

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

NIVAGEN, INC.,

Plaintiff

v.

SUN PHARMACEUTICALS INDUSTRIES,
INC.,

Defendant.

Case No.: 2:24-cv-36-RWS-RSP

JURY TRIAL DEMANDED

**DEFENDANT’S PRELIMINARY CLAIM CONSTRUCTIONS AND EXTRINSIC
EVIDENCE PURSUANT TO LOCAL PATENT RULE 4-2**

Defendant Sun Pharmaceuticals Industries, Inc. (“Sun”) hereby provides the following Preliminary Claim Constructions and identification of Extrinsic Evidence for the asserted claims of U.S. Patent No. 11,878,076 (“the ’076 patent”).

Sun reserves the right to supplement this disclosure, including the right to add to or remove from or otherwise modify or amend its proposed claim constructions and extrinsic evidence to the extent allowed by applicable law, rule, order, or other practice or agreement. Sun may also supplement this disclosure in light of the positions that Nivagen, Inc. (“Nivagen” or “Plaintiff”) takes in this litigation. Sun specifically notes that Nivagen’s infringement contentions are deficient, making certain of its positions as it relates to claim terms ambiguous. Should Nivagen be allowed to supplement its contentions later in the litigation, and if its supplementation clarifies its views on the meaning of any claim terms, Sun reserves the right to supplement this disclosure.

A. Preliminary Proposed Claim Constructions and Identification of Extrinsic Evidence

Subject to the above, Sun attaches its preliminary proposed constructions in **Exhibit A**. Sun's preliminary proposed claim constructions apply to each element of the asserted claims using the same or similar language as the terms and phrases proposed for construction. Sun also makes the preliminary identification of extrinsic evidence in **Exhibit A**, which Sun may rely on in connection with each of its preliminary claim constructions.

B. Expert Testimony

Sun may also offer the testimony of one or more experts, including Dr. Raj Suryanarayanan, who are persons of ordinary skill in the art of the '076 patent. For example, Dr. Suryanarayanan and/or another expert of similar technical background may provide testimony on the technology that underlies the alleged invention; the level of ordinary skill in the art; how the patent, claims, and intrinsic or extrinsic evidence would be understood by one of ordinary skill in the art; the alleged invention claimed in the patent-in-suit; the meaning of the disputed claim terms, phrases, and clauses to one of ordinary skill in the art, and/or why the disputed claim terms, phrases, and clauses are indefinite; or any other opinions or testimony that may be useful to the Court in conducting the requisite claim construction. Dr. Suryanarayanan and/or another expert may also rebut any evidence offered by Nivagen, including any expert opinions.

Date: May 1, 2025

s/ Samuel T. Lockner

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Attorneys for Defendant

Exhibit A

Claim Term	Claims of the '076 patent	Preliminary Construction	Extrinsic Evidence
"composition"	1, 7, all dependent claims	Plain and ordinary meaning, disclaiming formulations that contain organic solvents or preservatives	Dr. Raj Suryanarayanan and/or another expert of similar technical background may provide a declaration discussing the technology that underlies the alleged invention; the level of ordinary skill in the art; how the patent, prosecution history, claims, and intrinsic or extrinsic evidence would be understood by one of ordinary skill in the art; the alleged invention claimed in the patent-in-suit; and what a person of ordinary skill in the art would understand about the scope of the alleged invention based on the intrinsic evidence. NIVAGEN_PHENOBARB_0000281, NIVAGEN_PHENOBARB_0013788, NIVAGEN_PHENOBARB_0015052, NIVAGEN_PHENOBARB_0021517, NIVAGEN_PHENOBARB_0032505, NIVAGEN_PHENOBARB_0034151, NIVAGEN_PHENOBARB_0058235, NIVAGEN_PHENOBARB_0098260, and NIVAGEN_PHENOBARB_0308661. Sun reserves the right to cite and rely on internal Nivagen documents in addition to the above-identified documents relating to Nivagen and/or the inventors' description and understanding of the scope of their alleged invention and the meaning of this claim term. Sun received the bulk of Nivagen's document production only three weeks ago and review of this production is ongoing.

Exhibit A

“composition comprises no less than 98% phenobarbital sodium”	1, 7, all dependent claims	Indefinite	Dr. Raj Suryanarayanan and/or another expert of similar technical background may provide a declaration discussing the technology that underlies the alleged invention; the level of ordinary skill in the art; how the patent, prosecution history, claims, and intrinsic or extrinsic evidence would be understood by one of ordinary skill in the art; the alleged invention claimed in the patent-in-suit; and how a person of ordinary skill would understand this claim term in view of the intrinsic evidence that causes the claim term to be indefinite.
“aqueous solution to form a reconstituted composition”; “reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition”	2-4, 6-11, 13-14, 18-19	Indefinite	Dr. Raj Suryanarayanan and/or another expert of similar technical background may provide a declaration discussing the ambiguity in the intrinsic evidence relating to this claim term that causes the claim term to be indefinite.
“is stored”	2-4, 6-11, 13-14, 18-19	Indefinite	Dr. Raj Suryanarayanan and/or another expert of similar technical background may provide a declaration discussing how a person of ordinary skill would understand this claim term in view of the intrinsic evidence that causes the claim term to be indefinite, including discussion of how degradation of phenobarbital sodium may be impacted by a variety of factors in storage, including headspace humidity, physical properties of the container closure system, whether the vial is sparged with nitrogen or other inert gas prior to

