IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS INC.,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	**No. 16-876**
BIONPHARMA INC.,	:	
Defendant.	:	

Goldberg, J. **April 3, 2018**

MEMORANDUM OPINION

Before me are two consolidated patent infringement and invalidity cases arising under the Hatch-Waxman Act.[1] Plaintiff Silvergate Pharmaceuticals Inc., the owner of U.S. Patent No. 8,568,747 ("the '747 Patent") and U.S. Patent No. 8,778,366 ("the '366 Patent"), has filed two one-count complaints for patent infringement against Defendant Bionpharma Inc. alleging violation of 25 U.S.C. § 271(e)(2)(A) based upon Defendant's submission of an Abbreviated New Drug Application ("ANDA") with the Federal Drug Administration ("FDA") seeking approval of a generic version of Plaintiff Silvergate's liquid formulation of EPANED® (hereinafter "EPANED® product"). Defendant responded with counterclaims for non-infringement and invalidity. Presently before me are the parties' briefs on claim construction of seven terms contained in the '747 Patent and the '366 Patent's claims.[2]

[1] On May 18, 2017, Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

[2] Two additional terms—"homogenous" and "relative humidity"—were originally contested. Defendant has agreed to Plaintiff's proposed construction of "homogenous," thus it will be

I. Factual and Procedural Background

Plaintiff's EPANED® product treats hypertension in children and is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction. EPANED® is a pharmaceutical powder that is reconstituted into an oral liquid formulation.

The '747 Patent issued on October 29, 2013 and covers the approved formulation of the EPANED® product. Pursuant to 21 U.S.C. § 255, the '747 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with EPANED®.

Plaintiff is the assignee and exclusive licensee of the '747 Patent. Claims 1, 2, 4, and 5 are at issue in this case and state:

> Claim 1: A pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of:
>
> (a) About 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof,
> (b) About 85% (w/w) mannitol, and
> (c) About 1% (w/w) colloidal silicon dioxide,
>
> wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and 55±10% relative humidity.
>
> Claim 2: The pharmaceutical powder of claim 1, wherein the enalapril or pharmaceutically acceptable salt thereof is enalapril maleate.
>
> Claim 4: The pharmaceutical powder of claim 1, wherein the powder is reconstituted in syrup for the oral liquid.
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> Claim 5: The pharmaceutical powder of claim 1, wherein the powder is stable for at least six months at ambient, accelerated or refrigerated conditions.

On August 19, 2016, Defendant notified Plaintiff that it had submitted ANDA No. 209375 to the FDA under Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act,

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construed to mean "a solution with no visible, undissolved solids." As to "relative humidity," Defendant has consented to Plaintiff's proposal that this term does not require construction.

seeking to engage in the commercial manufacture, use, and sale of a generic version of the EPANED® product before the expiration of the '747 Patent.

The '366 Patent was issued to the same inventors on July 15, 2014. The claims of the '366 Patent cover one of the approved indications of the EPANED® product. The '366 Patent is also listed in the Orange Book in connection with EPANED®. On November 23, 2016, Defendant notified Plaintiff that it had submitted ANDA No. 209375 to the FDA seeking to engage in the commercial manufacture, use, and sale of a generic version of the EPANED® product before the expiration of the '366 Patent.

Of the fifteen claims in the '366 Patent, only Claims 14 and 15 are at issue in this case. They are:

> Claim 14: A method of treating heart failure in a subject in need comprising administering to that subject a therapeutically effective amount of a pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of: (a) about 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof, (b) about 85% (w/w) mannitol, and (c) about 1% (w/w) colloidal silicon dioxide, wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and 60±10% relative humidity.
>
> Claim 15: A method of treating left ventricular dysfunction in a subject in need comprising administering to that subject a therapeutically effective amount of a pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of: (a) about 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof, (b) about 85% (w/w) mannitol, and (c) about 1% (w/w) colloidal silicon dioxide, wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and relative humidity.

