

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,

Plaintiff,

v.

ALKEM LABORATORIES LTD.

Defendant.

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C.A. No. 19-2100-LPS

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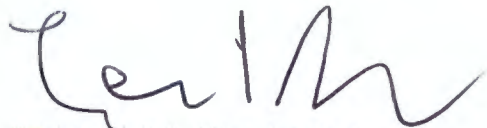
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MEMORANDUM OPINION

November 16, 2021
Wilmington, Delaware



STARK, U.S. District Judge:

In this action arising under the Hatch-Waxman Act, Azurity Pharmaceuticals, Inc.¹ (“Azurity” or “Plaintiff”) asserts claims of seven patents against Alkem Laboratories Ltd. (“Alkem” or “Defendant”) in relation to Alkem’s application to market a generic version of Azurity’s Epaned® before the patents-in-suit expire. (D.I. 1; D.I. 39) Epaned® is an angiotensin-converting enzyme (ACE) inhibitor used to treat hypertension, heart failure, and asymptomatic left ventricular dysfunction. (D.I. 39 ¶ 13) The patents-in-suit cover oral liquid formulations of enalapril, the active ingredient in Epaned®. (See D.I. 72 at 1-2)

The parties dispute five claim terms that appear in one or more of three patents: U.S. Patent Nos. 10,772,868 (the “868 patent”), 10,786,482 (the “482 patent”), and 10,918,621 (the “621 patent”). These three patents share a common specification. The parties submitted a joint claim construction brief (D.I. 72) and exhibits (D.I. 51-1, D.I. 73). The Court held a claim construction hearing on August 23, 2021, at which both sides presented oral argument. (D.I. 79) (“Tr.”)

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. See *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015) (citing *Markman v. Westview Instruments, Inc.* (“*Markman IP*”), 517 U.S. 370, 388-91 (1996)). “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

¹ Azurity was substituted for Silvergate Pharmaceuticals, Inc. on June 11, 2021. (D.I. 59)

claim construction.” *Id.* at 1324. The Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[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 [(“POSA”)] in 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 omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent “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.” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment” because “claim terms are normally used consistently throughout the patent.” *Id.*

It is likewise true that “[d]ifferences among claims can also be a useful guide.” *Id.* “For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15. This presumption of claim differentiation is “especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted).

In addition to the specification, a court should “consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.* (“*Markman I*”), 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the [U.S. Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[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.” *Id.*

Sometimes, “the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 574 U.S. at 331. “Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman I*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the ordinary and customary meaning of a term because such dictionaries “endeavor to collect the accepted

meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful to the court,” it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs SpA*, 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.” *Osrām GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks omitted).

II. CONSTRUCTION OF DISPUTED TERMS

A. “a buffer”²

Plaintiff “one or more buffers”
Defendant “one buffer”
Court “one or more buffers”

The parties dispute whether the claimed buffer is limited to just one buffer or may contain one or more buffers. In some claims, “a buffer” follows the transitional phrase “comprising,” while in others it follows “consisting essentially of.”³ Despite this variation, the parties agree the term should be defined consistently across all of the claims at issue. (*See* Tr. at 12-14, 19, 22-23)

“As a general rule, the words ‘a’ or ‘an’ in a patent claim carry the meaning of ‘one or more.’” *01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012). “The exceptions to this rule are extremely limited: a patentee must evince a clear intent to limit ‘a’ or ‘an’ to ‘one.’” *Id.* “An exception to the general rule arises *only* ‘where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule.’” *Id.* (quoting *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342-43 (Fed. Cir. 2008)).

As Alkem notes, this rule often arises in cases discussing claims with the open-ended “comprising” transitional term. (*See* D.I. 72 at 17-18) Courts have distinguished between

² This term appears in claims 1, 13, and 14 of the ’868 patent, claims 1, 13, and 14 of the ’482 patent, and claims 1, 19, and 30 of the ’621 patent.

³ Claims 1 and 14 of the ’482 patent use “comprising,” while claim 13 of the ’482 patent, claims 1, 13, and 14 of the ’868 patent, and claims 1, 19, and 30 of the ’621 patent use “consisting essentially of.”

