

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

NEXUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

EXELA PHARMA SCIENCES, LLC,

Defendant.

C.A. No. 22-1233-GBW

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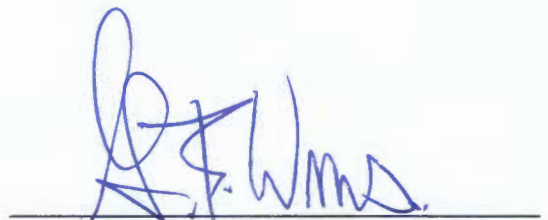
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**MEMORANDUM OPINION**

May 6, 2024  
Wilmington, Delaware



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GREGORY B. WILLIAMS  
U.S. DISTRICT JUDGE

Before the Court is the parties' joint request that the Court construe a single term found in the claims of U.S. Patent No. 11,426,369 (the "'369 patent"). The Court has reviewed the parties' briefing, D.I. 78, concludes that oral argument is not necessary, and construes the term at issue as set forth below.

#### **I. LEGAL STANDARDS**

“[T]he 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) (citation omitted); *Aventis Pharms. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) (same). “[T]here is no magic formula or catechism for conducting claim construction.” *Phillips*, 415 F.3d 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.* The ultimate question of the proper construction of a patent is a question of law, although “subsidiary factfinding is sometimes necessary.” *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326–27 (2015); see *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) (“the construction of a patent . . . is exclusively within the province of the court.”).

“The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history.” *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1313); *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358

(Fed. Cir. 2016) (similar). The “only two exceptions to this general rule” are (1) when a patentee defines a term or (2) disavowal of “the full scope of a claim term either in the specification or during prosecution.” *Thorner*, 669 F.3d at 1365 (citation omitted).

The Court “first look[s] to, and primarily rel[ies] on, the intrinsic evidence,” which includes the claims, written description, and prosecution history and “is usually dispositive.” *Personalized Media Commc’ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1340 (Fed. Cir. 2020) (citation omitted). “[T]he specification ‘ . . . is the single best guide to the meaning of a disputed term.’” *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1340 (Fed. Cir. 2016) (citation omitted). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.’ When the patentee acts as its own lexicographer, that definition governs.” *Cont’l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019) (quoting *Phillips*, 415 F.3d at 1316). However, “[the Court] do[es] not read limitations from the embodiments in the specification into the claims.” *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1310 (Fed. Cir. 2017) (citation omitted)). The “written description . . . is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The Court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370; *Cont’l Cirs.*, 915 F.3d at 796 (same). The prosecution history may “demonstrat[e] how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution . . . .” *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1377 (Fed. Cir. 2021) (quoting *Phillips*, 415 F.3d at 1317).

The Court may “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*, 52 F.3d at 980; *Phillips*, 415 F.3d at 1317 (same). Extrinsic evidence may be useful, but it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Cont’l Cirs.*, 915 F.3d at 799 (internal quotation marks and citations omitted). However, “[p]atent documents are written for persons familiar with the relevant field . . . . Thus resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002); see *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 899 (2014) (explaining that patents are addressed “to those skilled in the relevant art”).

## II. CONSTRUCTION OF DISPUTED TERMS

The following term is in dispute, requires construction, and is construed as set forth below for the following reasons:

### a. “sanitizing”

Term No.	Claim Term	Plaintiff’s Construction	Defendant’s Construction	Court’s Construction
1  '369 patent, claim 1	“sanitizing”	Plain and ordinary meaning, which is confirming, preventing, or reducing bacterial contamination	Plain and ordinary meaning, which is the act of reducing the amount of bacterial contamination prior to filling	Plain and ordinary meaning, which is the act of reducing the amount of bacterial contamination.

Generally, the '369 patent is directed to ready-to-use ephedrine sulfate compositions for use in a clinical setting that are suitable for long term storage, thus eliminating the need to dilute, reconstitute, or compound, an ephedrine sulfate composition prior to treating a patient with that composition. *See* '369 patent 1:20-2:5.

“Sanitizing,” the disputed terms, appears in claim 1 of the '369 patent. That claim recites:

A method of making a shelf-stable, ready-to-use ephedrine sulfate composition, the method comprising:

combining ephedrine sulfate, sodium chloride or dextrose, and water to form a batch solution comprising an initial ephedrine sulfate level of 5 mg/mL, 9 mg/mL sodium chloride or 5% dextrose, and no preservative;

optionally contacting the batch solution with an acid or a base to obtain an initial pH level of the solution of 4.5 to 7;

filtering the batch solution through a membrane filter to obtain a filtered batch solution;

sanitizing one or more containers;

placing not more than 20 mL of the filtered batch solution into one of the one or more sanitized containers to obtain one or more filled containers;

sealing each filled container to obtain sealed containers including a shelf-stable, ready-to-use ephedrine sulfate composition; and

maintaining a pH level of the shelf-stable, ready-to-use ephedrine sulfate composition in the sealed containers that is within 0.5 pH units of the initial pH level during storage at 25° C. and 60% relative humidity for at least 12 months or during storage at 40° C. and 75% relative humidity for at least 6 months.

