IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., ***Plaintiff*,** ***v.*** **ALKEM LABORATORIES LTD.,** ***Defendant*.**	**Civil Action** **No. 20-cv-1094**

MEMORANDUM OPINION

Goldberg, J.[1] **May 4, 2023**

This lawsuit was brought under the Hatch Waxman Act for patent infringement pursuant to 35 U.S.C. § 271(e)(2)(a). Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity") claims that an Abbreviated New Drug Application (ANDA), submitted by Defendant Alkem Laboratories Ltd. ("Alkem"), infringes U.S. Patent No. 10,959,948 (the '948 patent), titled "Composition and method for vancomycin oral liquid." Azurity asserts claims 5, 7, 8, and 9 of the '948 patent.

After presiding over a two-day bench trial, I find that Azurity has failed to establish, by a preponderance of the evidence, that Alkem's ANDA infringes any asserted claim. This opinion sets forth my reasons in reaching this verdict.[2]

[1] Pursuant to 28 U.S.C. § 292(b), I have been designated to serve as a visiting judge for the District of Delaware to handle this matter and other District of Delaware cases.

[2] I previously issued a decision in another case between these same parties, Azurity Pharms., Inc. v. Alkem Lab'ys Ltd., No. 19-cv-2100, 2023 WL 1927613 (D. Del. Feb. 10, 2023). That case is somewhat similar to the one currently before me in that the identity of the parties, plaintiff's main witness, the patents at issue being for liquid formulations of existing drugs, and the main infringement dispute being the presence of an unlisted ingredient, are the same.

I. BACKGROUND

Although most of the facts in this case pertain to oral liquids and are technical in nature, the issue comes down to a simple question: May Azurity prove infringement by grouping together two ingredients of Alkem's accused product, grape flavor and propylene glycol, such that the group, collectively, is a flavoring agent? If so, Azurity has proven infringement. If not, there is no infringement and Alkem is entitled to a judgment in its favor.

The patent in suit claims liquids containing the antibiotic vancomycin, as well as methods for treating Clostridium difficile bacterial infections using these liquids. Azurity's invention was to take vancomycin, which had been used in solid form for decades, and mix it with water while keeping the liquid stable and uniform over a period of at least one week. Alkem's ANDA is also a mixture of vancomycin in water that is stable for at least one week.

The parties agree that Alkem's ANDA satisfies most asserted claim limitations. But, according to Alkem, its ANDA contains an ingredient that is not recited in any asserted claim: a chemical called propylene glycol. Alkem argues that the presence of this unclaimed ingredient defeats infringement of all asserted claims. Alkem further presses that to the extent Azurity is asserting infringement based upon propylene glycol being included in the asserted claims, Azurity disclaimed that ingredient during the prosecution of the '948 patent.

Azurity responds that propylene glycol fits within the asserted claims because it is part of a "flavoring agent," which is an ingredient present in all asserted claims. At trial and in pretrial submissions, Azurity attempted to show that propylene glycol by itself was a flavoring agent because it has a slightly sweet taste that helps mask the bitterness of vancomycin. In post-trial briefing, however, Azurity's focus shifted to a more nuanced argument: that even if propylene glycol by itself is not a flavoring agent, once it is added to Alkem's ANDA product, it combines with the

drug's grape flavor to form a mixture that, collectively, is a flavoring agent. (See Azurity's Post-Trial Brief at 6 (describing how grape flavor dissolves into all the propylene glycol in the ANDA); id. at 9 ("All of the PG acts as a vehicle for flavor and thus as a flavoring agent.").)

Azurity disagrees with Alkem's prosecution history argument on two grounds. First, Azurity contends that Alkem forfeited its opportunity to make arguments about the scope of the asserted claims—including arguments based on the prosecution history—because Alkem stipulated that no claim terms required construction. Azurity also presents an alternative reading of the prosecution history in which it posits that statements to the Examiner did not disclaim all uses of propylene glycol in the claimed invention—such as in a flavoring agent.

II. PROCEDURAL HISTORY

Azurity initially filed this lawsuit on August 20, 2020, asserting claims against Alkem under patents that have since been dropped from the litigation. Claims for infringement of the '948 patent were added by way of a Second Amended Complaint on June 21, 2021.

An initial scheduling order set a hearing to construe patent claims under Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), for November 18, 2021. On August 18, 2021, the parties filed a letter stating that "they are in agreement that no terms of the patents-in-suit require construction." (ECF No. 84.) The Markman hearing was accordingly canceled and no briefing or evidence was taken on issues of claim construction.

On August 3, 2022, Alkem filed a letter to "advise the Court that a claim construction dispute will require resolution." (ECF No. 148.) According to Alkem, that dispute was whether Azurity limited the scope of its claims in the prosecution history to exclude propylene glycol. Azurity responded that it "has no objection to the Court resolving alleged claim construction issues

to the extent the Court finds it necessary as part of trial and post-trial briefing." (ECF No. 149.) However, Azurity argued that Alkem "waived" its prosecution history disclaimer argument by not raising it sooner—such as at a Markman hearing. Azurity repeated this waiver argument in its pretrial submissions.

I held a two-day bench trial on October 3 and 6, 2022. I decided that, in the interest of efficiency, I would allow Alkem to present evidence in support of its disclaimer argument but would also permit Azurity to advocate that it was prejudiced by Alkem's late assertion of this argument. (N.T. 23-24.) Azurity's counsel responded that it would make a showing of prejudice "at the appropriate time" but at trial Azurity did not point to evidence of prejudice. (N.T. 24; ECF No. 164.)

Following submission of post-trial briefs, I heard closing arguments on April 17, 2023. The issue of infringement is now ripe for decision.

III. FACTS

A. Scientific Background

(1) "Vehicles," "Solvents," and "Carriers"

This case involves liquid drugs made from water with added ingredients—i.e. "water with stuff in it." (N.T. 63 (Little).) When talking about these drugs, the terms "liquid vehicle," "carrier," and "solvent" are synonymous and refer to "something that dissolves something else," or, alternatively, "the large amount of stuff"—i.e., water—"that everything else is in." For example, water can be a solvent for sugar. (N.T. 63 (Little); N.T. 154-55 (Forrest).)

(2) Flavoring Agents

The active ingredient in Azurity's invention—vancomycin—has an unpalatable bitterness that needs to be masked if the drug is taken orally. (N.T. 81 (Little).) This is where flavoring agents come into play.

According to Azurity's expert Dr. Steven Little,[3] the term "flavoring agent" is used to mean "a mixture of ingredients that imparts flavor to a formulation." (N.T. 67 (Little).) Both parties' experts agreed that a single flavoring agent may contain multiple ingredients. (N.T. 80-81 (Little); N.T. 245 (Forrest); '948 patent at 11:20-24.) They also agreed that not every ingredient in a flavoring agent has to be flavorful by itself—the term encompasses other, non-flavorful, ingredients that "enable" the mixture as a whole to impart flavor. (N.T. 80-81 (Little); N.T. 245 (Forrest).)

(3) Propylene Glycol

The primary disputed infringement issue is whether Alkem's ANDA infringes the asserted claims despite containing propylene glycol. Some discussion of propylene glycol is therefore required.

Use in Flavoring Agents Propylene glycol is widely used as a solvent. (N.T. 156-57 (Forrest).) In particular, it is commonly used as a solvent in flavoring agents because it helps dissolve flavorful chemicals. It also has other properties desirable in flavoring agents, such as mixing readily with water and not evaporating. (N.T. 85, 89-91 (Little); N.T. 154, 245, 156-59 (Forrest).)

[3] Dr. Little was offered without objection as an expert in pharmaceutical formulations and the design and development of pharmaceutical dosage forms. (N.T. 53.) Dr. Little has undergraduate and graduate degrees in chemical engineering and has worked on numerous projects in pharmaceuticals over the course of his career, among other impressive qualifications. (N.T. 57-58.)