“comprising” claims and “consisting essentially of” claims. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998) (“A ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a ‘consisting of’ format and fully open claims that are drafted in a ‘comprising’ format.”). The “consisting essentially of” phrase signals that, while “the invention necessarily includes the listed ingredients,” it is also “open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *Id.* Given its partially open nature, courts have noted that the “consisting essentially of” phrase does not necessarily restrict subsequent modified articles to a singular form. *See Mylan Pharms., Inc. v. Kremers Urb. Dev. Co.*, 2004 WL 57218, at *4-5 (D. Del. Jan. 13, 2004).

Thus, despite the distinction between the two transitional phrases, the general rule that “a” in a patent claim means “one or more” provides support for Azurity’s construction, in both the “consisting essentially of” claims and (even more strongly) in the “comprising” claims.

The patents’ common specification offers further support for Azurity’s proposal. As Azurity observes (*see* D.I. 72 at 9), the specification expressly defines “a” in its “Certain Definitions” section:

As used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural reference unless the context clearly dictates otherwise. Thus, for example, reference to “an excipient” is a reference to one or more excipients and equivalents thereof known to those skilled in the art, and so forth.

(’482 patent at 29:20-25) Thus, based on both the law in general and the specification in particular, “a buffer” is not limited in the claims to just one buffer “unless the context clearly dictates otherwise.” (*Id.*)

Alkem argues the prosecution history provides such context, revealing (in its view) that the patentee and examiner understood “consisting essentially of” to exclude additional

components, including more than one buffer. (D.I. 72 at 11-14) During prosecution of U.S. Patent No. 9,669,008 (the “’008 patent”), the parent patent of all the patents-in-suit, the patentee distinguished the prior art by noting that the ’008 patent required comparatively fewer components. (D.I. 51-1 at Appx 121-22) To overcome a rejection based on obviousness, the patentee associated the phrase “consisting essentially of” with a narrow set of ingredients, adding that “none of [the prior art] references teach[es] or suggest[s] the claimed combination of *only* enalapril, citric acid, sodium citrate, sodium benzoate, sucralose and water at the recited concentrations and pH as stated in claim 20.” (*Id.* at Appx 117) Alkem argues these narrowing statements constitute a disavowal of additional components, including multiple buffers. (D.I. 72 at 11-12)

The Court disagrees. While the patentee distinguished the ’008 patent based on its relatively limited number of ingredients, it never stated that a single buffer was a unique element of the claims. (*See id.* at 21) Instead, it simply argued that, while two relevant prior art references contained ten or more components in addition to enalapril and water, the formulation of the ’008 patent claims had only four ingredients in addition to enalapril and water. (D.I. 51-1 at Appx 122) That the ingredients in the prior art may have included multiple buffers does not render the patentee’s statement a clear and unmistakable disavowal of multiple buffers. *See generally MIT v. Shire Pharms., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016) (“In order for prosecution disclaimer to attach, the disavowal must be both clear and unmistakable.”).

Defendant further asserts that the patentee similarly narrowed claim scope during prosecution of the ’868 patent, of which the ’621 patent is a continuation. (D.I. 72 at 13) The examiner rejected what are now claims 1, 13, and 14 of the ’868 patent as obvious in light of prior art references such as Nahata. (*See* D.I. 51-1 at Appx 221-23) In doing so, the examiner

noted that the claimed invention was drawn to a formulation *comprising* a list of four ingredients. (*Id.* at Appx 228) While the compositions claimed by Nahata comprised additional components, the examiner emphasized the open-ended nature of the term “comprising” and stated “there is no explicit proviso which would exclude the use of additional components in the instantly claimed formulation.” (*Id.* at Appx 228-29) The patentee subsequently amended “comprising” to “consisting essentially of” and overcame the rejection. (*Id.* at Appx 245-49) Accordingly, Defendant argues the patentee disavowed *any* additional components, including more than one buffer. (D.I. 72 at 13)

