



**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

NIVAGEN, INC.,

Plaintiff,

v.

SUN PHARMACEUTICALS INDUSTRIES,
INC.,

Defendant.

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Civil Action No. 2:24-cv-36-RWS-RSP



**PLAINTIFF NIVAGEN PHARMACEUTICALS, INC.'S
OPENING CLAIM CONSTRUCTION BRIEF**



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I. INTRODUCTION

Plaintiff Nivagen Pharmaceuticals, Inc. (referred to as “Nivagen, Inc.” on the case caption, hereinafter “Nivagen”) asserts U.S. Patent No. 11,878,076 (the “’076 patent,” a text-searchable version is filed herewith as Exhibit A to Brent A. Batzer, Esq.’s Declaration (“Batzer Decl.”)) against Defendant Sun Pharmaceuticals Industries, Inc.’s (“Sun”) phenobarbital sodium pharmaceutical product. Phenobarbital sodium is a barbiturate that is commonly administered as an anti-convulsant for the treatment of seizures, a sleep aide, or a pre-anesthetic. (*See* Batzer Decl. Ex. A at 1:41-44).

The ’076 patent is directed to a storage-stable, lyophilized, highly pure phenobarbital sodium pharmaceutical product that is essentially void of impurities upon reconstitution in water. (*Id.* at 1:18-21; 8:9-13). Previous liquid formulations of phenobarbital sodium would contain excipients (inactive ingredients) such as “ethanol, glycol and glycerol” in “undesirable quantities,” as well as toxic degradation impurities (breakdown products from the active ingredient phenobarbital). (*Id.* at 2:4-37). Those excipients were added to “decrease the formation of the toxic degradation products in the ... liquid formulations.” (*Id.* at 2:4-11). Because the previous liquid formulations were directly administered to patients, the excipients (and impurities) in the liquid are not suitable or desirable. (*Id.* at 2:29-37). The claimed invention, in contrast, is a lyophilized composition with high stability and purity, with less impurities and better stability than the liquid formulation products. (*Id.* at 2:45-59). The lyophilization process involves freezing a “bulk solution” (a liquid solution that may contain excipients) and then thoroughly (to the extent practical) drying it under vacuum to cause sublimation of the volatile components and to leave behind a solid “cake.” (*See* Declaration of Alexander M. Klibanov, Ph.D. (“Klibanov Decl.”), filed with this brief, at ¶ 22). This lyophilized solid cake should have “high purity” (i.e. with little

excipients besides the active ingredient) and is “void or essentially void of degradation impurities upon solubilization in water.” (i.e. maintains chemical stability without the extensive use of excipients found in liquid formulations). (*See* Batzer Decl. Ex. A at 1:18-21; 2:38-41; 8:9-13).

Prior to administration, a suitable aqueous liquid such as “saline or dextrose” is used to “reconstitute” or dissolve the lyophilized phenobarbital sodium cake, and the reconstituted liquid is administered to the patient by injection. (*See id.* at 4:54 – 5:3).

II. DISPUTED CONSTRUCTIONS OF THE '076 PATENT

Sun maintains that the “composition” claim term requires construction in this litigation:¹

Term	Nivagen’s Proposed Construction	Sun’s Proposed Construction
“composition” (all claims)	Plain and ordinary meaning	Plain and ordinary meaning, disclaiming formulations that contain organic solvents or preservatives

Sun proposes a plain and ordinary meaning construction except disclaiming formulations that contain organic solvents or preservatives. However, Sun recently took, and is maintaining as of the date of this filing, a directly contradictory claim construction position in the Patent Office. On April 22, 2025, Sun filed a Petition for *Inter Partes* Review seeking to invalidate the '076 patent at the Patent Trial and Appeal Board (“PTAB”). Sun’s Petition, Case IPR2025-00893,

¹ Until shortly prior to filing the Patent Rule 4-3 Joint Claim Construction and Prehearing Statement, D.I. 54, Sun contended in its Patent Rule 4-1 and 4-2 disclosures that numerous additional claim terms were all indefinite (i.e., “aqueous solution to form a reconstituted composition”; “reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition”; “is stored”; “amorphous”; and “the reconstituted composition contains no more than . . . % [PEAU/2EPMM/PBG],” “the reconstituted composition contains at most . . . % phenylethylacetylurea (PEAU)”). Sun did so despite that some of these terms and its “indefinite” position regarding these terms was not included in its invalidity contentions, which Sun amended *three* times. Sun withdrew all terms it initially proposed, except for “composition,” after the parties met and conferred prior to filing the Patent Rule 4-3 Joint Claim Construction and Prehearing Statement. Because Sun failed to properly and timely disclose its indefiniteness arguments, and having now waived any claim construction positions related thereto, Nivagen reserves all rights to move to strike any indefiniteness arguments should Sun seek to raise them in this litigation.

