IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD., *Plaintiff*, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., *Defendants*.	C.A. No. 21-900-RGA

MEMORANDUM OPINION

Before me is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,501,730 ("the '730 patent") and U.S. Patent No. 10,905,694 ("the '694 patent"). The parties submitted a Joint Claim Construction Brief (D.I. 53), and I heard oral argument on July 1, 2022.

The parties argued five terms. I orally ruled on two terms in their entirety. I rejected Defendants' indefiniteness argument in relation to the term "substantially free from." (Tr. at 47:8-48:11).[1] I also rejected Defendants' construction inserting "and is LH-11 low substituted hydroxypropylcellulose" into Claim 1 of the '694 patent. (Tr. at 89:21-24). I now construe the three remaining terms.

I. 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

[1] Citations to the transcript of the argument, which is not yet docketed, are in the format "Tr. __."

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.*, WL 47758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). 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).

"[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 (internal citations omitted).

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 Pharm. 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 (internal quotation marks and citations omitted). 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.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

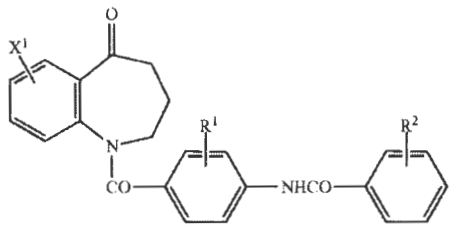
II. CONSTRUCTION OF DISPUTED TERMS

A. The '730 Patent

Claim 1 of the '730 patent is representative of the two disputed terms in the '730 patent:

> A highly pure 7-chloro-5-hydroxy-1-[2-methyl-4-(2-methylbenzoylamino)benzoyl]-2,3,4,5-tetrahydro-1H-1-benzazepine having a purity of more than 99.5%, or a salt thereof, which is produced by the process which comprises reducing a benzazepine compound of the formula (1):

(1)



> wherein X^1 is a halogen atom, R^1 and R^2 are independently a lower alkyl group or a salt thereof in the presence of a hydrogenating agent selected from the group consisting of lithium aluminum hydride, sodium borohydride, zinc borohydride, and diborane *in an amount of 0.25 to 1 mole per 1 mole of the compound (1).*

('730 patent, claim 1) (disputed claim construction term emphasized).

1. "in an amount of 0.25 to 1 mole per 1 mole of the compound (1)" ('730 patent, claims 1-4)

   a. *Plaintiff's construction*: No construction necessary, i.e., plain and ordinary meaning

   b. *Defendants' construction*: "using a total amount in a molar ratio of no less than one quarter of to no more than equal to the moles of compound (1)"

   c. *Court's construction*: No construction necessary

At the oral argument, I rejected Defendants' proposed insertion of "total" to modify "amount." (Transc. at 27:22-28:9). All that remains to consider is the proper construction of the numerical range.

In support of their construction of the numerical range, Defendants argue that the prosecution history and Plaintiff's previous statements indicate that the numerical range is not "soft" or an "approximation." (D.I. 53 at 14-15). Plaintiff argues that the term requires no construction because its meaning is clear to a POSA. (D.I. 53 at 8-10). Plaintiff also argues that Defendants' construction would generate confusion because it removes significant figures from the term and merely paraphrases the term. (D.I. 53 at 19-20).

The Court finds that this term does not require construction. Though the term lacks words of approximation in specifying the numerical range, it also lacks words indicating exactitude or a particular degree of precision. Because the term as written suggests neither approximation nor a particular degree of precision, I reject any construction intended to connote greater precision than "1 mole per 1 mole" or "0.25 [moles] . . . per 1 mole." Though "reading a margin of error into the disputed claim term" is not appropriate, *see Takeda Pharm. Co v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1363 (Fed. Cir. 2014), "[i]t is usually incorrect to read numerical precision into a claim from which it is absent[.]" *See Modine Mfg. Co. v. United States ITC*, 75 F.3d 1545, 1551 (Fed. Cir. 1996). Defendant is correct that because the claim term lacks "broadening words," the

numerical range in this claim involves a "strict numerical boundary." *See Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1381 (Fed. Cir. 2000). But whether a particular molar concentration exceeds the strict numerical boundary of a "1 mole per 1 mole" ratio is a factual determination that is left for trial, not claim construction.

Defendants argue that their construction is supported by Plaintiff's prior formulations of the numerical range using terms such as "equal molar or less" and "equimolar or less" and "the same" number of moles. (D.I. 53 at 12-14, 23). Defendants assert that these formulations more clearly reflect that the claim term does not involve a "soft" upper limit on the number of moles. (D.I. 53 at 14). But Defendants' construction is no more precise than the current term language.[2] Indeed, Defendants' own construction is just as subject to the same arguments they make in relation to the actual claim term. It can be understood "softly." "No more than equal" is no more precise than "1 per 1." Therefore, whether a molar concentration is within the term's numerical range remains a question of fact even under Defendants' construction.

