

**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 SUN PHARMACEUTICAL INDUSTRIES, INC.’s RULE 30(b)(6)
NOTICE OF DEPOSITION OF PLAINTIFF**

PLEASE TAKE NOTICE that, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure and the applicable Local Rules of the District Court for the Eastern District of Texas, Defendant Sun Pharmaceutical Industries, Inc. (“Sun”) by and through its undersigned attorneys, will take the deposition of Plaintiff by oral examination before a duly qualified notary public or other person authorized by law to administer oaths at a date, time and location to be agreed upon by counsel. The deposition will be recorded stenographically and by videotape and shall continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. You are invited to attend and cross-examine.

Pursuant to Rule 30(b)(6), Plaintiff shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on their behalf, to testify on each of the topics set forth on attached Exhibit A. Please notify Sun of the names and positions of the person(s) who will testify on Plaintiff’s behalf for each of the topics in Exhibit A at least ten (10) days prior to the scheduled deposition.

Date: June 27, 2025

s/ Justin T. Oakland

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EXHIBIT A

DEFINITIONS AND INSTRUCTIONS

1. “’598 patent” means United States Patent No. 11,406,598.
2. “’076 patent” means United States Patent No. 11,878,076.
3. “Patent-in-Suit” means the ’076 patent.
4. “All” means “all and each,” and the term “each” means “each and all,” so that the fullest and most complete disclosure of information is achieved.
5. “And” and “or” shall have both the conjunctive and disjunctive meaning and shall be construed to include, rather than exclude material from the scope of the topic.
6. “Any” or “each” shall be construed to encompass “all.” “Any” includes both “any” and “every.” “All” shall be construed to include and encompass “any.”
7. “Communication” means any transmission of information between two or more persons, including information transmitted by way of telephone conversations, letters, faxes, email, computer links, text messages, written memorandums or other documents, bulletin board posting, and face-to-face conversations.
8. “Concerning,” “referring to,” or “relating to” means pertaining to, mentioning, commenting on, connected with, discussing, describing, analyzing, explaining, showing, reflecting, dealing with, comprising, consisting of, containing, constituting, referring to, resulting from, or recording a particular subject in whole or in part and either directly or indirectly.
9. “Control” means actual and constructive control, custody, knowledge, and/or possession by any one or a combination of the following persons:
 - a. Nivagen Pharmaceuticals, Inc.;
 - b. Any corporation or other entity controlled by, directed by, or affiliated with Nivagen Pharmaceuticals, Inc.;
 - c. Any officer, principal, director, trustee, employee, staff member, agent, joint venturer, partner, accountant, consultant, advisor, investigator, or any other representative of Nivagen Pharmaceuticals, Inc.;
 - d. Any officer, principal, director, trustee, employee, staff member, agent, joint venturer, partner, accountant, consultant, advisor, investigator, or any other representative belonging to a corporation or other entity controlled by, directed by, or affiliated with Nivagen Pharmaceuticals, Inc.;
 - e. Counsel for Nivagen Pharmaceuticals, Inc.; and
 - f. Counsel for any corporation or other entity controlled by, directed by, or affiliated with Nivagen Pharmaceuticals, Inc.

10. Defendant Sun Pharmaceutical Industries, Inc. is referred to herein as “Sun.”
11. “Document” is defined to be synonymous in meaning and equal in scope to the usage of the term “documents or electronically stored information” in Federal Rule of Civil Procedure 34(a)(1)(A). A draft or non-identical copy is a separate document within the meaning of this term.
12. “FDA” means the U.S. Food and Drug Administration.
13. “Including” shall be construed broadly, as “including but not limited to” or “including without limitation.”
14. “Nivagen” means Plaintiff Nivagen Pharmaceuticals, Inc. and its predecessor and successor companies, affiliates, parents, any partnership or joint venture to which it may be a party, and each of its employees, agents, officers, directors, representatives, consultants, accountants, and attorneys, including any person who served in any of these capacities during any relevant time period.
15. “Named Inventors” means Bala Tripura Sundari Chodavarapu, Thirupathi Mangali, Jay Shukla, Anand Shukla, and Dasaradhi Lakkaraju.
16. “NDA” means New Drug Application.
17. “Sezaby®” means the product subject to NDA No. 215910 approved by FDA on November 18, 2022.
18. “Plaintiff’s lyophilized phenobarbital sodium product” means any lyophilized phenobarbital sodium product or formulation by developed or manufactured by Plaintiff disclosed by the Patent-in-Suit.
19. “Person” or “people” means any natural person, firm, association, partnership, government agency or other entity and its officers.
20. “Plaintiff,” “you,” and “your” means collectively, Nivagen Pharmaceuticals, Inc., and current and former officers, directors, employees, consultants, attorneys, experts, agents, partners, corporate parents, subsidiaries, subdivisions, predecessors, or affiliate, divisions, and any natural persons or entities acting under its respective or joint control.
21. “Prior Art” refers to art under 35 U.S.C. §§ 102 and 103 and includes, by way of example and without limitation, printed publications, prior public uses, prior offers for sale, or prior sales.
22. “Prosecution” means all proceedings before any patent office, including the PTO or any foreign patent office, in connection with the filing, issuance, reexamination, reissue or review of, or opposition to, a patent or patent application.