Paper 1, is attached to the Batzer Declaration as Exhibit E. In its petition, Sun noted that it “may contend in the district court case” its “disclaimer” theory, but nevertheless “agrees to apply the broader plain and ordinary meaning in [the IPR] proceeding” for “compositions” – without applying any disclaimer. (Batzer Del. Ex. E at 13 n. 2). Sun represented to the PTAB that it “does not believe any claim terms require specific construction for the purpose of deciding [Sun’s patent invalidity challenges].” (*Id.* at 13). It is well established, however, that the PTAB will apply “clear and unmistakable” disclaimers in its claim constructions. *See, e.g., Interactive Communications Int’l, Inc. v. Blackhawk Network Inc.*, 2025 WL 419216 at *5, *11 (P.T.A.B., February 6, 2025) (applying prosecution history disclaimer to narrow claim scope); *SynAffix B.V. v. Hangzhou DAC Biotech Co., Ltd.*, 2024 WL 1070148 at *4, *7 (P.T.A.B., March 4, 2024) (same). In an IPR proceeding, claims “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b); *see also CUPP Computing AS v. Trend Micro Inc.*, 53 F.4th 1376, 1380 (Fed. Cir. 2022) (“In IPR proceedings the Board now applies the *Phillips* claim construction standard governing federal courts.”); *Interactive Communications*, 2025 WL 419216 at *5 (same). Therefore, Sun has represented to the Patent Office that, using the same claim construction standard as this Court uses, no disclaimer is “clear and unmistakable” with respect to the “composition” claim term in the ’076 patent, and “the broader plain and ordinary meaning” should control. (Batzer Decl. Ex. E at 13 n. 2).

In this litigation, both parties appear to agree that there exists a plain and ordinary meaning for the “composition” term. Nivagen’s expert Dr. Klibanov opines that “composition” in the

context of a pharmaceutical product patent “means a mixture of pharmaceutical ingredients that is suitable for pharmaceutical purposes.” (Klibanov Decl. at ¶ 21). Sun proffered no expert declaration to elucidate how a person of ordinary skill in the art would understand this term. (*See* D.I. 54, Patent Rule 4-3 Joint Claim Construction and Prehearing Statement (“JCCPS”) filed on May 22, 2025, at 3-5 (no expert declaration in Defendant’s Evidence)). Sun did not refer to any dictionary that could provide a definition for “composition.” (*Id.*).

The sole dispute between the parties now is whether Nivagen disclaimed “formulations that contain organic solvents or preservatives” from the meaning of “composition” in the ’076 patent claims.² Despite the contradictory position Sun has taken at the PTAB, Sun maintains in this litigation that such a disclaimer is clear and unmistakable, and must be applied. Sun cites for support the prosecution history of the ’076 patent as well as the entire prosecution history of a related patent, *i.e.*, U.S. Patent No. 11,406,598 (the “’598 patent” or the “parent patent”). (D.I. 54 (JCCPS) at 3-4). The prosecution history of the ’076 patent and that of the ’598 patent are attached to the Batzer Declaration as Exhibit B and Exhibit C, respectively, and the ’598 patent in text-searchable form is attached to the Batzer Declaration as Exhibit D. Brief summaries of these

² It is not clear what Sun meant by “formulations” in its proposed “disclaimer” construction, as the word “formulation” is not necessarily synonymous to “composition,” and is not part of the plain and ordinary meaning of the claim term “composition.” (*See* Klibanov Decl. at ¶ 21 (meaning of “composition”), and the relevant definition (“a mixture of various ingredients”) found in the Webster Dictionary, attached to the Klibanov Decl. as Exhibit 2). For the purpose of this opening brief, Nivagen assumes that Sun’s use of “formulations” in its proposed “disclaimer” portion of the construction just meant “composition.” As Sun bears the burden of proving the existence of a disclaimer, if Sun adds to or modifies its proposed construction in its Responsive Claim Construction Brief, Nivagen reserves the right to reply accordingly, and/or move to strike improper and untimely disclosure of any new claim construction position by Sun.

Regardless of the precise meaning of Sun’s use of the word “formulations,” however, no disclaimer existed for “organic solvents or preservatives” to limit the scope of the claimed product or composition in the ’076 patent.

prosecution histories are provided below, followed by an explanation as to why they do not support Sun's construction. For the reasons that follow, Sun's claim construction contravenes binding Federal Circuit precedent. Sun's litigation-driven, narrowing construction should be rejected.