Taste Although propylene glycol is widely used in flavoring agents, by itself it has been described as "practically odorless," sweet, slightly acrid, and having a slight taste. (N.T. 157-58 (Forrest, citing Rowe); N.T. 87, 93 (Little).) The Centers for Disease Control (CDC) notes that propylene glycol is commonly used in food precisely because it is "practically tasteless." (N.T. 159-61 (Forrest, citing DTX-1018).) According to Alkem's expert Dr. Laird Forrest,[4] propylene glycol would generally not be considered for use as a flavor by itself because it has practically no taste. (N.T. 162 (Forrest).) Azurity's expert Dr. Little also could not name a single product that uses just propylene glycol for flavor. (N.T. 128 (Little).)

Azurity presented examples in published literature mentioning the possible use of propylene glycol to enhance taste—although those examples were quite different from Alkem's grape-flavored ANDA product. Those examples included: (1) a patent application for a lip balm mentioning that propylene glycol's somewhat sweet taste enhanced the flavor of the final composition, (N.T. 97 (Little); PTX-164 (Breha)); and (2) a patent application reporting that a small amount of propylene glycol could ameliorate the "resinous" taste of an ingredient in a beverage, (N.T. 98-99 (Little); PTX-165 (Fuwa).) Azurity also referenced a study of two subjects in which one subject was able to taste 0.8 milligrams per milliliter of propylene glycol in filtered water and the other subject could only taste it at a higher concentration. (N.T. 94-96 (Little); PTX-175 (Alexander).) For comparison, Alkem's grape-flavored ANDA liquid contains about 1 milligram per milliliter of propylene glycol. (Undisputed Facts ¶ 56.)

Neither party offered any direct evidence as to whether propylene glycol would have any

[4] Dr. Forrest was offered without objection as an expert in pharmaceutical formulation science. (N.T. 142-44.) He is a professor of pharmaceutical chemistry who has worked for many years in drug formulations, among other impressive qualifications. (N.T. 146.)

discernible effect on the taste of a grape-flavored liquid drug product. (See N.T. 102-03, 112-13 (Little); N.T. 168 (Forrest).)

B. Azurity's Patent on Vancomycin Oral Liquids

Azurity's patent in this case is U.S. Patent No. 10,959,948 (the '948 patent). Azurity asserts claims 5, 7, 8, and 9 of this patent. Claim 5 is representative of these claims and reads:

> A non-sterile stable liquid formulation formulated for oral administration, **consisting of**:
>
> (a) a buffering agent, wherein the buffering agent is selected from the group consisting of citric acid, sodium citrate, [and many other chemicals],
> (b) water,
> (c) a sweetener,
> (d) a preservative, wherein the preservative is selected from the group consisting of sodium benzoate, parabens, benzoic acid, potassium sorbate, benzyl alcohol or salts thereof,
> (e) vancomycin hydrochloride, and
> (f) **flavoring agent**,
>
> wherein the non-sterile stable liquid formulation is homogenous and stable for at least 1 week at ambient and refrigerated temperature and has a pH of 2.5-4.5.

('948 patent, claim 5 (emphasis added).) The term "consisting of," which introduces the ingredient list, "is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim" and "excludes any element[,] step, or ingredient not specified in the claim." Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1358 (Fed. Cir. 2016). Propylene glycol is not among the listed ingredients claim 5.

The '948 patent's specification mentions "propylene glycol" only one time—as an example of a "liquid vehicle" that could have been used instead of water to dissolve vancomycin. ('948 patent, col. 13:29.) The specification does not mention propylene glycol in connection with flavoring agents. However, the parties agree that "[s]uitable flavoring agents for use in the Asserted Claims include flavoring agents with or without propylene glycol." (Undisputed Facts ¶ 92.)

Dr. Little also testified that a person of ordinary skill in the art (POSA) would understand the specification's reference to "compounded" flavoring agents to include flavoring agents containing propylene glycol. (N.T. 129 (Little).)

C. Alkem's ANDA

The accused product is an abbreviated new drug application (ANDA) submitted by Alkem to the Food and Drug Administration (FDA). Like the claimed invention, Alkem's product is a liquid formulation of vancomycin designed for oral administration. (Undisputed Facts ¶¶ 44-48.) It is undisputed that Alkem's ANDA contains many of the same ingredients (and, where applicable, in the same amounts) as the asserted claims. (See Undisputed Facts ¶¶ 64, 68.)

(1) Relevant Ingredients

Only three ingredients of Alkem's ANDA are relevant to the infringement analysis. These are: paraben preservatives, grape flavor, and propylene glycol. More specifically:

1. The preservative in Alkem's ANDA consists of methyl paraben and propyl paraben (collectively, "parabens" or "paraben preservatives"). (Undisputed Facts ¶¶ 49, 84.)
2. The grape flavor in Alkem's ANDA consists of 0.0125 milligrams per milliliter of a substance identified as "Grape Flavor 501417C." (Undisputed Facts ¶ 51-52.) It is made up of three of its own ingredients, which are:
    a. 92.5% propylene glycol,
    b. 7.496% flavorings (i.e., grape-flavored chemicals), and
    c. 0.004% ascorbic acid.

    Thus, only about 7% of the grape flavor in Alkem's ANDA consists of substances that actually taste like grape; most of the rest is propylene glycol. (N.T. 68-70 (Little).) The reason for using propylene glycol is that the grape-flavored chemicals dissolve poorly in water but easily in propylene glycol. (N.T. 71-72 (Little); N.T. 164 (Forrest).) Alkem's ANDA describes the whole of Grape Flavor 501417C, including its propylene glycol, as a "flavoring agent." (N.T. 76-77 (Little).)
3. Alkem's ANDA also contains an additional 1 milligram per milliliter of propylene gly-

> col—about a hundredfold more propylene glycol than in the grape flavor. (Undisputed Facts ¶ 56; N.T. 164 (Forrest).) The ANDA describes this ingredient as a "co-solvent to dissolve preservative." (DTX-1041 at 360.)

It is important to note that propylene glycol is added to Alkem's ANDA in two different ways. First, the commercially available "Grape Flavor 501417C" that Alkem uses to flavor its ANDA contains propylene glycol. Second, Alkem's ANDA contains an additional 1 milligram per milliliter of propylene glycol described as a co-solvent. For clarity, I will refer to these two sources of propylene glycol as the "grape flavor" propylene glycol and the "co-solvent" propylene glycol. The parties' infringement dispute focuses on the "co-solvent" propylene glycol.

The parties' experts agreed that even though the two propylene glycols are added separately, they are chemically identical. It is also undisputed that, once mixed, both propylene glycols interact equally with the grape-flavored chemicals in Grape Flavor 501417C. (N.T. 78-79 (Little); N.T. 166, 246 (Forrest).)

Both sides presented somewhat speculative testimony regarding whether the "co-solvent" propylene glycol in Alkem's ANDA actually helps to dissolve the paraben preservatives. Dr. Forrest testified that the statement was "accurate, as far as [he could] tell." (N.T. 170-71 (Forrest).) He noted that methyl and propyl paraben are poorly soluble in water, and thus it would make sense to add propylene glycol to help dissolve them. (N.T. 163, 169-70 (Forrest).) Dr. Little seemed to agree with this testimony, acknowledging that the ANDA "somewhat accurately characterized" propylene glycol as a co-solvent, although he considered the ingredient "multifunctional." (N.T. 78, 118-19 (Little).) However, Dr. Little did suggest that even if propylene glycol did act as a solvent for the parabens, it was not "necessary" for that purpose. (N.T. 105-07 (Little).) Specifically, Dr. Little referenced a study in Alkem's ANDA submission in which the "co-solvent" propylene

glycol was removed and, with or without this ingredient, the drug was a "[p]ale yellow colored, grape flavored solution." (DTX-1041 at 368.) In Dr. Little's view, this lack of change when removing the "co-solvent" propylene glycol showed that the parabens would remain dissolved without it. (N.T. 105, 107 (Little).) Dr. Forrest disagreed with this interpretation, opining that the parabens were present in such a small amount that a failure to dissolve them would be invisible to this naked-eye test. (N.T. 186-87, 192 (Forrest).)