23. “PTO” means the United States Patent and Trademark Office.

24. “Related Patents” means any U.S. patent, non-U.S. patent, continuation, continuation-in-part, divisional, reexamination, reissue, counterpart patent, or patent application that shares all or substantially all of its specification with the Patent-in-Suit or claims priority to the Patent-in-Suit or from which the Patent-in-Suit claim priority.

25. SPARC means “Sun Pharma Advanced Research Company Limited.”

26. “Thing” means any physical specimen or tangible item including but not limited to samples, prototypes, mock-ups, test equipment, production equipment, three dimensional illustrations of physical or chemical phenomena and montages of physical items.

27. The singular form of any noun or pronoun herein includes within its meaning the plural form thereof and vice versa, so that the fullest and most complete disclosure of information is achieved.

28. The neuter, masculine, or feminine form of any pronoun used herein includes with its meaning the neuter, masculine, and feminine forms so that the fullest and most complete disclosure of information is achieved.

29. The use of any tense or form of any verb includes within its meaning all other tenses and forms of the verb, so that the fullest and most complete disclosure of information is achieved.

DEPOSITION TOPICS

1. The circumstances, including the earliest date, under which the subject matter of the Patent-in-Suit or any patent applications to which the Patent-in-Suit claims priority, on a claim-by-claim basis, was (i) first conceived and/or when the Named Inventor first thought their idea would work, (ii) first observed experimentally, (iii) first recorded and/or described in writing, (iv) first reduced to practice and/or first made, (v) first disclosed to a person other than the Named Inventors, (vi) first publicly disclosed, (vii) first used, (viii) first publicly used, (ix) first sold, and (x) first offered for sale.

2. The conception and reduction to practice of the alleged invention of the Patent-in-Suit on a claim-by-claim basis, including the earliest date by which the Named Inventors conceived of the claimed invention, and the earliest date by which the Named Inventors reduced

the claimed invention to practice, all persons involved in the conception and reduction to practice of the claimed invention and their roles in the conception and reduction to practice, and the information and documents supporting the alleged dates of conception and reduction to practice of the alleged invention and the diligence in reducing it to practice.

3. The prosecution of the Patent-in-Suit, including: (i) any rejection of claims during the prosecution; (ii) any claim amendments submitted by or on behalf of the Named Inventor; (iii) any declarations submitted by or on behalf of the Named Inventor; (iv) any interviews with the PTO; and (v) any information disclosure statements submitted during prosecution.

4. The preparation, filing, and contents of any affidavits, declarations, or factual information submitted to the PTO in connection with the Patent-in-Suit, including the May 10, 2021 Declaration of Dr. Dasaradhi Lakkaraju (“Lakkaraju Declaration”).

5. Any experiments performed in connection with the Lakkaraju Declaration, regardless of whether the results of said experiments were reported in the Lakkaraju Declaration.

6. All remarks made during prosecution of the '076 Patent, the '598 Patent, or any related patent applications, including but not limited to those discussing prior art compositions that contained organic solvents.

7. The applicant's Amendment dated December 22, 2021 submitted during the prosecution of the '598 patent that claim 28 (which issued as claim 1) claims a “phenobarbital sodium composition” wherein the “phenobarbital sodium solution does not contain an organic solvent.”

8. The applicant's Amendment dated September 20, 2023 submitted during the prosecution of the '076 patent that removed the claim language of the product containing

“residual quantities of tert-butanol, isopropanol, ethanol, or acetonitrile and wherein the phenobarbital sodium powder otherwise does not contain an organic solvent.”

9. All facts relating to the statement in the Patent-in-Suit that “the presently disclosed formulation does not contain any organic solvents . . . which is specifically advantageous for administration to newborns and neonates.” (’598 patent, 11:23-25; ’076 patent, 11:59-62).

10. All facts and information relating to the statements in the Patent-in-Suit that “the lyophilized composition may include no less than 98% Phenobarbital Sodium.” (’598 patent, 2:41-42, 4:36-38, 7:64-66, 15:29-33; ’076 patent, 2:49-50, 4:46-48, 8:13-15, 15:48-50).

11. All facts and information relating to the statements in the Patent-in-Suit that “the present disclosure produces an amorphous structure that contributes to the observed stability of this composition upon reconstitution in water.” (’598 patent, 2:60-67, 8:23-33; ’076 patent, 3:1-9, 8:41-46).

12. The experiments performed in connection with the Patent-in-Suit, including the examples and figures disclosed therein reflected in Figures 1A-5D and Tables 1-33 of the Patent-in-Suit, including the dates on which such work was performed, identity of all individuals involved in designing, performing, and/or analyzing the results of the experiments and the role of each individual, and all documents relating to the experiments, including but not limited to lab notebook pages, study protocols, test results, memoranda, and meeting minutes, regardless of whether the results of said experiments were reported in the Patent-in-Suit.

13. All facts and information underlying Your decision not to include the data reported in Tables 31 and 32 of the ’076 patent in the parent application to the ’076 patent.

14. The stability of the lyophilized phenobarbital sodium formulations disclosed by or otherwise prepared according to the methods described in the Patent-in-Suit and the person most knowledgeable about said stability.