The Court, again, disagrees. While the amendment from “comprising” to “consisting essentially of” narrowed the claim scope, the patentee chose not to use the even more closed phrase, “consisting of.” *See PPG*, 156 F.3d at 1354 (explaining that unlike “consisting of,” “consisting essentially of” is “open to unlisted ingredients that do not materially affect the basic and novel properties of the invention”); *see also* Tr. at 27-29. A POSA would understand that the resulting claim language – “consisting essentially of . . . a buffer” – yields narrower claim scope than existed before the amendment (“comprising . . . a buffer”) but does not disclaim (as part of the ongoing negotiation between the applicant and the examiner) all embodiments having more than one buffer.⁴ *See MIT*, 839 F.3d at 1119 (“Where the alleged disavowal is . . . amenable to multiple reasonable interpretations, we have declined to find prosecution disclaimer.”) (internal quotation marks omitted). In the context of the instant prosecution

⁴ Plaintiff also argues that the examiner’s rejection was based, at least in part, on the applicant’s failure to demonstrate unexpected results from buffers other than the single buffer combination recited in the claims. (*See* D.I. 72 at 23-24) (citing D.I. 51-1 at Appx 221) In response, the applicant submitted an inventor declaration demonstrating unexpected results from several other buffers. (*See id.*) (citing D.I. 51-1 at Appx 236)

history, the absence of any clear explanation by the patentee for the amendment does not result in a clear and unmistakable disavowal of multiple buffers.

Alkem argues further that, since the '482 patent is a continuation of the '008 patent, and the '621 patent is a continuation of both the '008 and '868 patents, the use of the phrase “consisting essentially of” should be understood with reference to the '008 and '868 patents' prosecution history and, thus, should be read to exclude additional components. (D.I. 72 at 14; *see Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1368 (Fed. Cir. 2007) (“The prosecution history of [a] parent application is highly instructive in light of the similarity between the claims of the application and those of the patents in suit.”)) Even if this principle is correct, it does not support the conclusion Alkem seeks. As the Court is not persuaded that the prosecution histories of the '008 or '868 patents contains a clear and unmistakable disavowal of multiple buffers, the prosecution histories of the '482 and '621 patents cannot pick up from them a nonexistent disclaimer.

Defendant's observation that “the specification is silent as to whether multiple buffers are contemplated” (D.I. 72 at 19) does not mean that the claims exclude embodiments containing multiple buffers. Nor do the facts that every embodiment in the specification uses a single buffer or that other components (e.g., buffering agents) are described with extensive lists that include mixtures (*see id.* at 16). Silence in a specification does not necessarily mean the undisclosed embodiment is excluded; claims are not limited to the embodiments expressly taught in a specification. *See, e.g., Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1288 (Fed. Cir. 2021).

Finally, Defendant suggests that Azurity's construction fails to sufficiently inform a POSA as to the scope of the buffer concentration limitations. (*See* D.I. 72 at 14-15) The Court

agrees, however, with Azurity that a POSA would understand from the plain language of the claims that “one or more buffers” would *together* need to meet the amount required by the claims. (*See id.* at 25-26; Tr. at 10)⁵

In sum, there is nothing in the claims, specification, or prosecution history that warrants a departure from the general rule that “a” means “one or more.” *See Baldwin Graphic*, 512 F.3d at 1342-43.

B. “a buffer to maintain the pH”⁶

Plaintiff “one or more buffers to maintain the pH”
Defendant “one buffer that maintains the pH”
Court “one or more buffers to maintain the pH”

For this term, the parties reiterate their arguments with respect to “a buffer.” (*See D.I. 72* at 34-36; Tr. at 34-35) The Court, thus, incorporates its construction of “a buffer” (“one or more buffers”) into its construction of this term. Further, as Alkem conceded at the hearing, there is no compelling reason to alter the language of the claim term from “to maintain the pH” to “that maintains the pH,” and the Court will not do so. (*See Tr.* at 35)

⁵ Further, to the extent Defendant asserts an indefiniteness argument, the parties agreed to defer such arguments for trial and not to address them as part of these claim construction proceedings. (*See D.I. 72* at 6)

⁶ This term appears in claims 1, 13, and 14 of the ’868 patent and claims 1, 19, and 30 of the ’621 patent.