(2) Effect of the "Co-Solvent" Propylene Glycol on the Taste of Alkem's ANDA

The parties disputed whether the "co-solvent" propylene glycol would affect the taste of Alkem's ANDA, but offered little evidence to support their respective positions. For example, neither expert tested (by tasting or otherwise) the product itself or any other grape-flavored liquid. (See N.T. 102-03, 112-13 (Little); N.T. 168 (Forrest).)

Based principally on statements in published literature that propylene glycol can have a perceptible taste in, for example, filtered water, Dr. Little opined that the "co-solvent" propylene glycol would "enhanc[e]" the taste of Alkem's ANDA. (N.T. 97-100 (Little).) But Dr. Little was vague as to what exactly its effect would be. He did not directly answer questions on cross-examination as to whether propylene glycol would make the ANDA product "grapier" or if the product would "taste right" without it:

> Q. In your view, it's grapier if we add the extra propylene glycol?
>
> A. I would say that it would, for all the reasons I said before, enhance the stability over time, the uniformity of that grape flavor. It would also aid in something that's not discussed here, which is masking the bitter flavor of the drug.
>
> Q. … Would Alkem's product taste right if Alkem didn't add the propylene glycol cosolvent?
>
> A. I don't think that particular experiment was done, but it would enable, especially at that concentration, for all the reasons I talked about in those references,

another level of uniformity and also masking and stability.

(N.T. 111-12.)

Dr. Little was questioned about an experiment described in Alkem's ANDA submission that reported the product remained "grape flavored" when the "co-solvent" propylene glycol was removed. (DTX-1041 at 386.) When asked to reconcile the experiment's conclusion that removing propylene glycol did not change whether the drug was "grape flavored" with his own opinion that propylene glycol enhances flavor, Dr. Little did not deny that removing the "co-solvent" propylene glycol might have no "discernible effect on the taste," but referred generally to the taste-related functions mentioned for propylene glycol in published literature. (N.T. 111-12 (Little).)

Alkem's expert Dr. Forrest testified that he had seen "no indication" that the co-solvent propylene glycol in Alkem's ANDA has "anything to do with the flavoring agent" or has "any discernible effect" on it. (N.T. 165, 168 (Forrest).) But again, Dr. Forrest offered no testing to support his opinion.

(3) Dr. Little's Opinion That the "Co-Solvent" Propylene Glycol Is Part of a "Flavoring Agent"

Azurity's primary infringement contention is not that propylene glycol is a flavoring agent by itself. Rather, Azurity's contention is that propylene glycol and grape flavor collectively are a flavoring agent. Dr. Little offered this opinion at trial, explaining that the "co-solvent" propylene glycol would contribute to the drug's flavor in the following ways: it would help keep the grape-flavored chemicals dissolved; it would increase the uniformity of the drug's flavor; and it would "mask unpalatable tastes." (N.T. 64, 77, 87-88 (Little).)

Dr. Little suggested (although he did not expressly opine) that if a "very large amount" of propylene glycol were added to a vancomycin liquid, it might no longer be accurate to call

propylene glycol a "flavoring agent." (N.T. 101-02, 116-17 (Little).) Dr. Little could not say exactly how much was a "very large amount," but suggested that if the drug were "60 percent" propylene glycol, that might be over the line. (N.T. 117-18 (Little).)

IV. PROSECUTION HISTORY OF THE '948 PATENT

Alkem urges that the prosecution history establishes that Azurity disclaimed propylene glycol. The patent in question, the '948 patent, issued from application 16/941,400 (the '400 application). The '400 application was a "continuation" of application 15/126,059 (the '059 application). The same patent examiner handled both.

"When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999). Alkem focuses its disclaimer argument on events that occurred during prosecution of the '059 application rather than the '400 application. On June 16, 2020, the Examiner notified Azurity that the claims of the '059 application would be allowed, and Azurity subsequently initiated the '400 application on July 28, 2020 using language very similar to what had recently been allowed in the '059 application. In particular, Azurity imported the identical claim limitations "flavoring agent" and "consisting of" from the '059 application into the '400 application. No other amendments or arguments relevant to this case occurred in the '400 application between July 28, 2020 and when the Examiner ultimately allowed those claims on October 30, 2020. Based on this timing and the identical similarity in the relevant claim language, I agree with Alkem that any actions Azurity took to narrow the scope of the terms "flavoring agent" and "consisting of" in the '059 application apply to the '400 application as well, and thus to the asserted

claims in this case from the '948 patent. Azurity does not argue to the contrary in its post-trial brief. (See Azurity's Post-Trial Brief at 14-15.)

The relevant parts of the prosecution history are summarized below.

A. Azurity's First Attempt at Claiming Vancomycin Liquids: Fully Open Claims

On September 14, 2016, Azurity sought approval of a set of claims for vancomycin liquids. The following claim (with independent claims inserted) is illustrative of that set:

> A non-sterile stable liquid formulation comprising a compounded solution of vancomycin hydrochloride that is homogenous and stable for at least 30 days at ambient and refrigerated temperature conditions, wherein the compounded solution is prepared from vancomycin hydrochloride and a liquid solution that is not Ora-Sweet, wherein the liquid solution comprises:
>
> (a) a buffering agent,
> (b) water,
> (c) a sweetener,
> (d) a flavoring agent,
> (e) a preservative, and
> (f) a dye.

(DTX-1004A at 5338.) Because this claim used the term "comprises," it was an "open claim"—one that allowed for unlisted ingredients in addition to what appeared in the claim. MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1383 (Fed. Cir. 2012).

The Examiner rejected Azurity's proposed open claim as being obvious in light of the prior art, in particular Palepu, U.S. Patent Application 2016/0101147, "Formulations of Vancomycin." (DTX-1004B at 53846-47.) Palepu disclosed vancomycin liquids for intravenous rather than oral administration, and its liquids were described as stable. (N.T. 277 (Little); PTX-188 at 8531.) Palepu did not disclose flavoring agents because Palepu's formulations were not taken orally, but the Examiner felt that adding flavoring agents to Palepu's formulations would have been obvious in light of other references. (DTX-1004B at 53848; N.T. 277 (Little).)

Azurity resisted the Examiner's obviousness determination based on arguments not relevant here, but the Examiner continued to reject Azurity's fully open claims. (DTX-1004C at 53876; DTX-1004D at 54076.)

B. Second Attempt: Negative Limitations

Azurity proposed new claim language on January 29, 2019. The following is illustrative:

> A liquid solution comprising:
>
> (a) 0.12% (w/v) anhydrous citric acid,
> (b) water,
> (c) 0.2% (w/v) sucralose,
> (d) 0.05% (w/v) of a flavoring agent,
> (e) 0.1 % (w/v) sodium benzoate,
> (f) 0.0002% (w/v) D&C Yellow No. 10,
> (g) 0.000038% (w/v) FD&C Red No. 40,
>
> wherein the liquid solution does not comprise a [sic] propylene glycol, and wherein the liquid solution is homogenous and stable for at least 30 days at ambient and refrigerated temperature conditions.[5]

(DTX-1004E at 54101.) The limitation beginning "wherein the liquid solution does not comprise" is known as a "negative limitation" because it states what ingredients are excluded from the invention. See Nike, Inc. v. Adidas AG, 812 F.3d 1326, 1347 (Fed. Cir. 2016), overruled on other grounds, Aqua Prod., Inc. v. Matal, 872 F.3d 1290 (Fed. Cir. 2017). Azurity argued that adding a negative limitation to exclude propylene glycol distinguished Palepu because Palepu's formulations used propylene glycol. (DTX-1004G at 54106-07.)