15. The purity of the lyophilized phenobarbital sodium formulations disclosed by or otherwise prepared according to the methods described in the Patent-in-Suit and the person most knowledgeable about said purity.

16. The contribution, if any, of any individual to the purported invention (including conception and reduction to practice) of each of the claims of the Patent-in-Suit, including the experimental work of each individual and any person working with them with respect to lyophilized phenobarbital sodium, and all facts related to each individual's notebooks, workbooks, investigations, summaries, meeting notes or minutes, reports, presentations, evaluations, analyses, protocols, experimental and equipment conditions, laboratory notebooks, test data, analytical data, and results or conclusions reached from such tests or studies.

17. Prior art, articles, books, and other references reviewed, considered or used during the development of the alleged invention described by the Patent-in-Suit.

18. All prior art known to Plaintiff, or identified by or for anyone associated with Plaintiff, in connection with any analysis or consideration of the claims of the Patent-in-Suit or any related patents or patent applications.

19. All facts and information relating to Nivagen's awareness of or efforts to monitor Sun's phenobarbital project, including but not limited to research and development, regulatory approval, and patent filings.

20. All facts and information relating to communications or information exchanged with JSS Medical relating to Sun, SPARC, and/or the development of any phenobarbital sodium

product by Sun, SPARC, or any entity related to Sun, including but not limited to the circumstances surrounding the information sent by JSS reflected in NIVAGEN_PHENOBARB_0205076-0205085.

21. The development and testing of Plaintiff's lyophilized phenobarbital sodium product including, but not limited to, invention disclosures, notebooks, workbooks, investigations, summaries, meeting notes or minutes, reports, presentations, evaluations, analyses, test data, analytical data, and results or conclusions reached from such tests or studies.

22. Any studies, analyses, data, reports, summaries, meeting minutes or evaluation comparing Plaintiff's lyophilized phenobarbital sodium product to Sezaby®.

23. Any analysis, testing, or evaluation of Sezaby® or its properties undertaken by You or on Your behalf prior to filing this Action, including but not limited to the testing referred to or reflected in NIVAGEN_PHENOBARB_0040262, NIVAGEN_PHENOBARB_0043278, and NIVAGEN_PHENOBARB_294557.

24. The composition of Plaintiff's lyophilized phenobarbital sodium product including any test data reflecting such compositions and the amount of each inactive ingredient.

25. The process used to manufacture Plaintiff's lyophilized phenobarbital sodium product(s).

26. The basis for the decision to develop a lyophilized phenobarbital sodium product that does not contain an organic solvent.

27. The basis for the decision to develop a phenobarbital sodium drug product that was lyophilized.

28. The basis for the decision to develop a phenobarbital sodium drug product that was amorphous.

29. Any pharmaceutical liquid formulations or lyophilized formulation of lyophilized phenobarbital sodium reviewed or considered by Plaintiff or the Named Inventors, including any investigations, contemplation or work, leading to any alleged invention claimed in the Patent-in-Suit or any related patents thereof.

30. Any experiments performed on any lyophilized phenobarbital sodium products to analyze, determine, assess, and/or characterize stability, including the motivation and basis for the decision, and all individuals involved in designing, performing, and/or analyzing the results and the role of each individual, and all documents relating to the experiments, including but not limited to lab notebook pages, study protocols, test results, stability test results, memoranda, and meeting minutes.

31. Any efforts and attempts by Plaintiff to improve purity and/or stability by creating an amorphous formulation such as Plaintiff's lyophilized phenobarbital sodium product, whether successful or not, including identification of each failed attempt and all documents and things concerning the attempts to create an amorphous formulation.

32. Any efforts and attempts to reduce levels of organic solvents in Plaintiff's lyophilized phenobarbital sodium product, whether successful or not, including identification of each failed attempt and all documents and things concerning the attempts to reduce levels of organic solvents.

33. Any efforts and attempts to formulate a lyophilized phenobarbital sodium product that did include organic solvents.

34. Any testing concerning the formulation, manufacture, properties, bioavailability, or stability of any lyophilized phenobarbital sodium product, including but not limited to Nobelbar®.

35. Nivagen's knowledge of Nobelbar®, including when Nivagen learned of such information.

36. The decision not to identify Nobelbar® or any documents related thereto as relevant prior art during the prosecution of the '598 patent, the Patent-in-Suit, or any related applications.

37. All actual or contemplated communications, meetings, and/or agreements between Nivagen and Nobelpharma relating to Nobelbar® or any other phenobarbital sodium product.

38. All communications and/or meetings between Nivagen and Sumitomo Corporation relating to Nobelbar® or any other phenobarbital sodium product, including the emails NIVAGEN_PHENOBARB_021743, NIVAGEN_PHENOBARB_0320210, NIVAGEN_PHENOBARB_0320221, and NIVAGEN_PHENOBARB_0320648.

39. All actual or contemplated communications, meetings, and/or agreements between Nivagen and Hikma Pharmaceuticals relating to any phenobarbital sodium product.

40. All actual or contemplated communications, meetings, and/or agreements between Nivagen and Long Grove Pharmaceuticals, LLC or Capstone Development Services Co., LLC relating to any phenobarbital sodium product.