C. “a citrate buffer [to maintain the pH about 4.5 or below comprising citric acid and sodium citrate]”⁷

Plaintiff No construction needed. To the extent a construction is needed, plain and ordinary meaning.
Defendant “one buffer comprising citric acid”
Court “one or more buffers made of citrate ions”

As an initial matter, it appears that the parties misunderstand one another’s positions with respect to this term. Plaintiff states that Alkem’s construction limits “a citrate buffer” to one that contains *only* citric acid. (See D.I. 72 at 42) Alkem clarified, however, that it is not arguing that *only* citric acid is present in a “citrate buffer;” instead, “a citrate buffer” *requires* citric acid *and* may also contain other components. (*Id.* at 43) For its part, Alkem suggests Plaintiff’s view is that in all claims “a citrate buffer” must *always* comprise citric acid and sodium citrate. (*Id.* at 40) If this were true, there would be no need to clarify within claim 26 that the buffer comprises these ingredients; this limitation would be “mere surplusage.” (*Id.* at 39) (quoting *Texas Instruments Inc. v. U.S. Int’l Trade Comm’n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993)) Plaintiff, however, does not propose construing “a citrate buffer” as always comprising citric acid and sodium citrate. In Plaintiff’s view, “‘a citrate buffer’ alone would not be read by a POSA to mean a buffer of only citric acid, of only sodium citrate, or of only citric acid and sodium citrate together.” (D.I. 72 at 42-43) (citing D.I. 73-1 at Appx 471-76) (Handbook of Pharmaceutical Excipients listing sodium citrate and potassium citrate as potential buffering agents) Instead, a POSA would understand that “a ‘citrate buffer’ indicates that the buffer is made of citrate ions,

⁷ This term appears in claim 26 of the ’868 patent.

which may be added to the solution through a number of ways, including citric acid, sodium citrate, and potassium citrate.” (*Id.* at 42 n.17)

In any event, Defendant’s proposed construction is not supported by the claim language. It would, as Plaintiff explains, read out the sodium citrate expressly recited in claim 26. (*See id.* at 41; Tr. at 38-39)

Defendant points to the ’868 patent’s prosecution, during which Dr. Mosher, one of the patent’s inventors, stated that certain formulations created to test stability were prepared using a “citrate-based buffer.” (D.I. 72 at 38-39) (citing D.I. 51-1 at Appx 236-37) Three of these formulations, H7-H9, were prepared with citric acid only, suggesting that the patentee understood that a “citrate-based buffer” does not necessarily include sodium citrate. (D.I. 51-1 at Appx 236-37) Plaintiff concedes that, since these three formulations lack sodium citrate, they are outside the scope of claim 26. (Tr. at 42-43) In Plaintiff’s view, however, this should not bear on the Court’s construction, as Dr. Mosher did not explain that claim 26 covered all of his examples; rather, claim 26 is a narrower claim. (*See id.*) Plaintiff also notes that Dr. Mosher described these formulations as “citrate-*based* buffers,” referring to the citrate ion and not the component excipients, and points to another formulation discussed by Dr. Mosher, H1, which contained both citric acid and sodium citrate. (D.I. 72 at 41-42)

In the Court’s view, this prosecution history supports Azurity’s articulation of a “citrate buffer” as, more generally, made of citrate ions. In claim 26, it is clear that these citrate ions are citric acid and sodium citrate, as in the H1 formulation.

In sum, since the parties dispute the scope of the claim term, the Court concludes that construction is necessary. *See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). The Court adopts the term’s plain and ordinary meaning consistent

with the remainder of the claim. It also incorporates its prior construction of “a buffer” to mean “one or more buffers.” This construction is supported by the claim language, the prosecution history, and – to a lesser extent – the excerpts from the Handbook of Pharmaceutical Excipients, which Alkem concedes explain that a citrate buffer may comprise citrate ions such as sodium citrate and potassium citrate. (See D.I. 72 at 44)

D. “[a buffer comprising] a mixture of citric acid and sodium citrate[, wherein the buffer is present at a concentration between about 5 mM and about 20 mM in the oral liquid formulation]”⁸

Plaintiff
No construction needed. To the extent a construction is needed, plain and ordinary meaning.
Defendant
“a combination of citric acid and sodium citrate distinct from the formulation’s other components”
Court
No construction needed.