III. RELEVANT PROSECUTION HISTORIES

A. Brief Summary of Prosecution History of the '076 Patent

U.S. Patent Application No. 18/100,804 (the "'804 App.") that matured into the '076 patent is attached to the Batzer Declaration as Exhibit B (Bates numbering added for this litigation and used in this brief). The '804 App. originally recited 20 claims, of which the application claim 1 was the sole independent claim. Original claim 1 recited:

A pharmaceutical product, comprising:

a container enclosing a single dose of lyophilized phenobarbital sodium powder;

wherein the phenobarbital sodium powder optionally contains residual quantities of tertbutanol, isopropanol, ethanol, or acetonitrile and wherein the phenobarbital sodium powder otherwise does not contain an organic solvent or preservative, and

wherein the phenobarbital sodium power is storage-stable.

(Batzer Decl. Ex. B at NIVAGEN_PHENOBARB_0000058).

On June 23, 2023, the examiner issued its first and only office action regarding the '804 App., in which it preliminarily rejected all 20 claims as obvious over "US 200/0215750 (Parker) in view of FDA_7/93 (11/11/2014)." (*Id.* at NIVAGEN_PHENOBARB_0000140). The "Parker" reference is actually U.S. Patent Application Publication 2017/0143719 A1,³ and the "FDA_7/93"

³ The Parker reference was sent to the Patent Office in an August 31, 2021 Third Party Submission by Attorney Jay Phillip Lessler, who apparently was working with Sun at the time, during the prosecution of Nivagen's U.S. Patent Application 17/025,881 that matured into the '598 patent, which is a "parent" of the '076 patent. (Batzer Decl. Ex. C (Bates-numbered '881 App. prosecution history), at NIVAGEN_PHENOBARB_0330610, -617). Attorney Lessler on behalf of "a third party" urged the Patent Office to consider Parker along with nineteen additional pieces of prior art,

reference is the 2014 FDA publication “Lyophilization of Parental Guide to Inspection of Lyophilized Parentals.” (*Id.* at NIVAGEN_PHENOBARB_0000143 (Notice of References Cited associated with the Office Action)).

The examiner explained that Parker teaches a storage stable phenobarbital sodium *solution for injection* with a concentration about between 15 and 200 mg/nl, and a pH between 9 and 12. (*Id.* at NIVAGEN_PHENOBARB_0000140 (emphasis added)). The examiner further stated that Parker teaches the solutions are extremely stable and do not generate significant amounts of the recited impurities. (*Id.*). The examiner then stated that the FDA_7/93 document provided the motivation to make a lyophilized product. (*Id.* at NIVAGEN_PHENOBARB_0000140-141).

On September 20, 2023, the applicant (Nivagen) cancelled all pending claims and submitted new replacement claims, which are substantially identical to the issued '076 patent claims. (Batzner Decl. Ex. B at NIVAGEN_PHENOBARB_0000156-158; *compare with* Batzner Decl. Ex. A (the '076 patent) at cols. 59-61 (issued claims)). Nivagen also submitted three remarks/arguments, which did not discuss organic solvents or preservatives. **First**, there would not have been a motivation to modify Parker’s liquid formulation in the manner claimed because the problem of stability was already solved in Parker itself. (Batzner Decl. Ex. B at NIVAGEN_PHENOBARB_0000161). **Second**, Parker uses non-volatile excipients such as polyols in quantities that exceed the amount of phenobarbital sodium, which will remain in the lyophilization vial together with the phenobarbital sodium, should anyone attempt to turn the Parker liquid formulation into a lyophilized solid composition (which attempt would fail due to the large quantity of non-volatile material in the Parker formulation). (*Id.*; *see also* Klivanov Decl.

in an ultimately failed attempt to derail the issuance of Nivagen’s '598 patent. (*Id.* at NIVAGEN_PHENOBARB_0330608, -636).

at ¶¶ 30-31). *Third*, “lyophilization” in general just means a process of water removal by sublimation, and there are a wide range of lyophilization processes such that even if one would have considered lyophilization of the Parker solution, FDA_7/93 which is a general reference fails to teach how to arrive at the claims. (*Id.* at NIVAGEN_PHENOBARB_0000161-62).

Shortly thereafter, on October 16, 2023, the examiner issued a notice of allowance, stating in the Reasons for Allowance that the prior art neither teaches nor suggests the claimed pharmaceutical, specifically, the amount of phenobarbital, the reaction conditions to form it, or its amorphous property. (*Id.* at NIVAGEN_PHENOBARB_0000172). Notably, the examiner did not comment on the presence or absence of either organic solvents or preservatives in the claimed product or composition, or how any such presence or absence would affect patentability. (*Id.*).