The Examiner was not convinced that excluding propylene glycol adequately distinguished Palepu because that prior art actually discussed two different solvents—propylene glycol and polyethylene glycol. Because Azurity had only excluded propylene glycol, Palepu was not dis-

[5] For readability, alterations are omitted from all quoted claim language.

tinguished. (DTX-1004F at 54096.)

Azurity also attempted to distinguish Palepu using a negative limitation that excluded a "suspending agent" (or, in some proposed claims, "propylene glycol or a suspending agent"). Over the next six months, Azurity tried and failed to convince the Examiner that propylene glycol and polyethylene glycol were suspending agents such that excluding suspending agents necessarily excluded both. (DTX-1004G at 54106-07.) The Examiner remained unpersuaded: even if propylene glycol and polyethylene glycol could sometimes be suspending agents, they were not suspending agents in Palepu. For that reason, the Examiner concluded that excluding "suspending agents" did not distinguish Palepu. (DTX-1004H at 54204.)

C. Third Attempt: A Mix of Negative Limitations and "Consisting of"

During a discussion between Azurity and the Examiner on January 30, 2019, the Examiner suggested that Azurity could overcome the problems with its negative limitation claims by "amend[ing] using consisting of language for the solvent or carrier such that it would no longer require the polyethylene or [propylene] glycol." (DTX-1004F at 54096.) Azurity heeded the Examiner's advice, but only partly.

On February 11, 2019, Azurity proposed new claims. Some of those claims continued to use negative limitations on "propylene glycol or a suspending agent," with Azurity still insisting that this limitation was adequate to exclude both of Palepu's solvents. But Azurity also introduced claims that lacked negative limitations and replaced them with the words "consisting of" (as proposed by the Examiner):

> A liquid solution comprising a carrier consisting of:
>
> (a) 0.1-0.4% w/v anhydrous citric acid,
> (b) water,
> (c) 0.1-0.3% w/v sucralose,

(d) 0.01-0.1% w/v of a flavoring agent,
(e) 0.08-0.2% w/v sodium benzoate, and
(f) 0.0001-0.0003% w/v of a dye,

wherein the liquid solution further comprises vancomycin.

(DTX-1004G at 54113.) By using "consisting of," Azurity made these claims "closed" to unlisted ingredients—such as those in Palepu, including propylene glycol. See PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998) ("[C]losed claims . . . are written in a 'consisting of' format . . . .").

Azurity continued to assert that both its negative-limitation claims and its new "consisting of" claims should be allowed over Palepu. (E.g., DTX-1004G at 54106-10.) Azurity attached to these assertions a declaration by chemical engineer Dr. Steven Dinh, which closed with the following observation:

> As shown in the Application, the diluent and the compounded solutions do not have propylene glycol or polyethylene glycol, both of which were noted as important components in Palepu's compositions.

(DTX-1004G at 54119.) Although Dr. Little testified that he read Dr. Dinh's statement about the lack of propylene glycol as only applying to Azurity's negative-limitation claims (and not, by implication, its "consisting of" claims), there is no language in the declaration itself identifying particular claims. (N.T. 308, 336 (Little).)

The Examiner rejected Azurity's new "consisting of" claims, but for different reasons than in previous rejections. The Examiner determined that the way Azurity had used "consisting of" was unclear and indefinite. Specifically, the claim recited "a liquid solution comprising a carrier consisting of" various ingredients. Thus the claim as a whole was open ("comprising"), but some subset of it—a subset called the "carrier"—was closed ("consisting of"). According to the Examiner, this made it "unclear which components [were] part of the carrier and which [were] not,"

and, consequently, "unclear which unrecited components [were] permitted by the claim and which [were] not." (DTX-1004H at 54185.)

The Examiner further rejected Azurity's new "consisting of" claims as obvious. But, presumably because it was unclear what, exactly, the "consisting of" limitation excluded from the invention, the Examiner's obviousness rejection did not discuss propylene glycol, polyethylene glycol, "consisting of," or Palepu (other than a single reference which seems to be a typo for "Ulrich"). (DTX-1004H at 54198-200.)

D. Fourth Attempt: "Consisting of"

Azurity followed up with the Examiner on August August 15, 2019, submitting amended claims and further argument. Because these new claims used the same limitations "flavoring agent" and "consisting of" that appear in the '948 patent, Azurity's statements about the scope of these claims are important to Alkem's disclaimer argument.

(1) Azurity's New Claim Language

Azurity's amended claims now exclusively used "consisting of" and abandoned negative limitations. Due to the complexity of prior and later amendments, it is necessary to examine three of those claims: (1) a negative limitation claim that Azurity converted to a "consisting of" claim but ultimately canceled entirely (claim 16); (2) a negative limitation claim that Azurity converted to a "consisting of" claim and that was eventually allowed (claim 20); and (3) a claim that had previously used "consisting of" (claim 24).

First, claim 16 had previously used negative limitations but Azurity amended it to use "consists of" (which has a similar construction to "consisting of"):

[Claim 16] A kit comprising a non-sterile 100% w/w vancomycin hydrochloride

> powder, pre-measured into a respective unit of use amount,
>
> a second container consisting of an oral liquid solution, pre-measured into a respective unit of use amount, and
>
> instructions for use,
>
> wherein the oral liquid solution consists of: anhydrous citric acid, water, a sweetener, a flavoring agent, sodium benzoate, and a die,
>
> wherein the first and second containers are of a size such that the vancomycin hydrochloride powder and oral liquid solution can be combined in either the first or second container to produce a compounded solution of vancomycin hydrochloride, and wherein the compounded solution of vancomycin hydrochloride has a pH of 2.5 to 4.5 and is homogenous and stable for at least 30 days at ambient and refrigerated temperature conditions.

(DTX-1004K at 54243.)

Claim 20 was also reworded to change its negative limitation to "consisting of":

> **[Claim 20]** A non-sterile stable liquid formulation formulated for oral administration, consisting of vancomycin hydrochloride, anhydrous citric acid, water, a sweetener, a flavoring agent, sodium benzoate, and a dye, wherein the non-sterile stable liquid formulation is a compounded solution of vancomycin hydrochloride that is homogenous and stable for at least 30 days at ambient and refrigerated temperature conditions, and wherein the compounded solution has a high solubility in water and a pH of 2.5-4.5.

(DTX-1004K at 54244.)

Claim 24 had previously used "consisting of" language but had suffered from an ambiguity in that only a subset of it (the "carrier") was brought within the limitation. Azurity reworded the claim to apply the "consisting of" limitation to the entire liquid:

> **[Claim 24]** A liquid solution consisting of:
>
> (a) 0.1-0.4% w/v anhydrous citric acid,
> (b) water,
> (c) 0.1-0.3% w/v sucralose,
> (d) 0.01-0.1% w/v of a flavoring agent,
> (e) 0.08-0.2% w/v sodium benzoate,
> (f) 0.0001-0.0003% w/v of a die, and
> (g) vancomycin hydrochloride, and
>
> wherein the liquid solution is formulated for oral administration, homogenous, and stable for at least 30 days at ambient and refrigerated temperature conditions.

(DTX-1004K at 54244-45.)

(2) Arguments Submitted to the Examiner in Support of "Consisting of" Claims

In arguments attached to its new claim language, Azurity told the Examiner that it had now deleted the problematic negative limitation on suspending agents—which had failed to exclude polyethylene glycol—from claim 16 in favor of "consists of" language. The new language, Azurity argued, excluded both propylene glycol and polyethylene glycol and thus distinguished Palepu:

> . . . Palepu discloses liquid vancomycin-containing compositions that include (a) vancomycin or a pharmaceutically acceptable salt thereof, (b) **a polar solvent comprising propylene glycol, polyethylene glycol, or mixtures thereof**, (c) lactic acid, a lactate salt or mixtures thereof, and optionally (d) a pH adjuster. . . . The absence of propylene glycol and polyethylene glycol in the claimed invention, in part, distinguishes it from the cited reference.
>
> Palepu clearly teaches that the polar solvent (comprising propylene glycol, polyethylene glycol, or mixtures thereof) and lactic acid . . . are important components in its compositions. . . . Palepu emphasizes that it is the interaction/combination of its polar solvent (e.g. propylene glycol) and lactic acid . . . that gives the solutions long-term stability. . . .
>
> . . .
>
> At least for the reasons stated above, the compositions of Palepu do not fall within the scope of the claimed invention. The claimed invention does not include the polar solvents or lactic acid of Palepu. . . .