The plain language of claims 1, 13, and 14 of the ’482 patent makes clear that citric acid and sodium citrate cannot meet the requirements of the claimed preservative in these claims. Unlike in earlier versions of the ’482 patent and certain prior art references, which recited “a preservative” more broadly, these claims in their current form specify that the preservative is “sodium benzoate” (’482 patent cls. 1, 13) or “a paraben or a mixture of parabens” (*id.* cl. 14). Citric acid and sodium citrate are excluded from the list of potential preservatives, eliminating the possibility that either component could serve “double duty as both a buffer and a preservative.” (D.I. 42 at 47) The Court agrees with Plaintiff that, consistent with this analysis, the claim language is readily understandable to a POSA. (See Tr. at 43-44) Further, it is not clear how Alkem’s “artificial separation of the claimed citric acid and sodium citrate from the

⁸ This term appears in claims 1, 13, and 14 of the ’482 patent.

other recited ingredients in the claimed liquid solution” would be achieved. (*See* D.I. 72 at 47)
 The Court sees no dispute here that would be resolved by adoption of any claim construction, including Defendant’s proposed construction.

E. “consisting essentially of”⁹

Plaintiff Plain and ordinary meaning.
Defendant “including, exclusively”
Court “including the listed ingredients and open to unlisted ingredients that do not materially affect the basic and novel properties of the invention”

The Court will construe “consisting essentially of” in accordance with its well-established legal meaning, which is: “includ[ing] the listed ingredients and . . . open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *PPG*, 156 F.3d at 1354; *see also* Manual of Patent Examining Procedure § 2111.03. As discussed above (in connection with the Court’s construction of “a buffer”), Alkem has not shown that the narrowing amendment – from “comprising” to “consisting essentially of” – means that “consisting essentially of” should be interpreted more narrowly than it is customarily understood. Nor is the Court convinced by Alkem’s citation to the common specification, which mentions that claims reciting “comprising” are open-ended. (D.I. 72 at 49-50) (citing ’868 patent at 29:35-42) Additionally, Alkem conceded at the hearing that a construction reflecting the well-established legal meaning of “consisting essentially of” would be agreeable. (*See* Tr. at 51)

III. CONCLUSION

An appropriate Order follows.

⁹ This term appears in claims 1, 13, 14, and 26 of the ’868 patent and claims 1, 19, and 30 of the ’621 patent.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AZURITY PHARMACEUTICALS, INC.,	:	
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Plaintiff,	:	
	:	
v.	:	C.A. No. 19-2100-LPS
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ALKEM LABORATORIES LTD.	:	
	:	
Defendant.	:	
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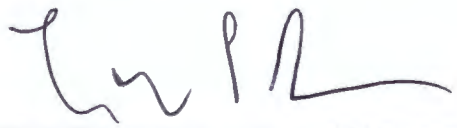
ORDER

At Wilmington this **16th** day of **November, 2021**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the following claim terms are construed as follows:

Claim Term	Court's Construction
a buffer	"one or more buffers"
a buffer to maintain the pH	"one or more buffers to maintain the pH"
a citrate buffer [<i>to maintain the pH about 4.5 or below comprising citric acid and sodium citrate</i>]	"one or more buffers made of citrate ions"
[<i>a buffer comprising</i>] a mixture of citric acid and sodium citrate[, <i>wherein the buffer is present at a concentration between about 5 mM and about 20 mM in the oral liquid formulation</i>]	No construction needed.
consisting essentially of	"including the listed ingredients and open to unlisted ingredients that do not materially affect the basic and novel properties of the invention"



UNITED STATES DISTRICT JUDGE