacubitril in a specific form known as a "complex," which combines the two drugs into a single unit-dose-form through weak, non-covalent bonds. Valsartan is an angiotensin receptor blocker ("ARB") that prevents angiotensin II from binding to its receptor, thereby reducing the blood-vessel-constricting effects of angiotensin II, a naturally occurring hormone. Sacubitril is a neutral endopeptidase ("NEP") inhibitor that, like valsartan, reduces blood vessel constriction, but does so through a mechanism-of-action not involving angiotensin. At the time of its initial approval, Entresto was indicated to treat heart failure with reduced ejection fraction. In 2019, Entresto was additionally approved for the treatment of heart failure in children, and, in 2021, it was approved for the treatment of heart failure with a preserved ejection fraction. In 2023 alone, sales of Entresto in the United States totaled more than $3 billion.

Entresto is protected by a number of patents, including the '659 patent, which was timely listed in the Orange Book. The '659 patent has a priority date of January 17, 2002, and will expire on January 15, 2025, due to the grant of Patent Term Extension ("PTE"). The '659 patent explains that, at the time of the invention, "the most widely studied" drugs to treat hypertension and heart failure were a class of drugs called angiotensin converting enzyme ("ACE") inhibitors. '659 patent, col. 1 ll. 55–61. Like valsartan and other ARBs, ACE inhibitors' function involves angiotensin. But instead of preventing angiotensin II from binding to its receptor, ACE inhibitors reduce vasoconstriction by blocking the initial formation of

angiotensin II. *See Decision*, at *4. The '659 patent explains that, although ACE inhibitors prevent the formation of vasoconstrictive angiotensin II, research showed that the effects of those drugs may be attributed to other pathways. '659 patent, col. 2 ll. 6–9. The patent also sets forth that, at the time of the invention, research showed that NEPs, like sacubitril, can lower blood pressure and exert effects such as diuresis. *Id.* col. 2 ll. 39–41. Sacubitril had been discovered and patented by a predecessor to Novartis in 1992, but as of the time of the invention, it "had never been administered to humans or tested in an animal model of hypertension and heart failure." *Decision*, at *7.

The patent explains that, because "the nature of hypertensive vascular diseases is multifactorial[,] . . . drugs with different mechanisms of action have been combined." '659 patent, col. 2 ll. 65–67. But "just considering any combination of drugs having different modes of action does not necessarily lead to combinations with advantageous effects." *Id.* col. 2 l. 67–col. 3 l. 3. Accordingly, the inventors of the '659 patent sought to discover a "more efficacious combination therapy which has less deleterious side effects." *Id.* col. 3 ll. 3–5. And as the specification explains, it was "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." *Id.* col. 6 ll. 41–44.

The '659 patent has four claims, all of which are asserted here. Claim 1, the sole independent claim, recites:

> 1. A pharmaceutical composition comprising:
>
> (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof;

> (ii) the NEP inhibitor [sacubitril] or [sacubitrilat][2] or a pharmaceutically acceptable salt thereof; and
>
> (iii) a pharmaceutically acceptable carrier;
>
> wherein said (i) AT 1-antagonist valsartan or pharmaceutically acceptable salt thereof and said (ii) NEP inhibitor [sacubitril] or [sacubitrilat] or a pharmaceutically acceptable salt thereof, are administered in combination in about a 1:1 ratio.

'659 patent, col. 16 ll. 17–33. Claim 2 recites that the valsartan and the NEP inhibitor "are administered in amounts effective to treat hypertension or heart failure," *id.* col. 16 ll. 34–41; claim 3 recites that the NEP inhibitor is sacubitril, *id.* col. 16 ll. 42–45; and claim 4, which depends from claim 3, recites that the composition is in the form of a capsule or tablet, *id.* col. 16 ll. 46–47. On appeal, the validity of all of the claims rests on the same bases, so we will not treat them separately.

II

In 2019, MSN, among other generic manufacturers, submitted an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market and sell a generic version of Entresto. Novartis sued MSN and the other generic manufacturers, alleging that the filing of the ANDA directly infringed claims 1–4 of the '659 patent.