(DTX-1004K at 54251-52 (bold text in original, underlining added).) Azurity made a similar argument with respect to claim 20 but with fewer words:

> As explained above, Palepu teaches that its polar solvents (e.g. propylene glycol) and lactic acid . . . confer its compositions with long-term stability. The claimed invention is an oral vancomycin formulation that is stable for 30 days, and it does not include the polar solvents or lactic acid of Palepu. The skilled artisan would not have had a reasonable expectation of success in producing a stable, oral vancomycin formulation, by combining Palepu and Accord and modifying the solution by removing the polar solvents and/or the lactic acid of Palepu.

(DTX-1004K at 54254 (underlining of "stable" and "oral" in original, other emphasis added).)

With respect to claim 24 (the claim that had previously used "consisting of" language), Azurity did not discuss the impact of Palepu or the presence or absence of propylene or polyethylene glycol. Although Azurity's reasons for not addressing Palepu cannot be known with certainty, the logical explanation is that the Examiner had also not previously discussed the impact of Palepu on claim 24—apparently because the claim's previously indefinite language made it unclear whether Palepu's ingredients were even excluded.

(3) Allowance

On February 20, 2020, the Examiner finally removed the obviousness rejection as to some claims—including claim 24—but continued to reject these claims for other reasons not relevant here. (DTX-1004M.) As to claim 16, the Examiner once again faulted Azurity for using a mix of open and closed language. (DTX-1004M at 54408.) Azurity ended up canceling claim 16. (DTX-1004N.)

On June 16, 2020, the Examiner stated that all remaining claims would be allowed. In doing so, the Examiner explained:

> The closest prior art to Palepu [sic][6] … teaches a non-sterile stable liquid formulation having vancomycin hydrochloride together with either propylene glycol or polyethylene glycol in the liquid formulation. The instant claims exclude the presence of propylene glycol or polyethylene glycol in view of the consisting of language, and thus overcome the teachings of Palepu which requires the propylene glycol or polyethylene glycol to be present with the vancomycin hydrochloride.

(DTX-1004O at 54460 (emphasis added).)

[6] Presumably this should read: "The closest prior art, Palepu, … ."

E. The '400 Application

The '400 application that became the '948 patent in this case started off with "consisting of" claims on July 28, 2020, chronologically after the back-and-forth recounted above from the '059 application. The following is illustrative of the '400 application's claims:

> A non-sterile stable liquid formulation formulated for oral administration, consisting of:
>
> (a) a buffering agent, wherein the buffering agent is selected from the group consisting of citric acid, sodium citrate, [and many others],
> (b) water,
> (c) a sweetener,
> (d) sodium benzoate,
> (e) vancomycin hydrochloride, and
> (f) flavoring agent,
>
> wherein the non-sterile stable liquid formulation is homogenous and stable for at least 1 week at ambient and refrigerated temperature and has a pH of 2.5-4.5.

(DTX-1008 at 56004.)

The Examiner first notified Azurity on September 18, 2020 that the '400 application's claims would be allowed. (DTX-1008 at 58509.)[7]

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[7] The Examiner's explanation for allowing these claims is not particularly informative on the disclaimer issue, but I include it for here for completeness:

> Palepu ... teaches that the vancomycin-containing compositions are stable for at least 24 months of storage at a temperature of from about 5 °C to about 25 °C. Without being bound by theory, it is believed that the surprising long-term stability of solutions prepared according to the present invention arises at least in part from the interaction between lactic acid ..., the polar solvent (e.g. propylene glycol) and vancomycin. Palepu's formulations require propylene glycol present as the polar solvent with lactic acid ... .
>
> ...
>
> Palepu ... teaches solutions which have propylene glycol or polyethylene glycol solvent present with lactic acid in the liquid formulation. The instant claims recite a composition consisting of ingredients a-f and is stable and homogenous for at least 1 week at ambient and refrigerated temperature, and thus are allowable over the teachings of Palepu. None of the prior art teaches or suggests a composition consisting of ingredients a-f as claimed that is homogenous and stable for

F. Backtracking in the '421 Application

Azurity emphasizes a statement it made to the Examiner in a different patent application after the events described above had occurred. Patent application number 16/892,421 (the '421 application) was a sibling of the '400 application—i.e., an application with a common parent. On October 13, 2020, Azurity wrote in a submission as part of the '421 application:

> . . . Applicant . . . notes that the instant application claims priority to [the '059 application]. During prosecution of [the '059 application], Applicant made certain arguments and claim amendments with respect to propylene glycol to overcome the cited prior art. For the record, Applicant did not disclaim propylene glycol when submitting the arguments in [the '059 application], and reserves the right to claim propylene glycol in the instant and future cases in this patent family.

(DTX-1007B at 61030.) To place this statement in context, at this point in time, the Examiner had already notified Azurity that the claims of the '400 application would be allowed (September 18, 2020), and Alkem had already submitted its Paragraph IV letter underlying this lawsuit (July 7, 2020). (Complaint ¶ 19.) Although some activity in the '400 application occurred between September 18, 2020 and October 30, 2020 when the '400 application's claims were finally allowed, no amendments or argument relevant to propylene glycol occurred during that time. (See generally DTX-1008 at 58509-58554.)

V. DISCUSSION

The parties agree that Alkem's ANDA satisfies all limitations of all asserted claims except for one: the "consisting of" limitation, and, in particular, whether the presence of propylene glycol in the ANDA violates this limitation. The phrase "consisting of" means that the invention "excludes any element[,] step, or ingredient not specified in the claim." Multilayer Stretch Cling

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at least a week and has a pH from 2.5-4.5.

(DTX-1008 at 58518-19 (emphasis in original).)

Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1358 (Fed. Cir. 2016). Alkem contends that its ANDA product contains propylene glycol and, because propylene glycol is not listed as an ingredient in any asserted claim, the "consisting of" limitation is not met.

A. Azurity's Infringement Theory

Ordinarily, infringement is analyzed by taking each element of the asserted claim and matching it to a feature of the accused product. See Union Carbide Corp. v. Tarancon Corp., 682 F. Supp. 535, 541 (N.D. Ga. 1988); Cole v. Kimberly-Clark Corp., 102 F.3d 524, 532 (Fed. Cir. 1996) ("Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device . . . ."). In this case, because the claim is "closed" to unlisted ingredients, the dispute is whether the accused product contains extra ingredients that cannot fit within any ingredient listed in the claims. Azurity advocates that in analyzing this question, certain ingredients that might otherwise not fit within the claims should be combined and treated as a single ingredient.

To prove infringement, Azurity needs to fit each ANDA ingredient within the asserted claims. No ANDA ingredient can be left over, because any remaining ingredient would violate the "consisting of" limitation. Multilayer Stretch Cling Film Holdings, 831 F.3d at 1358. Azurity contends it does not have to show that each ANDA ingredient individually corresponds to a claimed ingredient. Instead, Azurity asserts that it has proven that mixing and matching certain ANDA ingredients turns them into claimed ingredients. Specifically, Azurity argues that when grape flavor is mixed with propylene glycol—both ingredients of Alkem's ANDA—the combination is a "flavoring agent." And, because a "flavoring agent" is a claimed ingredient, propylene glycol is not a remaining unclaimed ingredient that would violate the "consisting of" limitation.

