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

[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.