The parties have fully briefed proposed claim constructions of the seven terms at issue, which are: "about"; "about 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof"; "about 85% (w/w) mannitol"; "about 1% (w/w) colloidal silicon dioxide"; "consisting of";

"mannitol"; and "stable." On February 15, 2018, I held a hearing on the parties' proposed claim constructions.[3]

II. Claim Construction of the '747 Patent and the '366 Patent

Claim construction is a two-step process. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). First, the court must define the meaning and scope of the disputed claim terms, which is an issue of law. Id. Second, those interpretations are used by the fact finder in comparing the asserted claims with the accused device or prior art. Id.

"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., No. 10-389, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (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, Inc., 52 F.3d at 977-80. 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 and citations 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

[3] Since the February 15, 2018 hearing, I have granted a motion filed by Plaintiff allowing it to amend the Complaint to include a third patent. While this patent will be litigated with the '747 and the '366 Patents, because claim construction is already underway as to those two patents, construction as to claims in the third patent will proceed separately.

question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1312-13 (internal quotation marks and citations 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).

A court may consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," in order to understand the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. Id. at 1317-19 (internal quotation marks and citations omitted). 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).

A. *Claim Terms Using the Word "About"*

The first term requiring construction is the word "about" as it is used in Claim 1 of the '747 Patent and Claims 14 and 15 of the '366 Patent.[4] "About" appears in the following claim terms: "**about** 14% enalapril or pharmaceutically acceptable salt thereof"; "**about** 85% w/w

[4] All Claim 1 terms discussed herein also incorporate all asserted dependent claims.

mannitol"; and "**about** 1% w/w colloidal silicon dioxide." Because the construction of "about" will bear on construction of these terms, I discuss all four terms in this section.

Plaintiff proposes I construe "about" to mean "approximately." Thus it contends I construe the three terms as "approximately 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof, wherein enalapril refers to enalapril base, its salt, or solvate or derivative or isomer or polymorph thereof"; "approximately 85% w/w mannitol"; and "approximately 1% w/w colloidal silicon dioxide." Plaintiff submits that this construction is applied by courts as the plain and ordinary meaning of "about" where a patentee has not acted as its own lexicographer by redefining the term in the common specification.

Defendant asserts that I construe "about" to mean "to indicate that a value includes the standard level of error for the evidence or method being used." Regarding the three "about" terms, Defendant proposes the following constructions: "13.86% to 14.14% (w/w) enalapril or a pharmaceutically acceptable salt thereof as determined by HPLC analysis, or any other scientifically acceptable method of equal or greater precision"; "82.45% to 87.55% (w/w) mannitol as determined by HPLC analysis, or any other scientifically acceptable method of equal or greater precision"; and "0.95% to 1.05% (w/w) colloidal silicon dioxide as determined by gravimetric analysis, or any other scientifically acceptable method of equal or greater precision."

According to Defendant, language in the common specification demonstrates that the patentee acted as its own lexicographer, defining the term. In support, Defendant points to the following language in Column 19 of the '747 Patent's common specification:[5] "The term 'about' is used to indicate that a value includes the standard level of error for the device or method being employed to determine the value." From this language, Defendant argues that a person of

[5] Although the parties address only Column 19 of the '747 Patent, the '747 Patent and '366 Patent share a common specification. I will therefore use "specifications" throughout this Opinion.

ordinary skill in the art ("a POSA") would recognize that the claim term requires the determination of acceptable devices or methods to employ in determining the weight percent of the drug component. Additionally, Defendant asserts that a POSA would apply this device or method to determine the standard level of error for that device or method in order to understand the literal scope of the claim.

Regarding the "about" phrases pertaining to enalapril and mannitol, Defendant contends a POSA would understand that a high-performance liquid chromatography ("HPLC") analysis is a common analytical method used to figure out the amount of compound in a mixed sample. For the "about" phrase pertaining to colloidal silicon dioxide, Defendant asserts that a POSA would understand that a gravimetric method is commonly used to determine the amount of colloidal silicon dioxide content in a mixed sample. Defendant argues that through applications of these methods, a POSA would understand the "about" phrases to yield the error rates that result in Defendant's above-proposed specific ranges of enalapril, mannitol, and colloidal silicon dioxide.