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[2] Sacubitrilat is the active metabolite of the prodrug sacubitril, which means that, when sacubitril is ingested into the body, it is metabolized to sacubitrilat. *Decision*, at *1 n.3. The parties and district court used the term "sacubitril" to refer collectively to sacubitril, sacubitrilat, and their pharmaceutically acceptable salts. *Id.* Unless it is otherwise clear from context, we follow that convention here.

Those cases were consolidated in multidistrict litigation in Delaware and proceeded to discovery.

A. Claim Construction

At claim construction, the parties disputed only a single term of the '659 patent: "wherein said [valsartan and sacubitril] are administered *in combination*." *See In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-md-2930, 2021 WL 2856683, at *3 (D. Del. July 8, 2021) ("*Claim Construction Decision*") (emphasis added). MSN argued that the term limited the claim to administration of the active agents valsartan and sacubitril "as two separate components." *Id.* As context for that position, according to MSN, the accused generic product, like Entresto, comprises a complex of non-covalently bonded valsartan and sacubitril. MSN Br. 1. Accordingly, if the claims were read to require the valsartan and sacubitril to be administered as separate components (*i.e.*, in a non-complexed form, such as a physical mixture), then MSN's generic product would not infringe the '659 patent. For its part, Novartis argued that the claim was not so limited, and that the term should be given its plain and ordinary meaning. *See Claim Construction Decision*, at *3.

The district court agreed with Novartis and gave the term its plain and ordinary meaning: "wherein said [valsartan and sacubitril] are administered in combination." *Id.* In rejecting MSN's proposal, the court observed that the intrinsic record "is silent on whether sacubitril and valsartan must be separate (and not complexed)." *Id.* It explained that "the absence of any indication in the written description that the patentee limited its invention solely to separate compounds means, in context, that a person of ordinary skill in the art [] would not read the claims as so limited." *Id.* The court found that the representations Novartis had made to the U.S. Patent and Trademark Office ("the Patent Office") to obtain PTE further bolstered that conclusion. *Id.* Specifically, Novartis told the Patent Office that the claims of the '659

patent recite compositions that include Entresto, a drug that includes "non-separate, complexed valsartan and sacubitril." *Id.*; *see* Novartis Br. 16. The court found that a person of ordinary skill in the art would have given that evidence at least some weight in understanding the meaning of the disputed term. *Claim Construction Decision*, at *3.

Based in part on those representations to the Patent Office, MSN argued that Novartis's position—that the plain and ordinary meaning of the claim scope encompasses valsartan-sacubitril complexes—would render the claims invalid for lack of written description and enablement because the specification nowhere describes such complexes. *Id.* at *4. The court rejected this argument, finding "no basis to believe that the construction [the court] adopt[ed was] necessarily consigning the asserted claims to a judgment of invalidity." *Id.* After claim construction, MSN stipulated to infringement of the asserted claims. *Decision*, at *1.

B. Bench Trial

The case proceeded to a three-day bench trial on the issues of obviousness, lack of written description, and non-enablement.[3] *Id.*

1. Obviousness

At trial, MSN set forth two theories of obviousness. First, it argued that a person of ordinary skill in the art would have been motivated to modify a prior art ARB-NEP inhibitor combination therapy—specifically, one using the

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[3] MSN also argued the claims were invalid as indefinite. Finding that MSN raised that argument only in a footnote of its opening post-trial brief, the district court deemed the argument forfeited. *Id.* at *22. Neither party addresses indefiniteness on appeal, so we too do not consider it.

ARB irbesartan and an NEP inhibitor named "SQ 28,603"—with valsartan and sacubitril to arrive at the claimed invention. *Id.* at *10. Alternatively, MSN argued that a person of ordinary skill in the art would have been motivated to individually select and combine sacubitril and valsartan from two different prior-art references to arrive at the claimed invention. *Id.* The court was unpersuaded by both theories.

