IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	Civil Action No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, NANJING NORATECH PHARMACEUTICAL CO., LIMITED, and GERBERA THERAPEUTICS INC., Defendants.	Civil Action No. 22-cv-1395-RGA

MEMORANDUM OPINION

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May 31, 2024

ANDREWS, U.S. DISTRICT JUDGE:

Before me is the issue of claim construction of one term in U.S. Patent No. 11,096,918 ("the '918 patent"). The parties submitted a Joint Claim Construction Brief. (D.I. 146).[1] I heard oral argument on March 12, 2024. (Markman Tr.).[2] At my request, the parties submitted post-*Markman* hearing supplemental briefing. (D.I. 163, 164, 165).

I. BACKGROUND

On October 24, 2022, Plaintiff Novartis filed a complaint alleging infringement of the '918 patent by Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, MSN Life Sciences Private Limited, and Nanjing Noratech Pharmaceutical Co., Limited. (D.I. 1). The complaint also accused several other firms who have since been terminated from this case. (*See* D.I. 68, 124, 140, 151). Gerbera Therapeutics Inc. was joined as a Defendant on April 26, 2024. (D.I. 181). This case is part of a group of patent infringement actions related to Plaintiff's Entresto product and associated patents. (*See* MDL No. 20-2930-RGA). The '918 patent covers the amorphous solid form of a compound ("TVS") present in Entresto that is comprised of sacubitril, valsartan, and sodium cations. (*See* D.I. 1 ¶ 1; '918 patent; Abstract). The '918 patent descends from U.S. Patent No. 9,388,134 ("the '134 patent") and U.S. Patent No. 8,877,938 ("the '938 patent"). The '134 patent is a child of the '938 patent. The '134 and '938 patents cover a compound ("TVSH") comprised of sacubitril, valsartan, sodium cations, and water molecules. (*See* D.I. 146 at 5; '134 patent, 31:41–45; '938 patent, 30:56–63).

[1] Docket citations are to Civil Action No. 22-1395 unless otherwise specified.

[2] Citations to the transcript of the argument, which is docketed as D.I. 172, are in the format "Markman Tr. at __."

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (alteration in original) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted). "While claim terms are understood in light of the specification, a claim construction must not import limitations from the specification into the claims." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1354 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1323).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim

construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (quoting *Markman*, 52 F.3d at 980). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

III. CONSTRUCTION OF DISPUTED TERM

The parties agree that claim 1 of the '918 patent is representative for the purpose of claim construction. Claim 1 states:

> 1. ***An amorphous solid form of a compound*** comprising anionic [valsartan[3]], anionic [sacubitril[4]], and sodium cations in a 1:1:3 molar ratio.

('918 patent, 32:42–46 (disputed terms bolded and italicized)).

[3] The chemical name "(S)-N-valeryl-N-{[2'-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine" recited in claim 1 describes valsartan.

[4] The chemical name "(2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester" recited in claim 1 describes sacubitril.

1. **"an amorphous solid form of a compound" ('918 patent, claims 1–2)**

    a. *Plaintiff's proposed construction*: no construction necessary; to the extent claim construction is required, "an amorphous solid form of a compound."[5]
    b. *Defendants proposed construction*: "a substantially pure amorphous solid form of a compound"
    c. *Court's construction*: "a solid form of a compound in which the amorphous form of the compound predominates. An amorphous solid form is mutually exclusive from a crystalline solid form, but not necessarily mutually exclusive from a partially crystalline solid form."

The parties dispute what limitation, if any, the claims contain regarding the purity of the claimed amorphous compound.[6] Plaintiff contends there is no such limitation. Defendants maintain that the amorphous compound must be "substantially pure."

Plaintiff maintains that, in "[a] mixture that contains the amorphous compound as well as other things, that amorphous compound in that mixture is still amorphous TVS. The other components that are present in that mixture with the amorphous TVS really are irrelevant to the claim construction . . . ." (Markman Tr. at 6:8–7:19). As an initial matter, I understand what Plaintiff refers to as a "mixture" to be the "amorphous solid form of a compound" at issue in the claim construction dispute, while the "compounds" and "components" refer to the molecules that make up the solid. This interpretation is consistent with the parties' agreement that a different solid form of the compound referenced in the specification, the "partially crystalline" solid form, "is a mixture of crystalline and amorphous forms." (D.I. 147-1, Ex. A ¶ 31; Markman Tr. at 15:8–10; *see* '918 patent, 17:43–45). This understanding is consistent with Judge Stark's adoption of a purity requirement for the '938 and '134 patent claims covering the crystalline

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[5] I am not sure what Plaintiff is trying to accomplish by proposing that the alternative to no construction is a construction that is word for word the same as the disputed term.