Plaintiff responds that the patentee did not act as its own lexicographer and thus there is no special definition for "about" in the patents. In support, Plaintiff first cites to the following language in the same paragraph of Column 19 in the specifications relied upon by Defendant:

> The terms "comprise," "have," and "include" are open-ended linking verbs. Any forms or tenses of one or more of these verbs, such as "comprises," "comprising," "has," "having," "includes" and "including," are also open-ended. For example, any method that "comprises," "has" or "includes" one or more steps is not limited to possessing only those one or more steps and also covers other unlisted steps.

According to Plaintiff, in light of this language, the sentence to which Defendant cites does not provide the only level of error for the device or method being employed. Rather, Plaintiff urges that the term "includes" is open-ended and merely sets the minimum for the scope of what "about" includes. Plaintiff also maintains that distinct definitional language further down in

Column 19—where the terms optional, optionally, therapeutic, and administering are expressly defined through the use of the words "mean," "means," and "meant"—as juxtaposed to the way "about" is described further demonstrates that "about" is not expressly defined.

"When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description." Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1370 (Fed. Cir. 2005) (citing Bell Atl. Network Servs. v. Covad Commun's Grp., Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001)). The Federal Circuit "has repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." Id. (citing Bell Atl. Network Servs., 262 F.3d at 1268) (finding ambiguity where language in the common specification was "amenable to a second . . . interpretation").

Where a patentee has not acted as his own lexicographer in redefining the word "about," courts have construed "about" to mean "approximately." See, e.g., id. at 1372 ("We thus hold that the term "about" should be given its ordinary and accepted meaning of "approximately."); UCB, Inc. v. KV Pharm. Co., No. 08-223, 2009 WL 2524519, at *5 (D. Del. Aug. 18, 2009) (construing "about" to mean "approximately" where "about" had not been clearly redefined).

Here, the language in the specification cited by Defendant—"The term 'about' is used to indicate that a value includes the standard level of error for the device or method being employed to determine the value"—is open to interpretation. Because Plaintiff's reading of the language, as merely indicating what "about" includes, is entirely plausible, ambiguity exists. Text in the same paragraph cited to by Defendant provides further information concerning "includes" such that it is impossible to conclude that only the first sentence constitutes an express definition.

Rather, the presence of the word "includes" suggests a more expansive understanding of "about." To construe "about" as Defendant urges would require me to ignore the rest of the paragraph, as well as text further down in Column 19 where express language is in fact used to define other terms. See Dkt. No. 16-876, Compl., Ex. 1 at Column 19 ("'Optional' or 'optionally' may be taken to mean that . . . .).[6]

Furthermore, as to the terms that use "about," in order to determine that Defendant's proposed specific ranges are correct, I would need to rely almost entirely on several layers of extrinsic evidence. First, I would need to agree with Defendant's expert, Dr. Anderson, that a POSA would understand that the clam term requires the determination of acceptable devices or methods to employ in determining the weight percent of the drug component. Second, I would have to conclude that a POSA would select HPLC to figure out the amount of enalapril and mannitol in a mixed sample. Third, I would have to accept that a POSA would understand the gravimetric method is commonly used to determine the amount of colloidal silicon dioxide content in a mixed sample. And fourth, I would need to agree that a POSA would apply these methods such that the specific constructions proposed by Defendant are accurate. In short, in

[6] Defendant relies upon Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321 (Fed. Cir. 2007). There, the Federal Circuit affirmed the district court's narrow construction of the term "about 1:5" as incorporating a range of ratios "no greater than 1:3.6 to 1:7.1." The Federal Circuit observed the presence of intrinsic evidence supporting this construction such as a difference between the claimed ratio and broader ratios in other claims, language in the specification suggesting a narrow interpretation of "about" in order to avoid rendering meaningless other claims, and language in the specification referring to ratios similar to the claimed ratio. Id. at 1327. Here, there is language in the specifications suggesting "about" is not as narrow as Defendant proposes. Additionally, finding that "about" should not be construed narrowly will not render other claims meaningless. For these reasons, I find Ortho-McNeil to be inapposite.

Defendant also cites to Otsuka Pharm. v. Torrent Pharm., 151 F. Supp. 3d 525 (D.N.J. 2015). In that case, the court found that "about" had been redefined in the patent in light of "clear language and under a heading bearing the title," as well as the fact that the specifications "specifically state[d] that the term [had] a particular meaning in the context of the patents-in suit." Id. at 540 (emphasis in original). There is no such clear language here.

order to adopt Defendant's proposed construction, I would have to rely upon external evidence as to these four inferences. I decline to do so.