Thereafter, the '076 patent issued. Issued claim 1 recites:

A storage stable pharmaceutical product, comprising:
a single use dose vial, and
a composition comprising a 65 mg dose, a 100 mg dose, a 130 mg dose, or
a 200 mg dose of phenobarbital sodium, in the single use dose vial,
wherein the composition is sterile and lyophilized, and
wherein the composition comprises no less than 98% phenobarbital sodium.

(Batzel Decl. Ex. A at 59:27-34).

B. Brief Summary of Prosecution History of the Parent '598 Patent

The '076 patent is a continuation of a continuation-in-part of U.S. Patent Application No. 17/025,881 (the “'881 App.”) filed on September 18, 2020. (Batzel Decl. Ex. A, the '076 patent at face page, field (63)). The '881 App. matured into the '598 parent patent. (*Id.*). The '881 App. prosecution history is attached as Exhibit C to the Batzel Declaration.

The '881 App. originally included 20 claims, of which claim 1 was a composition claim and the remaining claims were method/process claims. Relevant here, the independent application claim 2 (a method/process claim) recited as follows:

A method of producing a storage-stable form of lyophilized Phenobarbital sodium that forms no more than 0.2% phenylethylacetylurea (PEAU) when reconstituted in aqueous solution, the method comprising:

adding Phenobarbital Sodium to water to form a Phenobarbital Sodium solution;

if necessary, adjusting the pH of the Phenobarbital Sodium solution to or between 9.2 to 10.2; and

lyophilizing the Phenobarbital Sodium solution.

(Batzner Decl. Ex. C, at NIVAGEN_PHENOBARB_0330354).

After several rounds of office actions which did not discuss the “organic solvent” or “preservatives” issue, on September 23, 2021, the examiner rejected the pending claims as obvious over Parker in view of FDA_7/93. (*Id.* at NIVAGEN_PHENOBARB_0330665). Relevant to the claim construction issue here, the applicant cancelled all pending claims and proposed new claims in its December 22, 2021 Response to Office Action. (*Id.* at NIVAGEN_PHENOBARB_0330699 to -701). In remarks regarding these newly added claims, the applicant stated that, “*the present claims* expressly require that the phenobarbital sodium compositions must be free of organic solvents, and that in the preparation of the solution for lyophilization, the phenobarbital sodium is dissolved in an aqueous solution that does not contain organic solvents. Clearly, Parker fundamentally requires organic solvents, whereas *the present claims expressly exclude such solvents.*” (*Id.* at NIVAGEN_PHENOBARB_0330702-03 (emphasis added)).

Thereafter, the examiner issued a restriction requirement, and issued a notice of allowance for the pending method claims. (*Id.* at NIVAGEN_PHENOBARB_0330712; NIVAGEN_PHENOBARB_0330727). Indeed, the issued claims of the '598 patent contain a

specific written claim limitation that “expressly excludes” organic solvents from the liquid bulk *solution*, during the *process* of making a lyophilized composition. All fifteen issued ’598 patent claims are method/process claims. (Batzer Decl. Ex. D at cols. 33-34). Issued claim 1 of the ’598 patent, which is the only independent claim in the patent, recites as follows:

A method of producing a storage-stable form of lyophilized amorphous phenobarbital sodium composition, comprising:

adding phenobarbital sodium to water to form a phenobarbital sodium solution having a pH of between 9.2 and 10.2, wherein the phenobarbital sodium solution does not contain an organic solvent, and wherein the phenobarbital sodium solution optionally further comprises sodium chloride;

lyophilizing the phenobarbital sodium solution in a container under a protocol comprising a freezing step, a primary drying step, and a secondary drying step to thereby produce the lyophilized amorphous phenobarbital sodium composition;

wherein the freezing step comprises freezing the lyophilized amorphous phenobarbital sodium to a temperature of about -50°C . without application of vacuum;

wherein the primary drying step comprises application of vacuum at a pressure of between about 50 mTorr and 75 mTorr at a temperature of between about -50°C . and about 0°C . for at duration of at least 1,000 minutes;

wherein the secondary drying step comprises application of vacuum at a pressure of between about 50 mTorr and 75 mTorr at a temperature of between about 25°C . and about 50°C . for at duration of at least 200 minutes;

wherein the lyophilized amorphous phenobarbital sodium has an initial moisture content of equal or less than 1.5%; and

wherein the lyophilized amorphous phenobarbital sodium forms, upon storage over 3 months, no more than 0.2% phenylethylacetylurea (PEAU) when reconstituted in an aqueous solution.

(*Id.* at 33:8-41 (emphasis added)).