[6] Purity, in the context of the present dispute over the amorphous solid form of TVS, relates to the percentage of the compound that is amorphous rather than crystalline.

solid forms of TVSH.[7] (*See* D.I. MDL 20-2930, D.I. 294 at 8). Applying Plaintiff's proposition to the '938 and '134 patent, *i.e.* that one only need to pay attention to the crystalline TVSH "components" within the "mixture," would render the substantial purity requirement for crystalline TVSH meaningless. I therefore disagree with Plaintiff's assertion that construing the term at issue does not require looking at the overall makeup of the components within the "mixture."

Under this understanding, Plaintiff's position is essentially that any presence of amorphous molecules allows a solid form of a compound to be considered amorphous. (*See* Markman Tr. at 46:1–7). This interpretation conflicts with the prosecution history. During prosecution of the '918 patent, Plaintiff submitted a declaration by Dr. Michael J. Cima. (*See* D.I. 147-1, Ex. 9). Dr. Cima's declaration explains that amorphous and crystalline solid forms are distinguishable and exhibit different properties. (*See id.* ¶ 14 ("Morissette states that co-crystals have the potential to be much more useful in pharmaceutical products than solvates or hydrates. However, this is not pertinent or informative with respect to amorphous solids.") (citation omitted) (cleaned up); *id.* ¶ 17 ("Generally speaking, an amorphous complex of two drugs is not necessarily easier to form than a crystalline complex of these drugs. Likewise, the formation of such an amorphous complex is not any more reasonably predictable than the formation of the crystalline complex."); *id.* ¶ 18 ("Rodriguez-Spong notes that an amorphous solid form of a compound can exhibit greater solubility or bioavailability than the crystalline solid form of the same compound. *See* Rodriguez-Spong, p. 252 ('Pharmaceutical glasses or

[7] While the '938 and '134 patents do not claim the same compound as the '918 patent, TVSH and TVS are closely related compounds and the patents share similar specifications that discuss substantial purity and solid forms in the same way. (*Compare* '918 patent, 6:40–43, 17:43–45 *with* '134 patent, 6:6–10, 15:63-67 *and* '938 patent, 6:13–17, 16:60–64).

amorphous solids present an attractive approach to drug delivery because of their improved bioavailability compared to their crystalline counterparts.').") (emphasis omitted)). The prosecution history thus makes clear that these two forms are distinct from each other.

I note that I do not reach the same conclusion regarding mutual exclusivity between the amorphous solid form and other solid forms, namely the partially crystalline form. Defendants' argument for mutual exclusivity among all forms relies on one sentence from the patent specification: "In the solid state [TVS] can be in the crystalline, partially crystalline, amorphous, or polymorphous form, preferably in the crystalline form."[8] ('918 patent, 17:43–45; *see* D.I. 146 at 12–13). A facial reading of the cited text suggests that these forms are different, but does not exclude the possibility of overlap.[9] Defendants do not point to any intrinsic evidence that suggests these categories are mutually exclusive.[10] In contrast, the parties' agree that the

[8] I understand the polymorphous form to be a category not relevant to any issues in this case. I therefore focus on the relationship between the amorphous form and the partially crystalline form.

[9] I asked the parties to search for Federal Circuit case law in support of their positions about whether a series of terms in the specification should be read as suggesting mutual exclusivity. (Markman Tr. at 54:6–56:15). Defendants' identified cases, *Duke Univ. v. BioMarin Pharm. Inc.*, 685 F. App'x 967 (Fed. Cir. 2017) and *Perfect Surgical Techs., Inc. v. Olympus America, Inc.*, 841 F.3d 1004 (Fed. Cir. 2016), appear inapposite and do not affect my reading of the terms. Both cases involve only two terms, rather than a series of terms, determined to be alternatives based on broader context. *See Duke Univ.*, 685 F. App'x at 976 (discussing a precursor form and a mature form of human acid α-glucosidase that were referred to in the specification as "alternative[]" embodiments); *Perfect Surgical Techs.*, 841 F.3d at 1012 (concluding the specification's usage of the disjunctive phrase "or otherwise" in the sentence "the jaws may be perforated or otherwise provided with passages" demonstrated the terms did not refer to the same things).