Accordingly, I will construe "about" to mean "approximately" and thus the "about" terms to mean "approximately 14% enalapril or pharmaceutically acceptable salt thereof"; "approximately 85% w/w mannitol"; and "approximately 1% w/w colloidal silicon dioxide."

B. *"Consisting Of"*

The next term requiring construction is "consisting of" as it is used in Claim 1 of the '747 Patent and Claims 14 and 15 of the '366 Patent. In Claim 1, it appears as follows:

> Claim 1: A pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder **consisting of**:
> (a) About 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof,
> (b) About 85% (w/w) mannitol, and
> (c) About 1% (w/w) colloidal silicon dioxide,
> wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and 55±10% relative humidity.

In Claims 14 and 15, it appears as follows:

> Claim 14: A method of treating heart failure in a subject in need comprising administering to that subject a therapeutically effective amount of a pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder **consisting of**: (a) about 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof, (b) about 85% (w/w) mannitol, and (c) about 1% (w/w) colloidal silicon dioxide, wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and 60±10% relative humidity.
>
> Claim 15: A method of treating left ventricular dysfunction in a subject in need comprising administering to that subject a therapeutically effective amount of a pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder **consisting of**: (a) about 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof, (b) about 85% (w/w) mannitol, and (c) about 1% (w/w) colloidal silicon dioxide, wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and relative humidity.

Plaintiff argues that "consisting of" does not require construction, or, alternatively, that it means "containing designated ingredients." Regarding its proposed alternative construction, Plaintiff avers that "consisting of" does not mean that non-listed ingredients are excluded. Defendant responds that "consisting of" should be construed to mean "including all recited ingredients and excluding all non-recited ingredients." Defendant urges me to reject Plaintiff's position that construction is not necessary as well as Plaintiff's alternative construction, which Defendant contends finds no support in the intrinsic record or under the law.[7]

The term "consisting of" is a term of art in patents with a well-established meaning. Multilayer Stretch Cling Film Holdings, Inc., v. Berry Plastics Corp., 831 F.3d 1350, 1358 (Fed. Cir. 2016). "Transitional phrases, such as 'comprising,' 'consisting of,' and 'consisting essentially of,' are terms of art in patent law that 'define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.'" Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1360 (Fed. Cir. 2006) (quoting MPEP § 2111.03). The Federal Circuit has explained that "consisting of" is "a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim." Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331 (Fed. Cir. 2004). However, it has further explained that "[a]lthough 'consisting of' is a term of restriction, the restriction is not absolute." Conoco, Inc., 460 F.3d at 1360. Rather, "[t]he Patent Board of Appeals has interpreted 'consisting of' to 'close[ ] the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.'" Id. (quoting Ex parte Davis, 80

[7] Defendant presses that I should reject Plaintiff's invitation to give claims their plain and ordinary meaning. Defendant points to footnote 6 of the Scheduling Order entered by Judge Sue L. Robinson, which reads "Resorting to 'plain and ordinary' meaning is not sufficient, as it effectively leaves claim construction in the hands of the experts rather than the court." As I noted at the claim construction hearing, I am not bound by Judge Robinson's Scheduling Order and in fact have recently issued an Amended Scheduling Order that omits this language.

U.S.P.Q. 448, 450 (Pat. Office Bd. App. 1948)). Thus, "'consisting of' does not exclude additional components or steps that are unrelated to the invention." Id. (citing Norian Corp., 363 F.3d at 1331-32.)

There is no indication in the claim language, specifications, or prosecution history here that the patentee departed from the customary meaning of "consisting of." I will construe "consisting of" in accordance with Federal Circuit precedent and give it its plain and ordinary meaning as a POSA would understand it, such that "consisting of" means "including all recited ingredients, however, not excluding components or steps unrelated to the invention."

C. "Mannitol"

The next term requiring construction is "mannitol" as it is used in Claim 1 of the '747 Patent and Claims 14 and 15 of the '366 Patent. "Mannitol" appears in Claim 1 as follows:

> Claim 1: A pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of:
> (a) About 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof,
> (b) About 85% (w/w) **mannitol**, and
> (c) About 1% (w/w) colloidal silicon dioxide,
> wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and 55±10% relative humidity.