Although the court found persuasive MSN's argument that a person of ordinary skill in the art would have understood "that the combination of an ARB (irbesartan) and a NEP[inhibitor] (SQ 28,603) achieved synergistic results," the court ultimately concluded that, even if a person of ordinary skill in the art would have been motivated to pursue an ARB-NEP inhibitor combination, MSN "fail[ed] to provide clear and convincing evidence that a [person of ordinary skill in the art] would have been motivated to select the ARB valsartan and the NEP[inhibitor] sacubitril specifically." *Id.* Indeed, the court found that, as of 2002, sacubitril "had never been administered to humans or tested in an animal model of hypertension and heart failure," and that, of the NEP inhibitors that had been so tested, the results had been "discouraging." *Id.*

In rejecting MSN's challenges, the court further noted that none of the prior art "combined valsartan with sacubitril, sacubitril with an ARB, or valsartan with a[n] NEP[inhibitor]." *Id.* at *12. It also observed that neither valsartan nor sacubitril were considered promising treatments for cardiac conditions in 2002. *Id.* Most importantly, in the court's view, was "the fact that a large number of hypertension and heart failure drugs and drug classes were known in 2002—including multiple ARBs and a myriad of NEP[inhibitors]—with no clear hierarchy within the ARB and NEP[inhibitor] classes and no available information pointing directly at the claimed valsartan-sacubitril combination." *Id.* The court further

rejected MSN's "obvious-to-try" theory on the grounds that there was a "surfeit of potentialities with respect to drug combinations for heart failure and hypertension treatment," such that MSN's obviousness theory hinged on impermissible hindsight. *Id.* at *13.

Accordingly, the court determined that MSN had not shown by clear and convincing evidence that the claims of the '659 patent were invalid as obvious. *Id.*

2. Written Description and Enablement

The court then turned to the issues of written description and enablement. Guided by the understanding that the court had "construed the asserted claims to cover valsartan and sacubitril as a physical combination and as a complex," *id.* at *17, the parties' dispute centered on whether the '659 patent was required to enable and describe such complexes. MSN argued that it was, since a patent must enable and describe the full scope of the claims. *E.g.*, *id.* at *17, *21. Novartis disagreed, arguing that a complex of valsartan and sacubitril was an after-arising invention that need not have been enabled or described. *E.g.*, *id.* at *18–19. More specifically, Novartis contended that its "later, nonobvious discovery of valsartan and sacubitril in the form of a complex should not invalidate the '659 patent claims to Novartis's earlier invention: the novel combination of valsartan and sacubitril." J.A. 4219. The court agreed with Novartis on the issue of enablement, but with MSN on the issue of written description.

With respect to enablement, the court determined that, because enablement is judged as of the priority date, later-existing state of the art may not be properly considered in the enablement analysis. *Decision*, at *19 (relying on *In re Hogan*, 559 F.2d 595 (CCPA 1977); *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)). And because complexes of valsartan and sacubitril

were unknown in the art in 2002, the court determined that they need not have been enabled in the '659 patent. *Id.* at *20. The court further found that MSN had failed to establish that pharmaceutical complexes, more generally, were known or were nascent technology as of the 2002 priority date. *Id.* at *20–21. Accordingly, the court determined that MSN had failed to establish that the claims of the '659 patent were invalid for lack of enablement.

The court reached the opposite conclusion with respect to written description. Relying primarily on *Chiron*, the court found that "the facts that helped [Novartis] with respect to enablement proved fatal for written description." *Id.* at *21. Specifically, because it was undisputed that complexes were unknown to a person of ordinary skill in the art, "'[Novartis] scientists, by definition, could not have possession of, and disclose, the subject matter of [such complexes]' in 2002, and therefore, 'axiomatically, [Novartis] cannot satisfy the written description requirement' for such complexes." *Id.* at *22 (quoting *Chiron*, 363 F.3d at 1255 (first and second alteration in original)). Thus, the court found the claims invalid for lack of written description and entered judgment on that basis.

Novartis timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

Novartis challenges the district court's findings on written description. MSN counters that, even if the claims are supported by adequate written description, the judgment of invalidity should be affirmed by reversing the district court's determinations on obviousness and enablement. We address each issue in turn.

I

We begin with written description. The issue on appeal is whether the '659 patent describes what is claimed, viz.,

a pharmaceutical composition comprising valsartan and sacubitril administered "in combination." The issue is *not* whether the '659 patent describes valsartan-sacubitril complexes. Because the '659 patent does not claim valsartan-sacubitril complexes, those complexes need not have been described.