Exhibit A

			container closure, and whether the vial is sealed under vacuum, as well as how compatibility testing and extractable and leachable studies may be necessary to determine appropriate packaging components for storage.
“amorphous”	5, 12, 15, 20	Indefinite	Dr. Raj Suryanarayanan and/or another expert of similar technical background may provide a declaration discussing how a person of ordinary skill would understand this claim term in view of the intrinsic evidence that causes the claim term to be indefinite.
“the reconstituted composition contains no more than . . . % [PEAU/2EPMM/PBG],” “the reconstituted composition contains at most . . . % phenylethylacetylurea (PEAU)”	2-4, 6-11, 13-14, 18-19	Indefinite	Dr. Raj Suryanarayanan and/or another expert of similar technical background may provide a declaration discussing how a person of ordinary skill would understand this claim term in view of the intrinsic evidence that causes the claim term to be indefinite.

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NIVAGEN’S P.R. 4-2 PRELIMINARY CLAIM CONSTRUCTIONS AND EXTRINSIC EVIDENCE

Pursuant to Patent Rule 4-2 and the Docket Control Order (D.I. 37), Plaintiff Nivagen, Inc. (“Nivagen” or “Plaintiff”) hereby discloses its preliminary proposed constructions of each claim term, phrase, or clause (together hereinafter “terms”) which the parties have identified in their Rule 4-1 disclosures. Plaintiff’s proposed terms are based on information that is currently available to Plaintiff. Plaintiff reserves the right to modify this disclosure in light of Defendant’s preliminary constructions and should additional information become available through discovery. Further, Plaintiff reserve the right to supplement, amend, and/or modify this disclosure for any other reason including, consistent with P.R. 4-2(c), to facilitate the preparation of the Joint Claim Construction and Prehearing Statement, and in light of arguments made or positions taken by Defendant as this case proceeds.

Plaintiff also reserves the right to offer further extrinsic evidence to rebut preliminary claim constructions, testimony, or extrinsic evidence Defendant offer in support of their claim construction positions. Plaintiff may also provide expert declarations and/or testimony of Plaintiff’s expert Dr. Alexander Klibanov as evidence of how one having ordinary skill in the art at the time of the inventions would understand the technical background, the intrinsic evidence, and the claim terms at issue. Dr. Klibanov may opine on the definiteness of terms offered by Defendant, to the extent that Defendant asserts that any of the terms they propose for construction are indefinite under 35 U.S.C. §112. Dr. Klibanov may also opine on the plain and ordinary meaning and/or claim construction of any terms for which Defendant assert that no plain and ordinary meaning exists to a person of ordinary skill in the art. Such declarations or testimony may address both the general understanding of the relevant terms and phrases in the field of the Asserted Patent, as well as the understanding of terms and phrases in the context of the Asserted Patent specification and claims.

For instance, the expert is expected to testify that a person of ordinary skill in the art during the relevant time period would understand the claim terms identified by Defendant for construction as set forth below, and that Plaintiff's proposed constructions are derived from and supported by the intrinsic evidence and knowledge of a POSA. The experts may also provide testimony concerning the appropriate level of skill in the art at the time of the invention and the background of the technology at issue at the time of the invention. Plaintiff reserves the right to introduce further evidence including but not limited to expert declarations or testimony to rebut Defendant's positions and any expert declarations or testimony introduced by Defendant.

<u>Term</u>	<u>Nivagen's Disclosures</u>
"composition" (claims 1, 7, dependent claims)	Plain and ordinary meaning Nivagen may rely on testimony from Dr. Alexander Klibanov regarding the understanding of a POSA and technical issues
"composition comprises no less than 98% phenobarbital sodium" (claims 1, 7, dependent claims)	Plain and ordinary meaning Nivagen may rely on testimony from Dr. Alexander Klibanov regarding the understanding of a POSA and technical issues
"aqueous solution to form a reconstituted composition"; "reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition" (claims 2-4, 6-11, 13-14, 18-19)	Plain and ordinary meaning Nivagen may rely on testimony from Dr. Alexander Klibanov regarding the understanding of a POSA and technical issues
"is stored" (claims 2-4, 6-11, 13-14, 18-19)	Plain and ordinary meaning Nivagen may rely on testimony from Dr. Alexander Klibanov regarding the understanding of a POSA and technical issues
"amorphous" (claims 5, 12, 15, 20)	Plain and ordinary meaning

	Nivagen may rely on testimony from Dr. Alexander Klibanov regarding the understanding of a POSA and technical issues
“the reconstituted composition contains no more than . . . % [PEAU/2EPMM/PBG],” “the reconstituted composition contains at most . . . % phenylethylacetylurea (PEAU)” (claims 2-4, 6-11, 13-14, 18-19)	Plain and ordinary meaning Nivagen may rely on testimony from Dr. Alexander Klibanov regarding the understanding of a POSA and technical issues

DATED: May 1, 2025

/s/ Brent A Batzer

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CERTIFICATE OF SERVICE

I hereby certify that on May 1, 2025, a true and correct copy of the foregoing document was served upon Sun Pharmaceuticals Industries, Inc. *via* electronic mail.

By: /s/ Brent A Batzer

Brent A. Batzer