IV. LEGAL STANDARD ON CLAIM CONSTRUCTION AND DISCLAIMERS

Claim terms are generally given their ordinary and customary meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). The prosecution history can be informative

[REDACTED]

to “demonstrate 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.* at 1317. “[W]here the patentee has *unequivocally* disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (emphasis added). A patentee will only be bound to a disavowal that is “clear and unmistakable.” *CUPP Computing*, 53 F.4th at 1382. “[T]he alleged disavowing statements [are required] to be both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer.” *Omega Eng’g*, 334 F.3d at 1325. Accordingly, the Federal Circuit has declined to find prosecution disclaimer where “the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations.” *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016).

“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.” *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016).

V. ARGUMENT

A. The ’076 Patent Applies the Plain and Ordinary Meaning of “Composition”

1. The claim language is inclusive

The claims of the ’076 patent uses the well-known connective phrase “comprising,” which is open-ended and inclusive. *See, e.g., Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997). The patent specification notes that all claim terms “should be interpreted in the broadest possible manner consistent with the context.” (Batzner Decl. Ex. A at 59:13-15).

The term “composition” is commonly used, well-understood and requires no technical expertise to interpret. (*See* Klivanov Decl. at ¶ 21 (referencing a definition in *Webster’s New*

[REDACTED]

Universal Unabridged Dictionary)). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. “If the claim language is clear on its face, then [the court’s] consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified.” *Interactive Gift Exp., Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). Here, the claim language is clear on its face and the intrinsic record does not require any deviation from this plain meaning.

A person of ordinary skill in the art would understand “composition” to allow the presence of some amounts of solvents and preservatives which could come from the bulk solution or the active ingredient itself. (Klibanov Decl. at ¶¶ 22-24). As Dr. Klibanov explained, the lyophilization process involves freezing the bulk solution and then thoroughly, to the extent practical, drying the frozen material under vacuum to make a solid “cake.” (*Id.* at ¶ 22). This solid lyophilized cake is expected to contain a detectable solvent content (water or an organic solvent), and this water or organic solvent can come from an added excipient in the bulk solution and/or from the active ingredient. (*Id.* at ¶ 23). Even in situations when such residual solvents in a lyophilized solid are below detection, a person of ordinary skill in the art would understand that such solvents “are likely to be present in the lyophilized cake.” (*Id.* at ¶ 24).

It was indeed common knowledge in the relevant field of art that the phenobarbital sodium active ingredient in particular came with residual solvents. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Such residual solvents are “expected to carry over and remain in the lyophilized cake being bound to it.” (Klibanov Decl. at ¶ 23).

On the other hand, if an excipient (which may or may not function as a solvent or preservative in the bulk solution) is not volatile under lyophilization conditions, it cannot be used in the bulk solution at large quantities to make a lyophilized composition. (Klibanov Decl. at ¶¶ 30-31). The large quantity and non-volatility of an excipient in the bulk solution would result in the failure of lyophilization. This constraint on what to put in a bulk solution and how the lyophilization process can be successfully carried out is not based on or linked to such an excipient functioning as an “organic solvent” or a preservative, but only to its non-volatility and large quantity. (*See id.* at ¶ 31).

Had the patentee wanted to narrow the claim scope to those compositions without preservatives or organic solvents, then the patentee would have done so in the issued patent claims. To the contrary, the patentee here initially proposed narrower claims in the ’804 App. that excluded organic solvents (other than certain residual solvents) or preservatives, but then cancelled these narrower original claims and submitted new claims that *broadened* claim scope and *eliminated* any such limitation. (Batzer Decl. Ex. B, NIVAGEN_PHENOBARB_0000058; NIVAGEN_PHENOBARB_0000156). As discussed above, the plain and ordinary meaning of the term “composition” and the open-ended “comprising” format of the issued ’076 patent claims clearly encompass compositions that may contain organic solvents and preservatives. This actual

claim scope is confirmed by the patentee's broadening of claim scope during the '804 App. prosecution to remove any requirement of "no organic solvents or preservatives."

Dr. Klivanov confirmed that a POSA would readily understand the term "composition" to mean "a mixture of pharmaceutical ingredients that is suitable for pharmaceutical purposes," without any restriction regarding organic solvents or preservatives. (Klivanov Decl. at ¶ 21). Sun did not proffer pursuant to the Local Patent Rules and the Court's Docket Control Order any expert declaration or dictionary definition to support its proposed construction of "composition" with unwarranted restrictions on the claim scope. (D.I. 54 at 3-4).