In Claims 14 and 15, it appears as follows:

> Claim 14: A method of treating heart failure in a subject in need comprising administering to that subject a therapeutically effective amount of a pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of: (a) about 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof, (b) about 85% (w/w) **mannitol**, and (c) about 1% (w/w) colloidal silicon dioxide, wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and 60±10% relative humidity.
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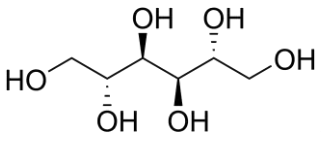
> Claim 15: A method of treating left ventricular dysfunction in a subject in need comprising administering to that subject a therapeutically effective amount of a pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of: (a) about 14% (w/w) enalapril or a

> pharmaceutically acceptable salt thereof, (b) about 85% (w/w) **mannitol**, and (c) about 1% (w/w) colloidal silicon dioxide, wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and stable for at least 12 weeks at about 25±5° C. and relative humidity.

Plaintiff asserts "mannitol" does not require construction. Plaintiff explains that "mannitol means mannitol" just as "[e]nalapril means enalapril and colloidal silicon dioxide means colloidal silicon dioxide." According to Plaintiff, a POSA would understand "mannitol" to be a reference to its name and not the chemical nomenclature proposed by Defendant. Plaintiff also initially proposed an alternative construction, contending that to the extent "mannitol" requires construction, I should construe it to mean "mannitol or sugars that perform substantially the same function in substantially the same way to yield substantially the same result." Plaintiff subsequently withdrew this proposed construction.

Defendant responds that it would agree "mannitol" does not require construction, except that Plaintiff's proposed alternative suggests Plaintiff's "motive . . . is to keep its meaning ambiguous so that it may later on down the line argue that the literal scope of 'mannitol' goes beyond the singular chemical compound that the term refers to." Thus, Defendant contends construction is required and proposes that "mannitol" be construed as "(2R,3R,4R,5R)-hexane-1,2,3,4,5,6-hexol." This is the common name for a singular chemical compound.[8] Defendant maintains its proposed construction is supported by the plain language of the claims and the common specifications because there is no indication that "mannitol" can be anything other than what that common name refers to. Additionally, Defendant asserts that the prosecution history

[8] The chemical structure is depicted as follows: 

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shows that the patentee "disavowed" any additional scope beyond the singular chemical compound.[9]

Plaintiff replies that Defendant's proposed construction does not appear in the patents and a POSA would not understand "mannitol" to mean a substance in which 100% of the molecules have the structure "(2R,3R,4R,5R)-hexane-1,2,3,4,5,6-hexol." Rather, Plaintiff explains, "the specifications and a certificate of analysis submitted to the FDA . . . explain that a substance that is mannitol could have not less than 96% mannitol molecules and include as much as 2% sorbitol or 2% isomalt or maltitol." According to Plaintiff, the claim language lists the ingredients of the invention, and not chemical structures.

"A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1361 (Fed. Cir. 2008) (finding the district court erred in determining a claim had a "plain and ordinary meaning" where the parties agreed that "only if" had a common meaning but disputed the scope of that claim term).

Although Plaintiff represents that it has withdrawn its alternative proposed construction—"mannitol or sugars that perform substantially the same function in substantially the same way to yield substantially the same result"—I agree with Defendant that Plaintiff's proposed alternative suggests it has a different understanding of the plain and ordinary meaning of "mannitol" than Defendant. Plaintiff appears to be seeking an understanding of "mannitol"

[9] In its Sur-Reply and supplemental brief, Defendant contends Plaintiff raises a "new de facto" construction in its Reply and asks that I reject it. According to Defendant, Plaintiff's "new de facto" construction is "a crystalline powder of mannitol having a certain purity and characteristics as recited in the U.S. Pharmacopeia, and including other chemical compounds." At the claim construction hearing, Plaintiff stated that it is not pursuing this construction of "mannitol," thus I need not address it.

that encompasses more than "mannitol," thus encroaching on issues to be resolved at the infringement stage of this case.[10] This is evidenced, for example, in Plaintiff's discussion of "mannitol" in its Reply brief where it argues a POSA would consider "mannitol" to be "mannitol" with as little as 96% "(2R,3R,4R,5R)-hexane-1,2,3,4,5,6-hexol." Plaintiff also cites to publication that states "mannitol" contains not less than 97.0% and not more than 102.0% of mannitol.