As we have long recognized, "[t]he invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991). "A specification adequately describes an invention when it 'reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021) (quoting *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). The scope of what is claimed (and must be adequately described) is, in turn, determined through claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ("It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled a right to exclude." (internal quotation marks and citation omitted)).

Recall that, at claim construction, MSN sought—as accused infringers often do—a construction that would exclude from infringement the accused product: a valsartan-sacubitril complex. The court ultimately rejected MSN's proposed construction because the '659 patent "is silent on whether sacubitril and valsartan must be separate (and not complexed)." *Claim Construction Decision*, at *3. The term was therefore given its plain and ordinary meaning: "wherein said [valsartan and sacubitril] are administered in combination." *Id*.

That invention is plainly described throughout the specification. For example, the opening sentence of the detailed description provides that "the present invention relates to pharmaceutical *combinations comprising*

valsartan . . . and *a NEP inhibitor* . . . and pharmaceutical compositions comprising them." '659 patent col. 3 ll. 20–25 (emphases added); *see also id.* col. 6 ll. 65–67 ("It can be shown that *combination therapy with valsartan and a NEP inhibitor* results in a more effective anti-hypertensive therapy[.]" (emphasis added)). The patent further specifies that the NEP inhibitor used in combination with valsartan can be sacubitril. *Id.* col. 7 ll. 33–36 ("Representative studies are carried out with a *combination* of valsartan and [sacubitril.]" (emphasis added)). And it further teaches that "[a] therapeutically effective amount of each of the component[s] *of the combination of the present invention* may be administered simultaneously or sequentially in any order." *Id.* col. 10 ll. 57–59 (emphasis added). Those disclosures (and more) plainly show that the inventors had possession of a pharmaceutical composition comprising valsartan and sacubitril administered "in combination." Indeed, even MSN's expert conceded that the '659 patent adequately discloses administration of valsartan and sacubitril in combination as a physical mixture. *See* J.A. 3322. Thus, the claims are supported by an adequate written description.[4]

The fact that the '659 patent does not describe a complexed form of valsartan and sacubitril does not affect the validity of the patent. That complex—not discovered until four years after the priority date of the '659 patent—is not what is claimed. By stating that the claims were "*construed to cover* complexes of valsartan and sacubitril," the district court erroneously conflated the distinct issues of patentability and infringement, which led it astray in evaluating written description. *Decision*, at *15 (emphasis added). Written description asks whether that

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[4] MSN does not argue that the other limitations of the asserted claims are not adequately described. Accordingly, we focus our inquiry on only the disputed claim term: "in combination."

which is claimed is adequately described. As we have explained:

> [C]laims are not construed "to cover" or "not to cover" the accused [product]. That procedure would make infringement a matter of judicial whim. It is only *after* the claims have been *construed without reference to the accused device* that the claims, as so construed, are applied to the accused device to determine infringement.

SRI Int'l, 775 F.2d at 1118.

Here, after claim construction, MSN stipulated to infringement of the as-construed claims.[5] In light of that stipulation and the fact that the '659 patent does not claim valsartan-sacubitril complexes, any further issue regarding such complexes is not before us.

For those reasons, we hold that the district court clearly erred in finding that claims 1–4 of the '659 patent are invalid for lack of written description. The patent has an adequate written description of what is claimed.

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[5] To the extent MSN maintains that the claims were construed to *claim* valsartan-sacubitril complexes (*i.e.*, to the extent MSN alleges that its stipulation of infringement was made on that basis), that construction would have been error. "Claim interpretation requires the court to ascertain the meaning of the claim to one of ordinary skill in the art *at the time of invention*." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1338 (Fed. Cir. 2005) (emphasis added); *see Phillips*, 415 F.3d at 1313. Because valsartan-sacubitril complexes were undisputedly unknown at the time of the invention, *see Decision*, at *20, the '659 patent could not have been construed as claiming those complexes as a matter of law.