[10] Defendants did provide extrinsic evidence in the form of an expert declaration by Dr. Edmund J. Elder. (*See* D.I. 147-1, Ex. A). Dr. Elder's opinion is the weakest sort of extrinsic evidence. Dr. Elder bases his opinion on a facial reading of the referenced sentence and what it "states explicitly." (*Id.* ¶ 31). I do not think his opinion is drawing on any scientific expertise, and, in any event, I do not credit it.

partially crystalline form of the compound "is a mixture of crystalline and amorphous forms" (D.I. 147-1, Ex. A ¶ 31; Markman Tr. at 15:8–10), which suggests potential overlap along the spectrum of amorphous, partially crystalline, and crystalline forms. I find that the intrinsic record does not support a finding of mutual exclusivity between amorphous and partially crystalline forms.

While I agree with Defendants that construction of the disputed term must distinguish between the amorphous and crystalline forms, I do not agree that "substantially pure" is the proper dividing line. The '918 patent specification only uses the term "substantially pure" in discussing a preferred embodiment. (*See*'918 patent, 6:40–41 ("Preferably, the linked pro-drug is substantially pure . . . .")). "[I]t is improper to read limitations from a preferred embodiment described in the specification . . . into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004). To support its position, Defendants primarily rely on the prosecution histories of the '134 and '938 patents, which are ancestors of the '918 patent. (*See* D.I. 146 at 13).

During prosecution of the '938 patent, Plaintiff and the Examiner agreed that the crystalline form of TVSH must be "substantially pure." (D.I. 147-2, Ex. 5). In construing claim terms of the '938 and '134 patents, Judge Stark ruled that claims covering crystalline compounds in the '134 patent, using the same language as the '938 patent claims, imported this purity limitation. (MDL 20-2930, D.I. 294 at 10–11 (citing *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999))). He declined to apply this requirement to other claims of the '134 patent that are not limited to a crystalline form. (*Id.* at 11 (citing *Ventana Med. Sys., Inc. v. Biogenex Lab'ys, Inc.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006) ("[T]he doctrine of prosecution

disclaimer generally does not apply when the claim term in the descendant patent uses different language."); *Broadridge Fin. Sols. Inc. v. Inveshare, Inc.*, 2012 WL 1245723, at *4 (D. Del. Apr. 11, 2012) ("[E]ven if the [parent] patent disclaimer relates to the same subject matter at issue in the [child] patent claims, it may not necessarily affect the [child patent's] claim construction if the claim language is materially different."))).

Defendants argue that their construction adopts "parallel claim language" required to make the disputed term "internally consistent with what came before." (Markman Tr at 42:15–18). I disagree. As I stated at oral argument, Defendants are "seizing on a construction . . . made in a related patent for a different term, based on a different intrinsic record." (*Id.* at 41:9–11). *Ventana* and *Broadridge*, the cases Judge Stark cited in the '134 patent claims that were not limited to crystalline compounds, suggest the limitation should not be applied to the disputed term. *See Ventana*, 473 F.3d at 1182; *Broadridge*, 2012 WL 1245723, at *4.

Defendants appeared to recognize the lack of support for their proposed terminology, as they expressed flexibility with alternative constructions, such as "not partially crystalline" or "isn't trace amounts." (Markman Tr. at 40:17–41:1, 46:1–7). Defendants indicated they were seeking "any construction that . . . distinguishes [the amorphous, partially crystalline, crystalline, and polymorphous] buckets from one another." (*Id.* at 42:12–14). A determination that a construction of the terms should include line-drawing, however, is an insufficient reason to adopt a specific demarcation that is unsupported by the intrinsic record.

While I reject Defendants' formulation, I concede the difficulty of pinpointing an appropriate limitation when the intrinsic record provides virtually no useful guidance. What is clear, from the prosecution history, is that a POSA can identify a compound as existing in an "amorphous solid form," as opposed to other forms (though it may, as indicated above,

simultaneously qualify as existing in a partially crystalline solid form). Additionally, an amorphous solid form exhibits certain distinctive properties, as described by Dr. Cima. To embody these properties, rather than properties associated with a crystalline solid, it follows that an amorphous solid form of a compound must be predominantly amorphous. I therefore adopt a definition that encompasses an amorphous solid form's primary nature and its distinctiveness from a crystalline solid form.

IV. CONCLUSION

For the reasons stated, I adopt the above construction.