Because the parties disagree as to the plain and ordinary meaning of "mannitol," I must construe the term. Review of the claim language and the specifications reflects that neither indicates that "mannitol" can be anything other than "mannitol." The specifications discuss various embodiments of the invention comprised of enalapril or a pharmaceutically acceptable salt thereof, mannitol, and colloidal silicon dioxide. They also run through a series of examples where the stability of enalapril with mannitol, lactose, or sucrose was assessed in order to determine when enalapril was most stable. None of the language contained therein contemplates "mannitol" as anything aside from "mannitol." To read into the language of the claims that the scope of "mannitol" contemplates ingredients beyond mannitol is unsupported. Rather, "mannitol" is simply "mannitol" throughout the specifications.

Plaintiff's expert Dr. Buckton states that a POSA working in the field of pharmaceutical formulation would obtain mannitol as a powder "made up of a vast number of crystals, where

[10] This is also true of Plaintiff's second proposed alternative construction of mannitol as "sugar compounds containing mannitol." Plaintiff requested leave to amend the Joint Claim Construction Chart on November 6, 2018 to add this second proposed alternative construction of "mannitol," as well as other alternative constructions. I denied this Motion on November 15, 2017, but have since vacated my Order and requested additional letter briefs on the second proposed alternative construction of "mannitol." Like "mannitol or sugars that perform substantially the same function in substantially the same way to yield substantially the same result," however, this second alternative proposal broadens the scope of "mannitol" beyond "mannitol." As discussed above, there is nothing in the claim language or specifications supporting this broad understanding of "mannitol."

each crystal is made up of enormous numbers of individual molecules." He concludes that the POSA would look at a pharmacopoeia (or similar text) to "understand the properties that make the powder that is sold as 'mannitol' suitable to use in a pharmaceutical formulation." Dr. Buckton goes on to state that "[t]he acceptable purity of mannitol in the U.S. Pharmacopeia acknowledges that it is either impossible, or not commercially viable, to manufacture excipients [like mannitol] to total chemical purity and that it is normal for other chemical compounds to be present." He concludes that Defendant's proposed construction is too narrow and "rul[es] out the use of any commercially available pharmaceutical grade of mannitol." (Buckton Decl. at 9-10.)

Dr. Buckton's declaration, and Plaintiff's incorporation of such in its arguments, illustrates that Plaintiff's understanding of "mannitol" is "mannitol" in its commercially available form versus its chemical name. The problem with this position is that there is nothing in the claim language or the specifications that suggests "mannitol" should be understood in this way. Rather, I would have to rely entirely on Dr. Buckton's declaration to reach this conclusion.

Although the claim language and specifications do not explicitly refer to the chemical structure of "mannitol," they do as to "enalapril." (See Dkt. No. 16-876, Compl., Ex. 1 at Columns 1, 5.) In the context of the entire patent, it is thus more plausible that a POSA would understand that "mannitol" signifies its chemical structure—that is, "(2R,3R,4R,5R)-hexane-1,2,3,4,5,6-hexol."[11] I will thus construe "mannitol" to mean its chemical structure.[12]

[11] In supplemental briefing, Plaintiff avers that this construction of "mannitol" makes it nearly impossible to practice the invention and should thus be rejected. This argument is premised on Plaintiff's position that "(2R,3R,4R,5R)-hexane-1,2,3,4,5,6-hexol" represents "mannitol" in its pure form and necessarily excludes any impurities. Importantly, Defendant does not argue that by construing "mannitol" as its chemical structure, it is only its pure form. Plaintiff again impresses that commercially available "mannitol" is not 100% mannitol, however, there is nothing in the claim language or specifications that indicates the scope of "mannitol"

D. *"Stable"*

The final term requiring construction is "stable" as it is used in Claim 1 of the '747 Patent and Claims 14 and 15 of the '366 Patent. "Stable" appears in Claim 1 as follows:

> Claim 1: A pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of:
> (a) About 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof,
> (b) About 85% (w/w) mannitol, and
> (c) About 1% (w/w) colloidal silicon dioxide,
> wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and **stable** for at least 12 weeks at about 25±5° C. and 55±10% relative humidity.

