

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

NIVAGEN, INC.,

Plaintiff,

v.

SUN PHARMACEUTICALS INDUSTRIES,
INC.,

Defendant.

Case No. 2:24-CV-00036-JRG-RSP

JURY TRIAL DEMANDED

**PATENT RULE 4-3 JOINT CLAIM CONSTRUCTION AND PREHEARING
STATEMENT**

Pursuant to P.R. 4-3 and the Docket Control Order (D.I. 37), Plaintiff Nivagen, Inc.¹ (“Nivagen”) and Defendant Sun Pharmaceuticals Industries, Inc. (“Sun”) hereby file this joint claim construction and prehearing statement.

The claim terms listed below occur in U.S. Patent No. 11,878,076 (“the ’076 patent”), which is asserted against Sun.

¹ Nivagen Pharmaceuticals Inc. is the correct name, and Nivagen, Inc. should be taken to mean Nivagen Pharmaceuticals Inc. throughout.

I. AGREED CONSTRUCTIONS

The parties do not present any agreed-upon constructions.

II. EACH PARTY’S PROPOSED CLAIM CONSTRUCTION OR INDEFINITENESS POSITION FOR EACH DISPUTED CLAIM TERM, PHRASE, OR CLAUSE, TOGETHER WITH AN IDENTIFICATION OF ALL REFERENCES FROM THE SPECIFICATION OR PROSECUTION HISTORY THAT SUPPORT THAT POSITION, AND AN IDENTIFICATION OF ANY EXTRINSIC EVIDENCE KNOWN TO THE PARTY ON WHICH IT INTENDS TO RELY EITHER TO SUPPORT ITS POSITION OR TO OPPOSE ANY OTHER PARTY’S POSITION

#	TERM	PLAINTIFF’S PROPOSED CONSTRUCTION	PLAINTIFF’S EVIDENCE	DEFENDANT’S PROPOSED CONSTRUCTION	DEFENDANT’S EVIDENCE
1	“composition” (claims 1, 7, dependent claims)	Plain and ordinary meaning	Intrinsic Evidence: The ’076 patent in its entirety, including the claims, specification, and prosecution history, including the priority applications and family members and their prosecution, with specific reference to, without limitation, the following specific disclosures: ’076 patent: 1:18-21; 1:41-50; 2:4-52; 3:9-22; 4:8-14; 5:4-12; 8:9-6:3; 10:26-38; 11:48-12:65; Tables 2-3; 15:43-16:49; 16:65-26:67 (end of page); 29:1-52:29 (Table 28); 51:30-53:17; 54:24-58:33; claims. 881 App. FH: 2/12/2021 Response to Office Action;	Plain and ordinary meaning, disclaiming formulations that contain organic solvents or preservatives	Intrinsic evidence: The ’076 patent in its entirety, including the claims, specification, and prosecution history, with specific reference to, without limitation, the following specific disclosures: ’076 patent, col. 11, ll. 59-61 ’076 patent, col. 2, ll. 25-37 ’076 patent, Table 1, col. 12, ll. 3-28 ’076 patent, Tables 2-3, 6-14, 16-28 ’076 patent, Table 31 (product manufacture date) ’076 patent, Table 32 (product manufacture date) ’076 patent file history:

#	TERM	PLAINTIFF'S PROPOSED CONSTRUCTION	PLAINTIFF'S EVIDENCE	DEFENDANT'S PROPOSED CONSTRUCTION	DEFENDANT'S EVIDENCE
			5/13/2021 Request for Continued Examination including Remarks/Arguments; 5/10/2021 Lakakraju Decl.; 8/24/2021 Response to Office Action; 12/22/2021 Response to Office Action; 2/8/2022 Office Action (including restriction requirement); 3/9/3033 Response to Restriction Requirement; Notice of Allowability and Reasons for Allowance; 3/15/2022 Interview Summary; Issued claims (U.S. Patent No. 11,406,598). 804 App. FH: 6/23/2023 Office Action; 9/20/2023 Response to Office Action; 9/29/2023 Notice of Allowability and Reasons for Allowance; 11/8/2023 Notice of Allowability; 11/22/2023 Amendment under 37 CFR § 1.312; 12/15/2023 Corrected Notice of Allowability.		-9/20/2023 Response to Office Action The '598 patent in its entirety, including the claims, specification, and prosecution history. Extrinsic 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 NIVAGEN_PHENOBARB_0308661

#	TERM	PLAINTIFF'S PROPOSED CONSTRUCTION	PLAINTIFF'S EVIDENCE	DEFENDANT'S PROPOSED CONSTRUCTION	DEFENDANT'S EVIDENCE
			<u>Extrinsic evidence:</u> Declaration of Dr. Alexander Klibanov Webster's New Universal Unabridged Dictionary published by Dorset & Baber, Second Edition (1983), pp. 372-373 NIVAGEN_PHENOBARB_0000281 SUNSZBY0000513 Sun's IPR Petition filed April 22, 2025		

III. THE ANTICIPATED LENGTH OF TIME NECESSARY FOR THE CLAIM CONSTRUCTION HEARING

The parties anticipate 1.5 hours as the total length of time necessary for the claim construction hearing.

IV. WHETHER ANY PARTY PROPOSES TO CALL ONE OR MORE WITNESSES, INCLUDING EXPERTS, AT THE CLAIM CONSTRUCTION HEARING, THE IDENTITY OF EACH SUCH WITNESS, AND FOR EACH EXPERT, A SUMMARY OF EACH OPINION TO BE OFFERED IN SUFFICIENT DETAIL TO PERMIT A MEANINGFUL DEPOSITION OF THAT EXPERT

The parties do not anticipate calling any live witnesses, including experts, at the claim construction hearing.

V. A LIST OF ANY OTHER ISSUES WHICH MIGHT APPROPRIATELY BE TAKEN UP AT A PREHEARING CONFERENCE PRIOR TO THE CLAIM CONSTRUCTION HEARING, AND PROPOSED DATES, IF NOT PREVIOUSLY SET, FOR ANY SUCH PREHEARING CONFERENCE

The parties suggest August 4 or 5, 2025 for a prehearing conference by remote means, if the Court desires a prehearing conference.

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DATE: May 22, 2025

s/ Brent A Batzer

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