2. The patent specification is also inclusive

The '076 patent specification also supports a construction of "plain and ordinary meaning" for the "composition" term. For example, the summary of the invention discloses that:

Disclosed herein are compositions of, methods of producing, and use of a lyophilized Phenobarbital Sodium formulation. The contemplated composition is an amorphous lyophilized Phenobarbital Sodium with high stability and purity. The lyophilized composition may include no less than 98% Phenobarbital Sodium. The amorphous composition is a storage-stable form of lyophilized Phenobarbital Sodium.

(Batzner Decl. Ex. A, '076 patent at 2:45-53). There is no disclaimer to the scope of the claimed composition.

The specification consistently describes the invention as "storage-stable lyophilized Phenobarbital Sodium" with high purity. (*Id.* at 1:18-21; 3:9-22; 4:7-14; 8:9-13). Nowhere did the inventors require the absence of organic solvent or preservatives for the claimed composition to achieve storage stability and high purity.

The specification of the '076 patent describes numerous embodiments. Sun pointed out three lines of the '076 patent specification as supporting their proposed construction. (D.I. 54 at 3

(referred to the '076 patent, col. 11, lines 59-61)).⁴ This passage is found within the disclosure of a long list of embodiments. In this passage, the '076 patent discloses a “presently disclosed formulation” that “does not contain any organic solvents or preservatives which is specifically advantageous for administration to newborns and neonates.” (Batzner Decl. Ex. A at 11:59-63). It would be improper to ignore the actual claim language and import limitations from the embodiments into the claims. *Phillips*, 415 F.3d at 1323 (noting that “the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court’s focus remains on understanding how a person of ordinary skill in the art would understand the claim terms”). Even when the embodiments are very specific, the Federal Circuit has warned against confining the claims to such embodiments. *See id.* (citing *Gemstar–TV Guide Int’l, Inc. v. Int’l Trade Comm’n*, 383 F.3d 1352, 1366 (Fed. Cir. 2004)). “That is not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.” *Id.*

Furthermore, the passage Sun focused on appears to be describing the formulation of a *bulk solution* that is used to make a lyophilized composition after a lyophilization process. The paragraph spanning col. 11, line 48 and col. 12, line 2 of the '076 patent consistently refers to a lyophilized solid as “lyophilized Phenobarbital Sodium” without the word “formulation.” Immediately after the three-line passage disclosing “[t]he presently disclosed formulation,” the specification continues, “[m]oreover, the *resulting* lyophilized Phenobarbital Sodium forms [very little impurities] when reconstituted in water”) (Batzner Decl. Ex. A at 11: 62-67 (emphasis added)). The claims of the '076 patent, however, are not constrained by any components of the

⁴ This is the only mention of “preservatives” in the entire '076 patent.

bulk solutions used during the process that would result in the claimed composition. Unlike the '598 patent, which contains only method (manufacturing process) claims, the '076 patent contains only product/composition claims, with *no* reference to any process steps for making the claimed product or composition. (Batzer Decl. Ex. A at cols. 59-61; *Cf.* Ex. D at cols. 33-34). “Ordinarily, courts should not read process steps . . . into composition claims,” unless “the patentee has made clear that process steps are an essential part of the claimed invention.” *Vectura Ltd. v. GlaxoSmithKline LLC*, C.A. No. 16-638-RGA, 2018 WL 4700222, at *3 (D. Del. Oct. 1, 2018), *aff'd*, 981 F.3d 1030 (Fed. Cir. 2020); *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007).

B. There Is No “Clear and Unmistakable” Prosecution History Disclaimer Here

There are at least three reasons why the Court should reject Sun’s narrowing claim construction disclaiming formulations that contain organic solvents or preservatives. **First**, it is widely recognized that the doctrine of prosecution disclaimer generally does not apply in cases such as this, when the claim term in the descendant patent uses claim language that differs from that of the parent patent. Therefore, the prosecution history of the '598 patent cannot serve to limit the scope of the claims of the '076 patent. **Second**, nothing in the prosecution history of the '804 App. (which matured into the '076 patent) amounts to a clear and unmistakable disavowal of claim scope and Sun cannot meet its burden of proving otherwise. **Third**, in its recent IPR Petition seeking to invalidate the claims of the '076 patent, Sun has conceded the “disclaimer” point already, and instead advocated for a plain and ordinary meaning of the “composition” term.

1. The Prosecution History of the Parent '598 Patent Cannot Limit the Claims of the '076 Patent

Federal Circuit law squarely rejects the notion that the prosecution of a related prior patent can be used to limit substantively different claims of a later patent. In *Maquet Cardiovascular*

LLC v. Abiomed Inc., 131 F.4th 1330 (Fed. Cir. 2025), the Federal Circuit held that it was improper to import a negative limitation from a parent patent’s prosecution history. To the extent Sun’s claim construction seeking to limit the claims of the ’076 patent is based on arguments made with respect to different claims during prosecution of the ’598 patent, Sun’s position has no merit.