A simple food analogy may help to explain Azurity's position. Suppose a patent has issued

for a beverage whose recipe calls for lemonade, ginger, and iced tea, and the accused product was made from lemonade, ginger, iced tea, and water. Applying this analogy to Azurity's mixing and matching theory, lemonade and water in the accused product should be grouped together and characterized, collectively, as "lemonade" (albeit weak lemonade), thus matching the patentholder's recipe with no extra ingredients. (See N.T. 4/17/23 at 46:4-8 ("[Azurity's Counsel]: It doesn't change the fact that it's lemonade. . . . It might be more diluted than lemonade.").) Similarly, Azurity contends that grape flavor plus propylene glycol should be grouped together and characterized, collectively, as less concentrated grape flavor. (See N.T. 116 (Little) (adding more propylene glycol to a flavoring agent makes it "[not] as concentrated").)

As a general matter, Alkem does not dispute that it is legally permissible to prove infringement by mixing and matching ingredients. Although neither party cites authority on point, Azurity's theory finds some support in the rule stating that claims to a mixture ordinarily go to "a composition that contains the specified ingredients at any time from the moment the ingredients are mixed together." Mars, Inc. v. H.J. Heinz Co., L.P., 377 F.3d 1369, 1374 (Fed. Cir. 2004) (emphasis deleted).

Before considering Azurity's mixing and matching theory, two additional points of clarification are needed. First, although Alkem does not contest that, in some cases, a mixing and matching theory might apply, Alkem urges that in this case Azurity "may not challenge Alkem's ANDA's consistent characterization of propylene glycol as a cosolvent" by calling it a flavoring agent. (Alkem's Post-Trial Brief at 2.) For support, Alkem cites cases holding that infringement in a Hatch-Waxman case "is controlled by the ANDA specification" because "drug manufactures are bound by strict statutory provisions to sell only those products that comport with the ANDA . . . ." Par Pharm., Inc. v. Eagle Pharms., Inc., 44 F.4th 1379, 1383 (Fed. Cir. 2022). But Alkem's cited

principle is not analogous and does not apply here. The issue in Par Pharmaceutical was whether the ANDA's specification of a drug's physical characteristics—there, its pH—controlled the infringement inquiry. Here, the physical characteristics of Alkem's ANDA are not in dispute. Rather, the dispute centers on how the ANDA's ingredients function. The fact that the ANDA calls propylene glycol a "co-solvent" does not preclude Azurity from offering evidence that propylene glycol also functions as a component of a flavoring agent.

Second, although Azurity sought to prove at trial that propylene glycol by itself is a flavoring agent, Azurity all but abandoned that argument in its post-trial brief and now takes the position that whether propylene glycol has flavor is "immaterial." (Azurity's Post-Trial Brief at 8.) Azurity pivots for good reason: the evidence it presented at trial in an attempt to show that propylene glycol (sometimes described as "virtually flavorless") has any impact on the taste of Alkem's ANDA was unpersuasive. Azurity did not test the effect of propylene glycol on the product, and its expert, Dr. Little, was not aware of a single product that uses only propylene glycol for flavor. (N.T. 112-13, 128 (Little).) Studies showing that propylene glycol can have a perceptible taste in, for example, filtered water were not persuasive in demonstrating the effect of propylene glycol in Alkem's grape-flavored ANDA liquid. I also credit Alkem's expert Dr. Forrest's testimony that propylene glycol is generally not something that would be considered for use as a flavor because it has "so very little taste." (N.T. 162.) Thus, I find that Azurity failed to demonstrate by a preponderance of the evidence that propylene glycol standing alone is a flavoring agent. Consequently, Azurity can only prevail on its infringement case if it is established that the ANDA contains a flavoring agent (ingredient (f) in claim 5) made from a combination of propylene glycol and grape flavor.

With that understanding, I turn to the claim construction dispute at the heart of this litiga-

tion.

B. Alleged Waiver of Alkem's Disclaimer Argument

Alkem's case is primarily focused on Azurity having disclaimed propylene glycol in the prosecution history. The parties agree that Alkem's disclaimer argument is properly viewed as "claim construction" because it affects the scope of the asserted claims. See U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement."). But Azurity asserts that claim construction is inappropriate at this late stage of the litigation, especially after the parties stipulated that "no terms of the patents-in-suit require construction." (ECF No. 84.)

A district court has discretion to consider claim-construction arguments at trial provided the parties are afforded notice and an opportunity to be heard and neither party is unfairly prejudiced by the procedure. See Pressure Prod. Med. Supplies, Inc. v. Greatbatch Ltd., 599 F.3d 1308, 1315-16 (Fed. Cir. 2010). Certainly there will be cases where a party should be precluded from pressing new claim construction disputes late in the litigation so as to avoid surprises at trial. See Keranos, LLC v. Silicon Storage Tech., Inc., 797 F.3d 1025, 1035 (Fed. Cir. 2015). However, two factors demonstrate that such preclusion does not apply here.

First, Alkem's disclaimer argument was not a surprise for Azurity. Alkem has maintained since filing its answer that the prosecution history prevents Azurity from proving infringement, and Alkem set out its view of the prosecution history in detail in its motion for judgment on the pleadings. (See Answer, Fourth Separate Defense; Motion, ECF No. 46.) Thus Azurity was on notice more than a year before trial as to precisely which statements in the prosecution history

Alkem considered significant and what Alkem contended the effect of those statements would be. I invited Azurity to establish prejudice at trial, and Azurity did not do so, nor did it point to any prejudice in its post-trial brief or during closing arguments. (N.T. 23-24.)

Second, refusing to consider evidence on the meaning of "flavoring agent," and whether that term should include propylene glycol, would make it substantially more difficult to resolve the infringement issue before me. I cannot determine whether grape flavor and propylene glycol can combine to make a "flavoring agent" without knowing what that term means. See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) (describing the required two-step process for deciding infringement). The phrase "flavoring agent" is not commonly used by non-scientists, and I must therefore rely on evidence of its "special meaning and usage in the field." Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998); see also Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) ("[T]he meaning of a claim term as understood by persons of skill in the art is often not immediately apparent . . . ."). Indeed, at the beginning of Azurity's case-in-chief, its counsel elicited testimony that "[t]he plain and ordinary meaning of a 'flavoring agent' would be a mixture of ingredients that imparts flavor to a formulation." (N.T. 67 (Little).) Such testimony would normally be appropriate for a Markman hearing, not trial. See Markman, 517 U.S. at 387; O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008). Azurity therefore tacitly acknowledges that some amount of claim construction analysis is necessary to decide this case.

Azurity proposes that I can leave the term "flavoring agent" "[u]nconstrued" and it will default to its "plain and ordinary meaning." (Proposed Pretrial Order, Ex. 4, ¶ 15.) This argument rests on a false distinction between construction and meaning. Determining "the meaning of a term in the relevant art" is not an alternative to claim construction; it is claim construction. Teva

Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 331 (2015); see also Network Com., Inc. v. Microsoft Corp., 422 F.3d 1353, 1359 (Fed. Cir. 2005) ("We construe a claim term as having its ordinary and customary meaning . . . ." (quotation marks omitted)). When judges say that a term "require[s] no construction," they mean that further elaboration is unnecessary because the term is "common parlance" and its meaning is "clear." Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283, 1291 (Fed. Cir. 2015); see also Schumer v. Laboratory Computer Sys., Inc., 308 F.3d 1304, 1312 (Fed. Cir. 2002) ("These are not technical terms or art, and do not require elaborate interpretation."). But the term here is "flavoring agent," which is more technical, and the question about whether it can refer to multiple, possibly flavorless ingredients that also serve non-flavoring functions is somewhat obscure. These issues cannot be resolved without engaging in some sort of claim construction. See Markman, 517 U.S. at 386-88.