41. Any current and past ownership, rights, title, licenses, transfers, royalty arrangements/payments, assignments of rights, and/or other interests that relate to the Patent-in-Suit, or the subject matter described in those patents, their patent applications, and/or priority applications, including any licensing agreements covering—and any efforts to license—the Patent-in-Suit, including Plaintiff's ownership of or other right, title or interest in the Patent-in-Suit and all documents that relate to such ownership or other right, title or interest.

42. Financial data, performance, predictions, and analyses for Plaintiff's lyophilized phenobarbital sodium product, including without limitation the sales, costs (including research and development costs), pricing, discounts, rebates, gross and net profits, revenues, market share, market definition, sales and profit projections, marketing and sales expenditures, and physician or managed care surveys associated with Plaintiff's lyophilized phenobarbital sodium product.

43. Any knowledge Plaintiff has regarding Renaissance SSA, LLC's phenobarbital orphan drug designation, including but not limited to, the status of its drug development, the composition of its drug product, the anticipated drug designation, and status of the project upon Sun's orphan drug exclusivity designation.

44. Any knowledge Plaintiff has regarding Genus Lifesciences' phenobarbital sodium orphan drug designation, including but not limited to, the status of its drug development, the composition of its drug product, the anticipated drug designation, and status of the project upon Sun's orphan drug exclusivity designation.

45. Any knowledge Plaintiff has regarding Accord Healthcare's phenobarbital and phenobarbital sodium orphan drug designations, including but not limited to, the status of its drug developments, the composition of its drug products, the anticipated drug designations, and status of the projects upon Sun's orphan drug exclusivity designation.

46. Any knowledge Plaintiff has regarding Hikma Pharmaceuticals, Inc.'s phenobarbital sodium orphan drug designation, including but not limited to, the status of its drug development, the composition of its drug product, the anticipated drug designation, and status of the project upon Sun's orphan drug exclusivity designation.

47. The planned marketing and promotion of Plaintiff's lyophilized phenobarbital sodium product, including but not limited to marketing plans, business plans, advertising plans,

sales plans, promotional plans, market studies, market research, market analyses, competitive research, analyses of competing products, evaluations, advertisements, communications with doctors, nurses, health insurance companies, pharmacies, any other healthcare providers, patients, training and instruction of marketing personnel, and the use of samples and/or coupons.

48. Market and financial analyses relating to any lyophilized phenobarbital sodium product.

49. Any knowledge Plaintiff has regarding commercial success, if any, related to the claimed features of the Patent-in-Suit, including Plaintiff's assertion that Sun's Sezaby product has a nexus to the asserted claims, has been commercially successful, and/or is projected to be a commercial success.

50. The need for a lyophilized phenobarbital sodium product at the time of the priority date for the Patent-in-Suit, including Plaintiff's assertion that there was a long-felt but unmet need for a storage-stable phenobarbital sodium product that contained low amounts of impurities and was approved by the FDA.

51. Any knowledge Plaintiff has regarding the failure of others to solve the problems addressed by the Patent-in-Suit, if any, related to the claimed features of the Patent-in-Suit.

52. Any knowledge Plaintiff has regarding acceptance in the industry and/or by the public, if any, related to the claimed features of the Patent-in-Suit.

53. Any knowledge Plaintiff has regarding industry praise, if any, related to the claimed features of the Patent-in-Suit.

54. Plaintiff's knowledge regarding whether there were any unexpected results associated with the claimed invention of the Patent-in-Suit, including any analyses, evaluations, and all facts relating to Plaintiff's assertion that a person of ordinary skill in the art would have

understood and expected that a solid in an amorphous physical state would be less stable than a crystalline material with the same chemical content.

55. Any knowledge Plaintiff has regarding any alleged copying, if any, related to the claimed features of the Patent-in-Suit.

56. The organizational structure of departments, groups, or teams within Plaintiff having responsibility for the alleged invention described by the Patent-in-Suit, including but not limited to organizational charts for such departments, groups, or teams.

57. The relationship between Nivagen, Inc. and Corbel Capital Partners.

58. All documents related to any of the foregoing Topics.

59. The authenticity of the documents produced by You in this litigation.

60. The identity of any persons with knowledge of each of the foregoing Topics.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was served by email on Plaintiff's counsel on this 27 day of June, 2025.

/s/Justin T. Oakland
Justin T. Oakland

**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 NOTICE OF DEPOSITION OF ANAND SHUKLA

PLEASE TAKE NOTICE, pursuant to Rule 30 of the Federal Rules of Civil Procedure, Defendant Sun Pharmaceutical Industries, Inc. (“Sun”), by and through the undersigned counsel, will take the deposition by oral testimony of Anand Shukla.

The deposition will take place at a time, date, and location as may be mutually agreed upon by counsel. The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or audiovisual means. Plaintiff is invited to attend and cross-examine.

Date: June 27, 2025

s/ Justin T. Oakland

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/s/ Justin T. Oakland
Justin T. Oakland

**UNITED STATES DISTRICT COURT
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JURY TRIAL DEMANDED

**DEFENDANT’S NOTICE OF DEPOSITION OF
BALA TRIPURA SUNDARI CHODAVARAPU**

PLEASE TAKE NOTICE, pursuant to Rule 30 of the Federal Rules of Civil Procedure, Defendant Sun Pharmaceutical Industries, Inc. (“Sun”), by and through the undersigned counsel, will take the deposition by oral testimony of Bala Tripura Sundari Chodavarapu.