In *Maquet*, the accused infringer advanced a construction that relied on an amendment made during the prosecution history of a different patent involving a different claim term. The Federal Circuit noted that “[t]he prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit.” *Id.* at 1339 (citing *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305 (Fed. Cir. 2001)). Conversely, “if the limitations at issue are dissimilar, we generally cannot accept, without more support, that an applicant’s disclaimer with respect to one claim would be equally applicable to another claim.” *Id.*; see also *Ventana Med. Sys., Inc. v. Biogenex Lab’ys., Inc.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006) (“the doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language”).

Accordingly, Sun’s argument would fail because of the key differences in the claim language between the ’598 patent and the ’076 patent. A court must not divorce the claim construction analysis from the claim language at issue by looking more broadly to the claims’ subject matter. *Maquet*, 131 F. 4th at 1340 (rejecting the defendant’s argument that prosecution disclaimer applies when patents share ‘common subject matter’); *Regents of Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 944 (Fed. Cir. 2013) (“Our requirement that the patents share ‘limitations in common’ is not a mere technicality.”). “In general, prosecution disclaimer will *only* apply to a subsequent patent if that patent contains the *same claim limitation* as its predecessor.” *Id.* at 943 (emphasis added). “This is why our cases evaluate the similarity between the earlier and

later claim limitations, carrying disclaimer forward if there are only immaterial differences.” *Id.* at 944; *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (requiring the same claim limitation to carry forward a prosecution history disclaimer from an earlier patent to a later one in the same patent family).

Here, the claim limitations at issue are dissimilar. Claim 1 of the ’076 patent recites a “composition” comprising “no less than 98% phenobarbital sodium,” with no process steps limitation. (Batzer Decl. Ex. A at 59:33-34). In contrast, the claims of the ’598 patent recite “solution does not contain organic solvent” in a process step limitation. (Batzer Decl. Ex. D at 33:11-16). During the ’598 patent prosecution, the patent prosecutor submitted a Response to Final Office Action on Dec. 22, 2021, and made arguments specific to “the present claims” which expressly, with words in the application claims, excluded organic solvent. (*See* Klibanov Decl. at ¶ 28 (referencing Batzer Decl. Ex. C, at NIVAGEN_PHENOBARB_0330702-03)). As discussed above in Part V.A.1, during the later ’076 patent prosecution, the applicant removed any such limitations from the application claims, then pursued and secured patent claims on a composition that is not restricted by any process steps and can include organic solvents or preservatives. (Batzer Decl. Ex. B, at NIVAGEN_PHENOBARB_0000156-58).

The differences in the claim language reflect different approaches the patentee took during the prosecution of the two patents. In prosecuting the ’076 patent, the patentee overcame the Parker reference by focusing on whether the non-volatile components in the Parker liquid formulation would prevent the making of a lyophilized solid composition comprising no less than 98% phenobarbital sodium. (Batzer Decl. Ex. B at NIVAGEN_PHENOBARB_0000161, -172; Klibanov Decl. at ¶ 30 (quoting the patent prosecutor: “lyophilization of the composition of Parker *will not produce a composition* that ‘comprises no less than 98% phenobarbital sodium’ as

presently claimed. (emphasis in the original))). In prosecuting the '598 patent, on the other hand, the patentee took a different approach to overcome the prior art by including the limitation that the bulk solution used at the beginning of a multistep lyophilization process does not contain an organic solvent. (See, e.g. Batzer Decl. Ex. C at NIVAGEN_PHENOBARB_ 0330702-03; Klibanov Decl. at ¶ 28 (quoting the patent prosecutor: “in the preparation of the solution for lyophilization, the phenobarbital sodium is dissolved in an aqueous solution that does not contain organic solvents”)). It is well established that a patentee is free “to take a different approach to claiming an invention in subsequent patents, either by adding limitations or by altering the claims’ format.” *Regents*, 717 F.3d at 944-45. “When the patentee does so, however, [the court] cannot rely on the dubious argument that ... the applicant’s disclaimer with respect to one claim would be equally applicable to another claim.” *Id.* at 945.

Indeed, the whole point of the '076 patent was to secure broader claims, and that is entirely proper under the law. The Federal Circuit has held that, when “an applicant adopts an explicit claim-narrowing limitation to achieve immediate issuance of a patent containing the narrowed claims and postpones to the prosecution of a continuation application further arguments about claims that lack the narrowing limitation,” “that process does not imply a disclaimer as to claims, when later issued in the continuation, that lack the first patent’s express narrowing limitation.” *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 650 (Fed. Cir. 2017); see also *Saunders Grp. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333 (Fed. Cir. 2007) (“When the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications . . . , those disclaimers do not apply.”). That is the situation here, and the Court should reject any argument by Sun that the prosecution history of the '598 patent somehow limits the claims of the '076 patent.