For these reasons, I will not adopt Defendants' proposed construction for this term. Plaintiff's proposal, while perhaps not the last word on the subject, does no harm and is more than sufficient at the present time.

2. "in an amount of 0.25 to 0.5 mole per 1 mole of the compound (1)" ('730 patent, claim 5)

   a. *Plaintiff's construction*: No construction necessary, i.e., plain and ordinary meaning

   b. *Defendants' construction*: "using a total amount in a molar ratio of no less than one quarter of to no more than half of the moles of compound (1)"

   c. *Court's construction*: No construction necessary

[2] "Equimolar" or "equal molar" or "the same" number of moles can be modified by words of precision, such that, for instance, "exactly equimolar" and "approximately equimolar" are more or less precise than "equimolar." If so, Plaintiff's past formulations do nothing to show that a more precise construction is warranted.

The parties' positions regarding this term parallel their positions regarding the previous term. For the same reasons as above, I do not think any construction is necessary.

B. The '694 Patent

This disputed term is the text of "Step 1"[3] listed in Claim 1 of the '694 patent:

> "producing amorphous composites consisting of (a) 7-chloro-5-hydroxy-1-[2-methyl-4-(2-methylbenzoylamino)benzoyl]-2,3,4,5-tetrahydro-1H-benzoazepine and/or salt thereof, and (b) hydroxypropylcellulose containing a hydroxypropoxyl group in an amount of 50% or greater"

('694 patent at 25:21-27). The term involves two chemical entities that the parties refer to as (a) tolvaptan and (b) hydroxypropylcellulose (hereafter, "HPC"). At oral argument, I rejected Defendants' construction of "amorphous composites" as "amorphous solids." (Tr. at 68:20-21). I also rejected Defendants' construction indicating that the amorphous composites are produced "from" tolvaptan and HPC. (Transc. at 88:21-24). The remaining dispute pertains to phrases that are meant to clarify the "consisting of" transition:

a. *Plaintiff's Proposed Construction*: ". . . in an amount of 50% or greater, which may include impurities and other elements unrelated to the amorphous composites of the invention"

b. *Defendants' Proposed Construction*: ". . . in an amount of 50% or greater, and no additional excipients"

c. *Court's Construction*: ". . . in an amount of 50% or greater, and no additional excipients"

The parties disagree on what amorphous composites can contain besides tolvaptan and HPC. Defendants argue that amorphous composites contain "no additional excipients" because of the "exclusionary aspects of the 'consisting of' transitional phrase." (D.I. 53 at 46). Plaintiff

[3] Claim 1 is unique (in my experience) as its four steps are denominated as Step 1, Step A, Step 2, and Step 3.

acknowledges that the "consisting of" transition signifies the exclusion of additional ingredients, but argues that caselaw indicates that "consisting of" does not exclude "impurities" or elements "unrelated to the invention." (D.I. 53 at 40).

I agree with Defendants' "and no additional excipients" construction. The "consisting of" transition "exclude[s] any elements, steps, or ingredients not specified in the claim." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016). Here, while the "restriction is not absolute" in that the amorphous composites can contain impurities, *see Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006), the amorphous composites cannot consist of additional excipients.

The Federal Circuit has held that "impurities normally associated with the component of a claimed invention are implicitly adopted by the ordinary meaning of the components themselves." *Id.* at 1361. Defendants do not dispute that the amorphous composites might contain impurities such as residual organic solvents. (Tr. at 76:20-25). If the presence of impurities is "implicit[]" in the ordinary meaning of the recited components, and the parties do not dispute that impurities may be present, then there is no need to include impurities in the construction.[4]

In opposing Defendants' construction, Plaintiff argues that solvents are excipients and that amorphous composites could contain residual solvents. (D.I. 53 at 41, 49-50). The Federal Circuit has held that "excipients" contrast with "impurities" in the pharmaceutical context. *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1347 (Fed. Cir. 2004). "[E]xcipients are almost universally used with the active ingredient, and therefore do not act to affect the purity of the

[4] Any trial will be a bench trial (D.I. 16, ¶ 15), so making sure the jury will understand a term is not an issue in this case.