The deposition will take place at a time, date, and location as may be mutually agreed upon by counsel. The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or audiovisual means. Plaintiff is invited to attend and cross-examine.

Date: June 27, 2025

s/ Justin T. Oakland

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/s/ Justin T. Oakland
Justin T. Oakland

**UNITED STATES DISTRICT COURT
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SUN PHARMACEUTICALS INDUSTRIES,
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Defendant.

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

JURY TRIAL DEMANDED

DEFENDANT'S NOTICE OF DEPOSITION OF DASARADHI LAKKARAJU

PLEASE TAKE NOTICE, pursuant to Rule 30 of the Federal Rules of Civil Procedure, Defendant Sun Pharmaceutical Industries, Inc. ("Sun"), by and through the undersigned counsel, will take the deposition by oral testimony of Dasaradhi Lakkaraju.

The deposition will take place at a time, date, and location as may be mutually agreed upon by counsel. The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or audiovisual means. Plaintiff is invited to attend and cross-examine.

Date: June 27, 2025

s/ Justin T. Oakland

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/s/ Justin T. Oakland
Justin T. Oakland

**UNITED STATES DISTRICT COURT
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Defendant.

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

JURY TRIAL DEMANDED

DEFENDANT’S NOTICE OF DEPOSITION OF THIRUPATHI MANGALI

PLEASE TAKE NOTICE, pursuant to Rule 30 of the Federal Rules of Civil Procedure, Defendant Sun Pharmaceutical Industries, Inc. (“Sun”), by and through the undersigned counsel, will take the deposition by oral testimony of Thirupathi Mangali.

The deposition will take place at a time, date, and location as may be mutually agreed upon by counsel. The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or audiovisual means. Plaintiff is invited to attend and cross-examine.

Date: June 27, 2025

s/ Justin T. Oakland

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this 27 day of June, 2025.

/s/ Justin T. Oakland
Justin T. Oakland

**UNITED STATES DISTRICT COURT
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Case No.: 2:24-cv-36-RWS-RSP

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DEFENDANT'S NOTICE OF DEPOSITION OF NIRAV PATEL

PLEASE TAKE NOTICE, pursuant to Rule 30 of the Federal Rules of Civil Procedure, Defendant Sun Pharmaceutical Industries, Inc. ("Sun"), by and through the undersigned counsel, will take the deposition by oral testimony of Nirav Patel.

The deposition will take place at a time, date, and location as may be mutually agreed upon by counsel. The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or audiovisual means. Plaintiff is invited to attend and cross-examine.

Date: June 27, 2025

s/ Justin T. Oakland

Eric H. Findlay (#00789886)
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aolson@carlsoncaspers.com
ekim@carlsoncaspers.com
joakland@carlsoncaspers.com

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was served by email on Plaintiff's counsel on
this 27 day of June, 2025.

/s/ Justin T. Oakland
Justin T. Oakland

**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 NOTICE OF DEPOSITION OF JAY SHUKLA

PLEASE TAKE NOTICE, pursuant to Rule 30 of the Federal Rules of Civil Procedure, Defendant Sun Pharmaceutical Industries, Inc. ("Sun"), by and through the undersigned counsel, will take the deposition by oral testimony of Jay Shukla.

The deposition will take place at a time, date, and location as may be mutually agreed upon by counsel. The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or audiovisual means. Plaintiff is invited to attend and cross-examine.

Date: June 27, 2025

s/ Justin T. Oakland

Eric H. Findlay (#00789886)
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ekim@carlsoncaspers.com
joakland@carlsoncaspers.com

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was served by email on Plaintiff's counsel on
this 27 day of June, 2025.

/s/ Justin T. Oakland
Justin T. Oakland

**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

**NIVAGEN PHARMACEUTICALS, INC.’S NOTICE OF DEPOSITION TO
DEFENDANT PURSUANT TO F. R. Civ. P. 30(b)(6)**

PLEASE TAKE NOTICE that, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiff Nivagen Pharmaceuticals, Inc.¹ (“Nivagen” or “Plaintiff”) by and through their undersigned attorneys, will take the deposition(s) by oral testimony of Defendant Sun Pharmaceutical Industries, Inc. (“Sun” or Defendant”) on the topics set forth in Schedule A hereto, commencing at 9:00 a.m. on July 9, 2025, at a location mutually determined by the parties, or at such other place and time as may be mutually agreeable. The deposition(s) shall be taken before an officer, notary public, or other person duly authorized to administer oaths. The deposition shall continue from day to day, excluding weekends and holidays, until completed. The deposition may be videotaped and/or offered via live web feed with real-time transcripts and instant messaging to persons located off-site (in such a case, the persons will be identified on the deposition record).

Pursuant to Federal Rule of Civil Procedure 30(b)(3), the testimony will be recorded by stenographic, audio, and video means. The deposition(s) will be taken for the purposes of discovery, use at trial in this action, and any other purposes permitted under the Federal Rules of Civil Procedure. Pursuant to Rule 30(b)(6), Sun shall designate one or more officers, directors, managing agents, or other representative(s) who consent to testify on its behalf to matters known or reasonably available to Sun regarding the topics listed herein. To the extent more than one deponent is identified, Sun shall state in advance of the deposition which portions of this Notice each deponent is prepared to address.