2. Nivagen Did Not Disavow Claim Scope During Prosecution of the '076 Patent

Nivagen did not make any disavowal of organic solvents or preservatives in prosecuting the '076 patent. It is well-established that “when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer *narrows* the meaning of the claim consistent with the scope of the claim surrendered.” *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013) (emphasis added). Here, the opposite occurred. Nivagen did the contrary: it expressly broadened the application claims to secure a set of claims that *rejected* any limitations based on “organic solvent” or “preservatives.”

The original claim 1 in the '804 App. recited that “the phenobarbital sodium powder otherwise does not contain an organic solvent or preservative.” (Batzer Decl. Ex. B at NIVAGEN_PHENOBARB_000058). In overcoming the first and only Office Action, the applicant emphasized that the prior art (Parker) uses a number of co-solvents (some of which are non-volatile and will remain in the lyophilization vial together with the phenobarbital sodium) in quantities that exceed the amount of phenobarbital sodium. (*Id.* at NIVAGEN_PHENOBARB_0000161). The non-volatile nature of the unsuitable excipients is not linked to the function of the excipients in the liquid solution. (See Klibanov Decl. at ¶ 31). Because the '076 patent applicant's approach to overcome the prior art was not based on any presence or absence of organic solvents or preservatives (but only on the unsuitability of large quantities of non-volatile material in the bulk solution), the applicant removed the original application claims containing limitations on “organic solvent” or “preservative,” and added a set of broader new claims that do *not* have such requirements. (Batzer Decl. Ex. B at NIVAGEN_PHENOBARB_000058-60 (original claims in the '804 App.); NIVAGEN_PHENOBARB_0000156-58 (9/20/2023 Amendments to the Claims)).

Nivagen explained above in Part V.B.1 why the earlier prosecution history of the '598 patent cannot generate any disclaimer on the "composition" term in the '076 patent claims. However, even if the '598 patent prosecution history is included for consideration, it would not add any support for finding a disclaimer. The applicant never characterized any absence of organic solvents or preservatives as an essential part of the claimed invention. To the contrary, one of the '598 patent inventors (who is also an inventor on the '076 patent), Dr. Dasaradhi Lakkaraju, submitted a declaration and stated that, "[o]ptimization of lyophilization technique to suit the formulation of interest to obtain a stable finished product is ... very critical to obtain a stable finished product." (Batzer Decl. Ex. C at NIVAGEN_PHENOBARB_0330537-38 (paragraph 8)); *see also* Klibanov Decl. at ¶ 32). The focus was on inventing a lyophilized product that is "stable." Dr. Lakkaraju listed a number of factors to "optimize" for the lyophilization technique, including "numerous process parameters such as temperatures, temperature gradients, degree of vacuum applied, and/or time periods at specific temperatures and partial vacuum," but notably did *not* mention adding or eliminating organic solvents or preservatives. (*Id.* at NIVAGEN_PHENOBARB_0330537).

3. Sun Represented to the Patent Office That *No* Disclaimer Should Apply on the "Composition" Claim Term

As noted above in Part II, Sun represented to the Patent Office that no terms in the '076 patent claims "require specific construction," and, in particular, it urged the PTAB to "apply the broader plain and ordinary meaning" to any "compositions" terms. (Batzer Decl. Ex. E at 13). Yet, Sun "reserves the right to address claim construction issues in the federal court litigation," including arguing for a disclaimer in this Court. (*Id.* at 13 n. 2). Sun's extraordinary "eating the cake and having it too" position is completely baseless and unacceptable, especially because the same claim construction standard applies at the PTAB and in court. 37 C.F.R. § 42.100(b); *CUPP*

Computing, 53 F.4th at 1380. At the very least, Sun’s position at the Patent Office confirms that there is no “clear and unmistakable” or “unequivocal” disclaimer on the meaning of “composition” in the ’076 patent claims. The law is clear that, if “the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations,” there is no disclaimer. *Avid Tech.*, 812 F.3d at 1045.

VI. CONCLUSION

For all of the foregoing reasons, Nivagen respectfully requests that the Court reject Sun’s narrowing proposed construction and construe the claim term “composition” found in all claims of the ’076 patent as “plain and ordinary meaning.”

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served on June 2, 2025, with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3).

By: s/ Brent A Batzer
Brent A. Batzer