Finally, it would be inappropriate to consider Azurity's expert testimony on the meaning of "flavoring agent" without also considering the prosecution history evidence Alkem has offered to rebut it. Expert testimony (extrinsic evidence) on claim meaning may not be considered "in a vacuum," and it is required to view such testimony in "the context of the written description and the prosecution history." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005). Where "expert testimony . . . is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history," it is the intrinsic record, not the expert's testimony, that controls. Phillips v. AWH Corp., 415 F.3d 1303, 1318 (Fed. Cir. 2005) (quotation marks omitted). It would be a peculiar result to enforce the parties' stipulation that no claim terms require construction by admitting only "less reliable" expert testimony to the exclusion of more reliable evidence in the patent's intrinsic record. SkinMedica, Inc. v. Histogen Inc., 727 F.3d 1187, 1195 (Fed. Cir. 2013).

C. Alkem's Proposed Limiting Construction Based on the Prosecution History

Azurity contends that a "flavoring agent" is any "mixture of ingredients that imparts flavor to a formulation." (N.T. 67 (Little).) Alkem does not propose an alternative, complete definition of "flavoring agent" or dispute that flavoring agents can be mixtures of ingredients. Instead, Alkem advocates a partial limitation on Azurity's construction: as it relates to Azurity's invention, whatever else a flavoring agent might contain, it cannot contain propylene glycol. Alternatively, Alkem argues that, at the very least, a flavoring agent cannot contain additional, separately added propylene glycol that serves a function other than flavoring. Alkem grounds this limitation in the prosecution history of the '948 patent.

(1) Standard for Prosecution History Disclaimer

"[T]he words of a claim are generally given their ordinary and customary meaning," and there is a "heavy presumption" that the ordinary meaning controls. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quotation mark omitted); Housey Pharms., Inc. v. Astrazeneca UK Ltd., 366 F.3d 1348, 1352 (Fed. Cir. 2004). But "[t]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Trading Techs. Int'l, Inc. v. eSpeed, Inc., 595 F.3d 1340, 1352 (Fed. Cir. 2010). "For example, a patentee may, through a clear and unmistakable disavowal in prosecution history, surrender certain claim scope to which he would otherwise have an exclusive right by virtue of the claim language." Id. (quotation mark omitted). "Any explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to capture the scope of the actual invention that is disclosed, described,

and patented." Trivascular, Inc. v. Samuels, 812 F.3d 1056, 1063 (Fed. Cir. 2016) (quotation marks omitted). "The party seeking to invoke prosecution history disclaimer bears the burden of proving the existence of a 'clear and unmistakable' disclaimer that would have been evident to one skilled in the art." Id.[8]

(2) Azurity's Representation That Its Claimed Invention Lacked Propylene Glycol

I begin with the clearest representation Azurity made to the Examiner that its claimed invention did not contain propylene glycol:

> . . . Palepu discloses liquid vancomycin-containing compositions that include (a) vancomycin . . . , (b) **a polar solvent comprising propylene glycol, polyethylene glycol, or mixtures thereof**, (c) lactic acid, . . . and optionally (d) a pH adjuster. . . . The absence of propylene glycol and polyethylene glycol in the claimed invention, in part, distinguishes it from the cited reference.
>
> Palepu clearly teaches that the polar solvent (comprising propylene glycol, polyethylene glycol, or mixtures thereof) and lactic acid . . . are important components in its compositions. . . . Palepu emphasizes that it is the interaction/combination of its polar solvent (e.g. propylene glycol) and lactic acid . . . that gives the solutions long-term stability. . . .
>
> . . .
>
> At least for the reasons stated above, the compositions of Palepu do not fall within the scope of the claimed invention. The claimed invention does not include the polar solvents or lactic acid of Palepu. . . .

(DTX-1004K at 54251-52 (bold text in original, underlining added).) There is no other way to read the underlined statements than as representing that the claimed invention does not contain propylene glycol. The words "absence" and "does not include" are unambiguous. But this does not end the inquiry because Azurity made the above statements in support of a draft claim (claim

[8] The parties stipulated that a person of ordinary skill in the art (POSA) would be "a pharmaceutical formulator that has either a very high level of education or a lower level of education with a certain amount of experience in the field." (N.T. 54.)

16) that was later canceled. Thus, I must further determine whether the above unambiguous representations apply to the claims that did issue. See MIT v. Shire Pharms., Inc., 839 F.3d 1111, 1120 (Fed. Cir. 2016) (evaluating whether arguments made in support of some claims applied to other claims). For the following reasons, I conclude that they do.

First, the above arguments were made in support of a draft claim that used the same terms "consisting of" and "flavoring agent" that appear in the issued claims. Cf. MIT, 839 F.3d at 1120 (finding no disclaimer where claim under consideration "did not include the terms" found in the issued claims).[9] Second, Azurity itself pointed out that the same argument would support the claims that did issue. With respect to draft claim 20 (which did issue), Azurity referenced the above representations and told the Examiner:

> As explained above, Palepu teaches that its polar solvents (e.g. propylene glycol) and lactic acid … confer its compositions with long-term stability. The claimed invention is an oral vancomycin formulation that is stable for 30 days, and it does not include the polar solvents or lactic acid of Palepu. The skilled artisan would not have had a reasonable expectation of success in producing a stable, oral vancomycin formulation, by combining Palepu and Accord and modifying the solution by removing the polar solvents and/or the lactic acid of Palepu.

(DTX-1004K at 54254 (underlining of "stable" and "oral" in original, other emphasis added).) By referencing its argument with respect to claim 16 ("As explained above") and repeating its representation that the claimed invention "does not include" Palepu's polar solvents ("e.g. propylene glycol"), Azurity clearly and unmistakably represented that the invention did not include propylene glycol. Even standing alone, the statement that Azurity's invention "does not include the polar solvents or lactic acid of Palepu" is a clear and unmistakable representation that the invention does

[9] Technically, draft claim 16 used "consists of," but that term is synonymous with "consisting of." Shire Dev., LLC v. Watson Pharms., Inc., 848 F.3d 981, 984 (Fed. Cir. 2017).

not include propylene glycol.

Moreover, the Examiner also understood Azurity to be representing that all claims using "consisting of" language excluded propylene glycol:

> The instant claims exclude the presence of propylene glycol or polyethylene glycol in view of the consisting of language, and thus overcome the teachings of Palepu which requires the propylene glycol or polyethylene glycol to be present with the vancomycin hydrochloride.

(DTX-1004O at 54460.) While an examiner's statement cannot by itself constitute a disclaimer, it may be considered in interpreting the applicant's own statements. Arendi S.A.R.L. v. Google LLC, 882 F.3d 1132, 1136 (Fed. Cir. 2018). The Examiner's statement shows there was a common understanding that Azurity's purpose in adding the "consisting of" language was to exclude propylene glycol. It is also evident that Azurity agreed with the Examiner's interpretation, because Azurity submitted the claims that would become the '948 patent shortly after the Examiner made the above statement—and, in doing so, repeated the "consisting of" language in its new claims. For these reasons, the above representations by Azurity were a "clear and unmistakable" disclaimer that its invention did not include propylene glycol. Trivascular, 812 F.3d at 1063.

In urging that Alkem has not proven disclaimer, Azurity offers three responses, none of which is persuasive. Azurity first asserts that the above representations are more nuanced than they first appear. In Azurity's view, they conveyed, at most, that the claimed invention lacked so much propylene glycol that it could be called the drug's "solvent." Azurity points to the language "[t]he claimed invention … does not include the polar solvents … of Palepu" as bearing this interpretation. Although nothing in that sentence references a particular amount of propylene glycol, Azurity argues that it was implied by the word "solvent" and accompanying discussion of Palepu, which did describe formulations containing propylene glycol as the drug's primary solvent.

(See N.T. 294-98 (Little).)

I disagree with Azurity's reading of this language. Azurity defined "the polar solvents" as "propylene glycol," not "a lot of propylene glycol." Azurity's reading also fails to explain why it further represented that there was an "absence of propylene glycol … in the claimed invention," words that are not susceptible to an interpretation that only a certain quantity of propylene glycol was disclaimed.