DATED: June 24, 2025

/s/ Brent A Batzer

¹ Also referred to in this lawsuit as “Nivagen, Inc.”

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Yixin Tang (yixin@ipfdalaw.com)
Brent Batzer (brent@ipfdalaw.com)
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109 Symonds Dr. #174
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312-327-3326

*Counsel for Plaintiff Nivagen
Pharmaceuticals, Inc.*

SCHEDULE A: 30(b)(6) Deposition Topics

The Definitions and Instructions set forth in Nivagen's First Set of Requests to Defendant for the Production of Documents and Things are incorporated herein by reference.

In accordance with the Federal Rules of Civil Procedure 30(b)(6), Nivagen identifies the following matters for examination:

1. The contents of Sun's NDA No. 215910 including, without limitation, the composition of Sun's Product and all testing results set forth in the NDA.
2. The decision to develop a phenobarbital sodium lyophilized product.
3. The decision to file a New Drug Application (NDA) for a phenobarbital sodium lyophilized product.
4. The selection of and decision to develop the formulations (bulk solution and the lyophile) used for Sun's Product.
5. The development, testing, and production of Sun's Product, including, without limitation, development of the formulation for Sun's Product, any impurity testing of Sun's Product, any high-performance liquid chromatography (HPLC) and gas chromatography (GC) testing during and for the development of Sun's Product, and any studies of the crystalline or amorphous nature of Sun's Product, including any powder X-ray diffraction (XRPD/XPD/PXRD) analysis performed on Sun's Product, or such analysis performed during and for the development of Sun's Product.
6. Identifications and descriptions of the locations at which Sun's Product is developed, tested manufactured, produced, distributed, imported, and/or exported.

7. Identifications and descriptions of each entity involved in the development, testing, manufacturing, production, distribution, importation, and/or exportation of Sun's Product.
8. The assay % of the active pharmaceutical ingredients in Sun's Product.
9. The amount of impurities in Sun's Product, including but not limited to the impurities phenylethylacetylurea (PEAU), 2-ethyl-2-phenylmalonamide (2EPM), and alpha-phenylbutyrylguanidine (PBG), any testing methods for determining the amount of impurities in Sun's Product, and the specifications for impurities in Sun's Product.
10. The stability testing for Sun's Product, and such testing during and for the development of Sun's Product.
11. The actual sales of Sezaby, including the amount sold, costs of goods sold, net profits, and any other financial information relating to the sales of Sezaby.
12. Any market analysis, including but not limited to projected sales and profit, of Sun's Product.
13. Sun's marketing of Sezaby, including but not limited to any marketing materials or marketing programs targeting doctors or purchasers.
14. Any projections made by Sezaby concerning the amount of Sezaby that will be produced in the future.
15. Any estimated, projected, or incurred direct and indirect costs associated with using, designing, developing, and implementing the alleged acceptable alternatives to Sezaby.
16. A reasonable royalty rate or amount for the Asserted Patent, and the amount, calculation, and factual bases of said reasonable royalty.

17. To the extent that You contend that Plaintiff is not entitled to a reasonable royalty from You because of Your alleged infringement of the Asserted Patents, all factual bases supporting Your contention, and if You have calculated or estimated a reasonable royalty amount that You believe is reasonable, the amount, calculation, and factual bases of said reasonable royalty.
18. Customer demand for Sun's Product
19. The monetary and non-monetary value, benefits, and goodwill that You expected to and/or did receive, gain, or derive from Sun's Product.
20. To the extent that Sun contends that Plaintiff is not entitled to its lost profits because of the alleged infringement of the Asserted Patent, all factual bases supporting Sun's contention.
21. Any alternatives You considered during the planning, creation, and/or development of Sun's Product.
22. For each alternative response to Topic No. 21, the feasibility of the alternative, including both the technical and economic feasibility of the alternative.
23. Your belief as to the acceptability, viability, and/or feasibility of any alternative to Sun's Product, including any documents or studies supporting Your belief and including the time periods during which You held such a belief.
24. Any efforts You have made to design around or avoid infringement of any of the Asserted Patents, including any steps You have considered or taken to alter the design or to terminate the sale or development of any product, including the identity of all persons involved in any such efforts.
25. Any alternative to Sun's Product that you contend does not infringe any of the Asserted Patents.

26. For each alternative response to Topic No. 25, the feasibility of the alternative, including both the technical and economic feasibility of the alternative.
27. Any licensing agreements, settlement agreements, covenants-not-to-sue, technology transfer agreements, or any other agreements or contracts providing any rights to patents or technologies (“Licenses”) to which You are or have been a party, signatory, or beneficiary that relate to Sun’s Product or products that are technologically comparable to the Sun’s Product, including all license agreements and all documents and communications (including internal and external correspondence and presentations) relating to such license negotiations.
28. All fees, royalties, and royalty rates received or paid by You as a result of the license agreements referenced in Topic No. 27, including the terms and conditions of said license agreements (i.e., terms of license fee agreements and whether they are based on monthly installments, annual installments, per subscriber installments, etc.).
29. Sun’s attempts to remove other phenobarbital products from the market via the US Food and Drug Administration (FDA).
30. The obtaining of the Orphan Drug Designation (ODE) for Sun’s Product, including but not limited to the generation and submission of any study data that supported Sun’s ODE application.
31. Sun’s policies and practice regarding intellectual property and patents from 2019 to the present, including any policies and practice regarding searching for patents, any instructions not to conduct any patent searches or general searches concerning intellectual property owned by a third party, evaluation of a third party’s intellectual property, and licensing.