In Claims 14 and 15, it appears as follows:

> Claim 14: A method of treating heart failure in a subject in need comprising administering to that subject a therapeutically effective amount of a pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of: (a) about 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof, (b) about 85% (w/w) mannitol, and (c) about 1% (w/w) colloidal silicon dioxide, wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and **stable** for at least 12 weeks at about 25±5° C. and 60±10% relative humidity.
>
> Claim 15: A method of treating left ventricular dysfunction in a subject in need comprising administering to that subject a therapeutically effective amount of a pharmaceutical powder that is reconstituted into an oral liquid formulation, the powder consisting of: (a) about 14% (w/w) enalapril or a pharmaceutically acceptable salt thereof, (b) about 85% (w/w) mannitol, and (c) about 1% (w/w) colloidal silicon dioxide, wherein, when the powder is reconstituted into an oral liquid, the liquid is homogenous and **stable** for at least 12 weeks at about 25±5° C. and relative humidity.

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contemplates the commercially available form of the ingredient. Rather, in the context of the patents, "mannitol" is "mannitol."

[12] I need not resolve whether Plaintiff disavowed during prosecution any additional scope beyond the chemical structure of "mannitol." The Federal Circuit has observed that courts do "not rely on the prosecution history to construe the meaning of the claim to be narrower than it would otherwise be unless a patentee limited or surrendered claim scope through a clear and unmistakable disavowal." 3M Innovative Properties Co. v. Tredegar Corp., 725 F.3d 1315, 1322 (Fed. Cir. 2013) ("[D]isavowal must be both clear and unmistakable."). Because I construe "mannitol" as its chemical structure, I need not determine whether it is made narrower through disavowal.

Plaintiff asserts that "stable" does not require construction and should have its plain and ordinary meaning, or, alternatively that it means "resistant to change." Defendant requests that I construe "stable" as "having at least about 90% enalapril and 5% or less total impurities or substances at the end of a given storage period." Defendant urges that this is the express definition for "stable" of the disclosed liquids in the common specifications at lines seven through ten of Column 13. Defendant argues that I should reject Plaintiff's position that this term be given its plain and ordinary meaning, as well as Plaintiff's alternative construction because it finds no support in the intrinsic record and is vague.

Plaintiff responds that Defendant "misuses select language from the specification" that merely describes a single embodiment of the term and is then followed by other embodiments. Additionally, the proposed definition does not account for other ways in which stability is demonstrated. Thus, according to Plaintiff, the language selectively chosen by Defendant is not a clear definition of "stable."

As explained above, in order to determine that a patentee has acted as his own lexicographer, the patentee "must clearly express that intent in the written description." Merck & Co., 395 F.3d at 1370 (citing Bell Atl. Network Servs., 262 F.3d at 1268). "[T]he statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." Id. (citing Bell Atl. Network Servs., 262 F.3d at 1268).

In order to find that the patentee acted as its own lexicographer as to the term "stable," I would have to ignore the rest of Column 13, as well as Column 14, which details other embodiments of the enalapril oral liquid. Defendant's proposed construction is one sentence (and one embodiment) among many that describe "stable" and cannot be said to constitute a

clear definition of the term. As such, I find that Plaintiff did not act as its own lexicographer and will instead apply the plain and ordinary meaning of "stable" such that the liquid is "resistant to change."

Although the words "resistant to change" do not expressly appear in the patent, they are implied. That the oral solution remain "stable" is imperative to the invention, demonstrated by the numerous places throughout the patent where stability over different periods of time is addressed. (See, e.g., Dkt. No. 16-876, Compl., Ex. 1 at Columns 2, 3, 13, 14.) Such stability requires the solution to maintain a purity such that a pharmaceutically effective dose will be delivered. As explained in Phillips, "the ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." 415 F.3d at 1321. After reading the entire patent here, a POSA would understand "stable" to mean "resistant to change."

III. Conclusion

The claims shall be construed as set forth above and in the Claim Construction Order that follows.