Azurity's contention that it only disclaimed enough propylene glycol to make a solvent is also belied by the lack of any mention of how much propylene glycol that would be. Even at trial, Azurity's expert could not say how much propylene glycol it takes to make a solvent. (N.T. 117-18 (Little).) Palepu itself discloses formulations containing widely varying amounts of propylene glycol—all the way down to 1.2%. (N.T. 330-34; PTX-188 at 8534, [0054].) Given that the Examiner had just rejected Azurity's proposed negative limitation on "suspending agents" because it was unclear what that limitation excluded, it would make little sense for the Examiner to then allow Azurity to distinguish Palepu based on an undefined notion of enough propylene glycol to be called a solvent.

The dialogue between Azurity and the Examiner regarding negative limitations is also instructive. Although I agree with Azurity that arguments in support of negative-limitation claims cannot by themselves be disclaimers because negative limitations do not appear in any asserted claim, this dialogue nevertheless shows that Azurity and the Examiner had long been discussing the possibility of distinguishing Palepu based on the presence or absence of propylene glycol, not any particular amount of it. Azurity's view thus has to be that at some point the dialogue silently switched to being about a particular amount of propylene glycol, without anyone ever saying what that amount was. That interpretation is not plausible. For these reasons, I disagree with Azurity's

reading that only a certain quantity of propylene glycol was disclaimed.

Azurity's second proposed reading of the prosecution history is that it did not disclaim propylene glycol by itself, only propylene glycol in conjunction with lactic acid. In support, Azurity points to the below statement:

> Palepu emphasizes that it is the interaction/combination of its polar solvent (e.g. propylene glycol) and lactic acid (or the lactate molecule used in some embodiments) that gives the solutions long-term stability.

(DTX-1004 at 54251.) To the extent Azurity is suggesting that it might have been possible to distinguish Palepu more narrowly because Palepu required certain ingredients to be present in its formulations, "the scope of surrender is not limited to what is absolutely necessary to avoid a prior art reference; patentees may surrender more than necessary." Tech. Properties Ltd. LLC v. Huawei Techs. Co., 849 F.3d 1349, 1359 (Fed. Cir. 2017). "An applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well." SpeedTrack, Inc. v. Amazon.com, 998 F.3d 1373, 1380 (Fed. Cir. 2021). Azurity may well have pointed to lactic acid as a difference between its invention and Palepu's, but that does not change the fact that Azurity unambiguously stated that its invention did not contain propylene glycol.

Finally, Azurity argues that I should consider its later statement to the Examiner that it "did not disclaim propylene glycol" and "reserve[d] the right to claim propylene glycol in the instant and future cases in this patent family." (DTX-1007B at 61030.) This statement is insufficient to overcome Azurity's clear and unambiguous disclaimer, nor does it render Azurity's disclaimer amenable to "multiple reasonable interpretations." The above statement, which was not made in the '400 application or an ancestor to it, was presented after this lawsuit began, after the Examiner had told Azurity that language materially identical to the claims of the '948 patent would be allowed,

and after Alkem had provided its Paragraph IV notice to Azurity regarding the ANDA in this case.[10] The statement does not reference the claims of the '948 patent, does not mention their "consisting of" language, does not amend the claims, and does not ask the Examiner to do anything. In fact, the statement does not even assert that any claims then under consideration encompassed propylene glycol, just that Azurity "reserve[d] the right" to submit such claims if it so chose. And Azurity's statement certainly did not put the Examiner or the public on notice that Azurity planned to use the "flavoring agent" ingredient to undermine its representation that its invention excluded propylene glycol. Azurity's disclaimer of propylene glycol remains clear and unmistakable. With respect to Azurity's alternative argument that the above statement shows its "good faith belief" that it did not disclaim propylene glycol, (Azurity's Post-Trial Brief at 25 n.14,) "good faith belief" is not the standard for evaluating disclaimer, which is an "objective" inquiry. SkinMedica, Inc. v. Histogen Inc., 727 F.3d 1187, 1203 (Fed. Cir. 2013).

For these reasons, I conclude that Azurity clearly and unmistakably represented to the Examiner that its invention lacked propylene glycol.

D. Application to Alkem's ANDA

Having determined that Azurity disclaimed propylene glycol in its invention, deciding infringement becomes straightforward. Alkem's ANDA includes 1 milligram per milliliter of propylene glycol. (Undisputed Facts ¶ 56; N.T. 166 (Forrest).) Therefore, Alkem's ANDA does not infringe any asserted claim. In light of my previous findings, Azurity does not seriously dispute this conclusion. (See N.T. 262 ("THE COURT: If I find that you disclaim PG, can you still win the

[10] In closing arguments, Azurity acknowledged that it made this statement in response to Alkem's noninfringement position. (N.T. 4/17/23 at 37:24-38:6.)

case? [Azurity's Counsel]: No, because they have PG in the product, so I agree with that.").)

Azurity nevertheless argues that its disclaimer does not apply to propylene glycol contained within a "flavoring agent" because the parties stipulated that "[s]uitable flavoring agents for use in the Asserted Claims include flavoring agents with or without propylene glycol." (Undisputed Facts ¶ 92.) As I understand this argument, Azurity reads "suitable … for use in the Asserted Claims" to mean "infringing" and asserts that because there exists some, unspecified infringing product containing propylene glycol, disclaimer must not apply.

Azurity's argument regarding the parties' stipulation is unpersuasive. The stipulation says nothing about whether Alkem's ANDA contains a flavoring agent with propylene glycol, and by its terms acknowledges that there are also flavoring agents without propylene glycol. Moreover, even if there does exist an unknown infringing flavoring agent with propylene glycol, Azurity at least disclaimed using the term "flavoring agent" to encompass additional propylene glycol, not added as part of a flavoring agent, that does not contribute to the flavor of the drug. Any contrary conclusion would be incompatible with Azurity's repeated statements to the Examiner.[11]

Finally, I note that: (1) Alkem's "co-solvent" propylene glycol is added separately from the ANDA's grape flavor; (2) Azurity failed to prove the "co-solvent" propylene glycol has any perceptible effect on the ANDA's taste; and (3) Azurity failed to prove that the "co-solvent" propylene glycol does not function as a co-solvent for the parabens. Azurity's disclaimer of propylene glycol therefore applies to the "co-solvent" propylene glycol, irrespective of whether there might

[11] By analogy, assuming a mixture of ten parts water to one part lemonade could be called "lemonade" or even "just lemonade," it would be inaccurate to call it "just lemonade and not water." Likewise, Azurity represented to the Examiner that its invention was just the listed ingredients and not propylene glycol.

exist other, unspecified infringing flavoring agents that contain propylene glycol.[12]

VI. CONCLUSION

For the reasons set forth above, I conclude that Azurity has not proven, by a preponderance of the evidence, that Alkem's ANDA meets the "consisting of" limitation of any asserted claim, and, consequently, Alkem's ANDA does not infringe any asserted claim.

An appropriate order follows.

[12] It is unnecessary to discuss the parties' stipulation that Alkem's ANDA product is a "non-sterile stable liquid formulation" because the scope of this term is immaterial. (ECF No. 110.)

Azurity contends that two additional facts are relevant to the infringement inquiry, but it is unclear how these facts relate to the asserted claim limitations. First, Azurity stresses that the "grape flavor" propylene glycol and the "co-solvent" propylene glycol in Alkem's ANDA are "chemically identical" and both interact with the grape-flavored chemicals. (N.T. 78-79 (Little); N.T. 25 (Azurity's counsel).) But if a recipe calls for one cup of water, adding two cups of water is not following the recipe, even if it is later impossible to tell which cup was which. Second, Azurity points out that the amount of "co-solvent" propylene glycol in Alkem's ANDA is similar to an amount of a substance that could be added as a "flavoring agent," as indicated by the patent's specification. (N.T. 137 (Little).) But the claim term is "flavoring agent," not "any ingredient in an amount similar to a flavoring agent." Because the "co-solvent" propylene glycol in Alkem's ANDA is not a flavoring agent, it does not prove infringement to show that a flavoring agent could have been added in a similar amount.