32. Sun's first awareness of U.S. Patent Application No. 17/025,881.
33. Sun's first awareness of U.S. Patent Application No. 18/100,804.
34. Sun's first awareness of U.S. Patent 11,878,076.
35. Sun's awareness of the Third Party Submission made by Attorney Jay Lessler during the prosecution of U.S. Patent Application No. 17/025,881.
36. Sun's involvement and participation, directly or indirectly, of the Third Party Submission made by Attorney Jay Lessler during the prosecution of U.S. Patent Application No. 17/025,881.
37. Sun's first awareness of any of the prior art references included in the Third Party Submission made by Attorney Jay Lessler during the prosecution of U.S. Patent Application No. 17/025,881.
38. Sun's attempt to license Nivagen's intellectual property pertaining to U.S. Patent Application No. 17/025,881, U.S. Patent No. 11,406,598, U.S. Patent Application No. 18/100,804, and/or U.S. Patent 11,878,076.
39. Sun's knowledge of and communications regarding Nivagen.
40. Sun's knowledge of and communications regarding the Asserted Patents.
41. The factual bases for Sun's assertions that the Patent-in-Suit is invalid.
42. The factual bases for Sun's assertions that the claims of the Patent-in-Suit are not infringed by Sun's Product.
43. The factual bases for Sun's assertions at the FDA that Sun's Product is superior to any unapproved phenobarbital sodium products.
44. The authenticity of all documents produced by Defendant in this litigation.
45. The search for and collection of the documents produced by Defendant in this litigation.

46. Sun's document retention and destruction policies.
47. The identity of the person(s) most knowledgeable about the subject matter in each of the Deposition Topics in this deposition notice.
48. The location of documents reflecting the subject matter in each of these Deposition Topics, including the identity of the persons in possession, custody, or control of such documents.

CERTIFICATE OF SERVICE

I hereby certify that on June 24, 2025, a true and correct copy of the foregoing document was served upon Sun *via* electronic mail.

By: s/ Brent A Batzer

Brent A. Batzer

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

NIVAGEN, INC.,	§	
	§	
	§	
Plaintiff,	§	Civil Action No. 2:24-cv-36-RWS-RSP
	§	
v.	§	
	§	
SUN PHARMACEUTICALS INDUSTRIES,	§	
INC.,	§	
	§	
Defendant.	§	

PLAINTIFF’S NOTICE OF RULE 30(B)(1) DEPOSITION
OF AJAY KHOPADE

PLEASE TAKE NOTICE, pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure, Plaintiff Nivagen, Inc. by and through the undersigned counsel, will take the deposition by oral/video testimony of Ajay Khopade.

This deposition will take place at a mutually agreed location beginning on July 30, 2025 at 9:00 a.m. CDT or at such other date, time, or location as the parties may mutually agree.

The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or web-based platform. The deposition will be taken for the purposes of discovery for use as permitted under the Federal Rules of Civil Procedure and the local rules of this Court. Defendant is invited to attend and cross-examine.

Respectfully submitted,

DATED: July 11, 2025

/s/ Brent A Batzer

Shashank Upadhye

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Yixin Tang

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Brent Batzer

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Telephone: (903) 230-9090

Facsimile: (903) 230-9661

Counsel for Plaintiff Nivagen Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served on July 11, 2025, with a copy of this document via electronic mail.

/s/ Brent A Batzer

Brent A. Batzer

**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’S NOTICE OF RULE 30(B)(1) DEPOSITION
OF ANIL GITE**

PLEASE TAKE NOTICE, pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure, Plaintiff Nivagen, Inc. by and through the undersigned counsel, will take the deposition by oral/video testimony of Anil Gite.

This deposition will take place at a mutually agreed location beginning on August 6, 2025 at 9:00 a.m. CDT or at such other date, time, or location as the parties may mutually agree.

The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or web-based platform. The deposition will be taken for the purposes of discovery for use as permitted under the Federal Rules of Civil Procedure and the local rules of this Court. Defendant is invited to attend and cross-examine.

Respectfully submitted,

DATED: July 11, 2025

/s/ Brent A Batzer

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Yixin Tang

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Brent Batzer

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Facsimile: (903) 230-9661

Counsel for Plaintiff Nivagen Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served on July 11, 2025, with a copy of this document via electronic mail.

/s/ Brent A Batzer

Brent A. Batzer

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

NIVAGEN, INC.,	§	
	§	
	§	
Plaintiff,	§	Civil Action No. 2:24-cv-36-RWS-RSP
	§	
v.	§	
	§	
SUN PHARMACEUTICALS INDUSTRIES,	§	
INC.,	§	
	§	
Defendant.	§	

PLAINTIFF’S NOTICE OF RULE 30(B)(1) DEPOSITION
OF BUSHAN BAROLE

PLEASE TAKE NOTICE, pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure, Plaintiff Nivagen, Inc. by and through the undersigned counsel, will take the deposition by oral/video testimony of Bhushan Barole.