II

We affirm the district court's enablement determination for reasons similar to those that led us to reverse its written description determination: a specification must only enable the *claimed* invention. *See Amgen v. Sanofi*, 598 U.S. 594, 610 (2023).

The invention of the '659 patent, as construed by the district court, is a composition in which valsartan and sacubitril are administered "in combination." As explained above, the patent does not claim as its invention valsartan-sacubitril complexes. Indeed, Novartis obtained separate, later patents to such complexes. *See Claim Construction Decision*, at *1 (noting that "[s]everal years" after filing the '659 patent, "Novartis developed a novel compound comprising non-covalently bound valsartan and sacubitril salts," which are disclosed in U.S. Patents 8,877,938 and 9,388,134).

The district court correctly recognized that valsartan-sacubitril complexes, which include the claimed invention along with additional unclaimed features, are part of a "later-existing state of the art" that "may not be properly considered in the enablement analysis." *Decision*, at *19; *see In re Hogan*, 559 F.2d 595, 606 (CCPA 1977) (holding that enablement must be judged in light of the state of the art at the time of filing); *Plant Genetic*, 315 F.3d at 1340 ("[O]ne [can]not use a later-existing state of the art to invalidate a patent that was enabled for what it claimed at the time of filing."). As our predecessor court explained:

> The use of a subsequently-existing improvement to show lack of enablement in an earlier-filed application on the basic invention would preclude issuance of a patent to the inventor of the thing improved, and in the case of issued patents, would invalidate all claims (even some "picture claims") therein. Patents are and should be granted to later inventors upon unobvious improvements. Indeed,

> encouragement of improvements on prior inventions is a major contribution of the patent system and the vast majority of patents are issued on improvements. It is quite another thing, however, to utilize the patenting or publication of later existing improvements to "reach back" and preclude or invalidate a patent on the underlying invention.

Hogan, 559 F.2d at 606. That is precisely the case here. 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.

Thus, because the '659 patent does not expressly claim complexes, and because the parties do not otherwise dispute that the '659 patent enables that which it does claim, we affirm the district court's determination that MSN failed to show that the claims are invalid for lack of enablement.

III

Finally, we turn to obviousness. "Obviousness is a question of law based on underlying findings of fact." *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1364 (Fed. Cir. 2022) (citations omitted). Whether a person of ordinary skill in the art would have been motivated to combine the prior-art references to arrive at the claimed invention is a factual question we review for clear error. *Id.*

We see no clear error warranting reversal of the district court's obviousness analysis. The district court found that, even if a person of ordinary skill in the art had been motivated to provide an ARB-NEP inhibitor combination therapy, there was no motivation in the relied-upon prior art to combine valsartan and sacubitril, let alone with any reasonable expectation of success. As of 2002, sacubitril was one of over 100 known NEP inhibitors, it had never

been administered to humans or animals, and the clinical results of other NEP inhibitors in hypertension and heart failure patients had been "discouraging." *See Decision*, at *7.

Those facts, as the district court acknowledged, distinguish this case from *Nalproprion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019), and *BTG International Ltd. v. Amneal Pharmaceuticals LLC*, 923 F.3d 1063 (Fed. Cir. 2019), on which MSN relies. In each of those cases, the prior art showed that the claimed drugs "were both together and individually considered promising . . . treatments at the time [of the invention]." *BTG*, 923 F.3d at 1074; *see Nalproprion Pharms.*, 934 F.3d at 1354 (concluding that, because the prior art taught that each drug could cause weight loss effects, "a person of ordinary skill would have been motivated to combine them" to promote weight loss). That is not the case here, at least with respect to sacubitril. We therefore agree with the district court that MSN's obviousness theories impermissibly use valsartan and sacubitril as a starting point and "retrace[] the path of the inventor with hindsight." *Decision*, at *13 (citation omitted).

Accordingly, because we see no errors in the district court's factual findings or application of the law, we affirm the district court's determination that MSN failed to establish that the claims would have been obvious.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we reverse the district court's finding that the claims lack adequate written description, and we affirm its determinations that the claims were not shown to have been obvious or non-enabled.

AFFIRMED IN PART, REVERSED IN PART

COSTS

Costs to Novartis.