drug." *Id.* While an "impurity is considered an unwanted reaction product formed during synthesis," excipients are "inactive ingredients that are routinely and purposefully added to the active ingredient to enhance the performance of the active ingredient." *Id.* Here, though residual solvents might be labelled "excipients" in certain contexts (*see* D.I. 56-1, Ex. V at 4), they are not "excipients" in the sense of "purposefully added" ingredients that "enhance the performance" of the active ingredient. Solvents also qualify as impurities to the extent that they are an "unwanted reaction product." Therefore, residual solvents are not excluded by Defendants' construction.[5]

In support of its construction, Plaintiff cites the holding in *Conoco* that "'consisting of' does not exclude additional components or steps that are unrelated to the invention." 460 F.3d at 1360. At oral argument, I asked Plaintiff to provide an example of something that is "unrelated to the amorphous composites of the invention" that is not an impurity. Plaintiff provided "organic solvents" as an example (Tr. at 51:16-18, 53:11-13) but conceded that residual organic solvents are impurities (Tr. at 54:19-22). Plaintiff stated that "excipients" and "carrier excipients" are not related to the amorphous composites, but also stated that excipients are "not part of the amorphous composites" and that the amorphous composites do not "include[] the carrier." (Tr. at 55:16-19). Plaintiff suggested that the amorphous composites might be mixed with or else be "on" another excipient, even though the excipient is not "part" of the amorphous composite in that case. (Tr. at 60:23-61:2, 88:2-5).

[5] I construed "consisting of" to indicate what the amorphous composites contain, not what they are produced from. Plaintiff stated at oral argument that in its construction of the term, "we are trying to make clear . . . that you can have other excipients present when you're preparing these amorphous composites." (Tr. at 56:23-57:1). I make no determination on this point, because I held that this term states what the amorphous composites contain, not the conditions under which the amorphous composites are produced.

I agree that an excipient on which amorphous composites adhere is not excluded by the "consisting of" transition.[6] An excipient on which the amorphous composites adhere is not "related" to the amorphous composites, as understood in *Conoco*. But if X is "on" Y, then X does not "consist of" Y. *See Multilayer*, 831 F.3d at 1366 (Taranto, J., dissenting in part) ("As the court's opinion explains, in patent law (and probably in the dominant strand of formal English), 'consisting of' means 'including *only*' ('containing only,' 'composed of only,' 'made of only')."). Therefore, none of the examples Plaintiff provides are both (a) something of which the amorphous composites consist (that is, something that is part of the amorphous composite) and (b) something unrelated to the amorphous composites.[7] For this reason, Plaintiff has not explained how amorphous composites could "consist[] of . . . elements unrelated to the amorphous composites of the invention."[8]

A closer examination of the caselaw reveals why Plaintiff's construction fails to clarify this term. The case Plaintiff relies on for its construction, *Conoco*, 460 F.3d at 1360-61, follows from an analysis of *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1332 (Fed. Cir. 2004). In *Norian*, the Federal Circuit held that "consisting of" did not permit inclusion of additional

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[6] To be clear, I am not making any factual findings about the disputes in this case. I am merely responding to the hypotheticals as I understand them from oral argument.

[7] The closest Plaintiff comes to providing an example is that, in certain preparations of the amorphous composite, excipients might "bleed[] into the amorphous composite." (Tr. at 83:19-21, 83:24-84:3). But even here, Plaintiff assumes that the excipient mixes with the amorphous composite, not that the amorphous composite "consists of" an excipient that is unrelated to the amorphous composite.

[8] Removing the intervening phrases, Plaintiff's construction ultimately states that "amorphous composites consist[] of . . . elements unrelated to the amorphous composites of the invention." But Plaintiff does not explain what it is for something to "consist of" elements unrelated to itself. This paradox did not arise in *Norian*, where the spatula in question (the element unrelated to the invention) was "not part of the invention" at all. *See Norian*, 363 F.3d at 1332.

chemicals in a bone-repair kit. *See Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1332 (Fed. Cir. 2004). The item that was "irrelevant to the invention" was not a chemical, but a "spatula." *Id.* Moreover, the item that was irrelevant or unrelated to the invention was "not part of the invention at all." *Id.* Here, unlike in *Norian*, Plaintiff claims that chemicals unrelated to amorphous composites are items of which the amorphous composites consist, even though they are not parts of the amorphous composite. But Plaintiff does not explain what it is for an amorphous composite to "consist of X" if X is not a "part" of the amorphous composite. Because Plaintiff's construction relies on inapposite caselaw, I will not adopt it.[9]

III. CONCLUSION

The claims shall be construed as set forth above.

SO ORDERED this 26 day of July 2022.

Richard G. Andrews
United States District Judge

[9] I think what Plaintiff is arguing is that anything contained in the amorphous composites that is neither tolvaptan nor hydroxypropylcellulose is unrelated to the amorphous composites of the invention, thereby turning the "consisting of" transition to a "comprising" transition.