This deposition will take place at a mutually agreed location beginning on August 1, 2025 at 9:00 a.m. CDT or at such other date, time, or location as the parties may mutually agree.

The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or web-based platform. The deposition will be taken for the purposes of discovery for use as permitted under the Federal Rules of Civil Procedure and the local rules of this Court. Defendant is invited to attend and cross-examine.

Respectfully submitted,

DATED: July 11, 2025

/s/ Brent A Batzer

Shashank Upadhye

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Yixin Tang

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Brent Batzer

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Facsimile: (903) 230-9661

Counsel for Plaintiff Nivagen Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served on July 11, 2025, with a copy of this document via electronic mail.

/s/ Brent A Batzer

Brent A. Batzer

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

NIVAGEN, INC.,	§	
	§	
	§	
Plaintiff,	§	Civil Action No. 2:24-cv-36-RWS-RSP
	§	
v.	§	
	§	
SUN PHARMACEUTICALS INDUSTRIES,	§	
INC.,	§	
	§	
Defendant.	§	

PLAINTIFF’S NOTICE OF RULE 30(B)(1) DEPOSITION
OF MALAY SHAH

PLEASE TAKE NOTICE, pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure, Plaintiff Nivagen, Inc. by and through the undersigned counsel, will take the deposition by oral/video testimony of Malay Shah.

This deposition will take place at a mutually agreed location beginning on August 4, 2025 at 9:00 a.m. CDT or at such other date, time, or location as the parties may mutually agree.

The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or web-based platform. The deposition will be taken for the purposes of discovery for use as permitted under the Federal Rules of Civil Procedure and the local rules of this Court. Defendant is invited to attend and cross-examine.

Respectfully submitted,

DATED: July 11, 2025

/s/ Brent A Batzer

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Brent Batzer

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Counsel for Plaintiff Nivagen Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served on July 11, 2025, with a copy of this document via electronic mail.

/s/ Brent A Batzer

Brent A. Batzer

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

NIVAGEN, INC.,	§	
	§	
	§	
Plaintiff,	§	Civil Action No. 2:24-cv-36-RWS-RSP
	§	
v.	§	
	§	
SUN PHARMACEUTICALS INDUSTRIES,	§	
INC.,	§	
	§	
Defendant.	§	

PLAINTIFF’S NOTICE OF RULE 30(B)(1) DEPOSITION
OF PRADEEP R. PATIL

PLEASE TAKE NOTICE, pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure, Plaintiff Nivagen, Inc. by and through the undersigned counsel, will take the deposition by oral/video testimony of Pradeep R. Patil.

This deposition will take place at a mutually agreed location beginning on July 21, 2025 at 9:00 a.m. CDT or at such other date, time, or location as the parties may mutually agree.

The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or web-based platform. The deposition will be taken for the purposes of discovery for use as permitted under the Federal Rules of Civil Procedure and the local rules of this Court. Defendant is invited to attend and cross-examine.

Respectfully submitted,

DATED: July 11, 2025

/s/ Brent A Batzer

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Facsimile: (903) 230-9661

Counsel for Plaintiff Nivagen Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served on July 11, 2025, with a copy of this document via electronic mail.

/s/ Brent A Batzer

Brent A. Batzer

**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’S NOTICE OF RULE 30(B)(1) DEPOSITION
OF SHIBA S. NAYAK

PLEASE TAKE NOTICE, pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure, Plaintiff Nivagen, Inc. by and through the undersigned counsel, will take the deposition by oral/video testimony of Shiba S. Nayak.

This deposition will take place at a mutually agreed location beginning on July 25, 2025 at 9:00 a.m. CDT or at such other date, time, or location as the parties may mutually agree.

The deposition will continue from day to day until completed or adjourned if authorized by the Court or stipulated by the parties. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths, and will be recorded by videographic, stenographic, audio, and/or web-based platform. The deposition will be taken for the purposes of discovery for use as permitted under the Federal Rules of Civil Procedure and the local rules of this Court. Defendant is invited to attend and cross-examine.

Respectfully submitted,

DATED: July 11, 2025

/s/ Brent A Batzer
Shashank Upadhye
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Yixin Tang
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Facsimile: (903) 230-9661

Counsel for Plaintiff Nivagen Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served on July 11, 2025, with a copy of this document via electronic mail.

/s/ Brent A Batzer
Brent A. Batzer

NIVAGEN, INC.,

Plaintiff,

v.

SUN PHARMACEUTICALS INDUSTRIES,
INC.,

Defendant.

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§ Civil Action No. 2:24-cv-36-RWS-RSP
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Nivagen Ex. 2011
Sun v. Nivagen
IPR2025-00893

Respectfully submitted,

DATED: July 11, 2025

/s/ Brent A Batzer

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Yixin Tang

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Brent Batzer

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Telephone: (903) 230-9090

Facsimile: (903) 230-9661

Counsel for Plaintiff Nivagen Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served on July 11, 2025, with a copy of this document via electronic mail.

/s/ Brent A Batzer

Brent A. Batzer