'369 patent, claim 1. The parties raise two<sup>1</sup> disputes with respect to the term “sanitizing,” namely (1) whether the sanitizing step must occur prior to the filling step, and (2) whether

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<sup>1</sup> The parties initially also disputed whether sterilization (the elimination of all bacteria) is within the scope of the term “sanitizing.” Defendant’s revised proposed construction reflects the

sanitizing a container includes confirming that a container is sanitized, or preventing a sanitized container from becoming un-sanitized. D.I. 78 at 41. For the reasons stated below, the Court finds that (1) the sanitizing step must occur prior to the filling step, and (2) confirming that a container is sanitized, or preventing a sanitized container from becoming un-sanitized, does not fall within the scope of “sanitizing one or more containers.”

The Court finds that the sanitizing step must occur prior to the filling step. *See* '369 patent, claim 1 (reciting, *inter alia*, “placing not more than 20 mL of the filtered batch solution into one of the one or more sanitized containers”). Both parties agree that (at least) these two steps of the '369 patent are ordered. *Compare* D.I. 78 at 41, (Exela’s proposal: “Plain and ordinary meaning, which is the act of reducing the amount of bacterial contamination prior to filling”) *with id.*, (Nexus noting that “[t]here does not appear to be any dispute that claim 1 of the '369 patent refers to filling containers after they have been sanitized”). The Court agrees with Nexus that the term “sanitizing” does not inherently require the sanitization of a container prior to the filling of that container, and that the claim language makes it sufficiently clear that the sanitizing step is ordered without an additional and potentially confusing claim construction. Thus, the Court declines to explicitly construe “sanitizing” as an ordered limitation, but notes for posterity that Nexus has conceded that claim 1 refers to filling containers after they have been sanitized. The Court will not permit later-conflicting testimony or attorney argument.

The Court finds that sanitizing a container does not include “confirming” that a container is sanitized or “preventing” a sanitized container from becoming un-sanitized. While the specification is “the single best guide to the meaning of a disputed term,” *Akzo*, 811 F.3d at 1340,

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parties’ shared understanding that sanitizing “does not require—but also does not preclude—eliminating bacterial contamination.” D.I. 78 at 41.

“sanitizing” appears only once in the ’369 patent—i.e., in claim 1. Accordingly, the Court looks beyond the intrinsic evidence. *Teva*, 574 U.S. at 331. “Sanitizing” is a commonly-used term that possesses a plain and ordinary meaning. *See, e.g.*, D.I. 78, Ex. 9 (“sanitize” means “to make sanitary, as by cleaning or disinfecting”); *id.*, Ex. 10 (“Sanitization is a regulated term and is widely used in the United States to define disinfectants used to reduce, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.”). Nothing in the specification contradicts that plain and ordinary meaning, or lexicographically re-defines “sanitizing.” *See generally* ’369 patent.

Nexus argues that Example 1 of the ’369 patent compels a different construction, because it refers to the use of vials that “had been [sanitized].” *See, e.g.*, D.I. 78 at 16; ’369 patent, 17:7-18:27. Nexus’s argument appears to be that the patentee meant “use a sanitized container” or “prevent a sanitized container from becoming un-sanitized” when the patentee used the term “sanitize one or more containers,” because Example 1’s use of the past perfect tense shows that the claimed method does not require the claimed containers to be sanitized by the individual carrying out the steps of the claimed method. *Id.* The Court, however, finds that the process described in Example 1 is consistent with the plain and ordinary meaning of “sanitizing”—for example, the vials describe in Example 1 could “ha[ve] been” sanitized by the individual executing the process described in that example at a prior step. *See* ’369 patent, 17:7-18:27. Accordingly, the Court finds that its construction does not read out a preferred embodiment. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) (explaining that excluding a preferred embodiment is “rarely, if ever correct”).

If the patentee wanted to claim a method that uses a sanitized container, as opposed to a method that requires sanitizing a container prior to using it, the patentee could have done so. *Cf.*,

*e.g.*, '369 patent, claim 1 (reciting the use of ephedrine sulfate, without first reciting a method-of-making ephedrine sulfate). The patentee, however, claimed “sanitizing one or more containers.” *Id.* Accordingly, finding that nothing in the specification lexicographically defines “sanitizing,” and that the sanitizing step must occur prior to the filling step, the Court gives that term its plain and ordinary meaning: “the act of reducing the amount of bacterial contamination.”

## V. CONCLUSION

The Court will construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.