UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

Nivagen, Inc., **Plaintiff, v.** **Sun Pharmaceuticals Industries, Inc.,** **Sun Pharmaceutical Industries Ltd.,** **Sun Pharma Advanced Research Company Ltd.,** **Sun Pharmaceutical Medicare Ltd.,** **Defendants.**	**Case No. 2:24-cv-36** **JURY TRIAL DEMANDED**

ORIGRINAL COMPLAINT FOR PATENT INFRINGEMENT OF U.S. PATENTS: 11,406,598 and 11,878,076

Nivagen, Inc. ("Nivagen" or "Plaintiff") files this Original Complaint for Patent Infringement against Sun Pharmaceuticals Industries, Inc. ("Sun"); Sun Pharmaceutical Industries Ltd. ("SPIL"); Sun Pharma Advanced Research Company Ltd. ("SPARC"); and Sun Pharmaceutical Medicare, Ltd. ("SPM") (collectively "Defendants" or individually as "Defendant"), and alleges, upon information and belief, as follows:

THE PARTIES

1. Nivagen, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3050 Fite Circle, Suite 100, Sacramento, CA 95827.

2. Upon information and belief, that: (i) Sun is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 2 Independence Way, Princeton, NJ 08540; (ii) SPARC is a corporation organized and existing under the laws of India, having its principal place of business at 17-B

Mahal Industrial Estate, Off Mahakali Caves Road, Andheri (East), Mumbai 400 093, India; (iii) SPM is a corporation organized and existing under the laws of India, and has a principal place of business at Baska Ujeti Road, Ujeti Halol -389350, Gujarat, India; and (iv) SPIL is a corporation organized and existing under the laws of India, having its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India 400063.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this case under 28 U.S.C. §§1331 and 1338(a).

4. This Court has personal jurisdiction over Defendants because Defendants conduct business in and have committed jointly or individually acts of patent infringement in this District and the State of Texas and have established minimum contacts with this forum state such that the exercise of jurisdiction over Defendants would not offend the traditional notions of fair play and substantial justice.

5. Defendants are subject to this Court's general and specific jurisdiction pursuant to due process and/or the Texas Long Arm Statute due at least to Defendants' substantial business in the State of Texas and this District, including through its past and ongoing infringing activities, because Defendants regularly do and solicit business herein, and/or because Defendants have engaged in persistent conduct and/or have derived substantial revenues from goods and services provided in the State of Texas and this District.

6. Defendants transact substantial business with entities and individuals in the State of Texas and this District, by among other things, willfully using the infringing

methods and drug products throughout the State of Texas and this District. Defendants rely on the infringing methods and drug products to introduce and sell these products into the stream of commerce with the knowledge and expectation that they will be sold in the State of Texas and this District.

7. Defendants maintains regular, physical, continuous, and established places of businesses, including places of business for team leaders of sales, sales representatives, account managers, in his District, which Defendants have established, ratified, and controlled; have employed people to conduct their business from within this State and this District; and from which they have willfully infringe the Asserted Patents in order to benefit themselves in this District. Defendants commit acts of infringement in this District, including as explained further below by making and/or using the infringing drug products and/or relying on the importation of such infringing drug products.

8. Upon information and belief, Defendants employ sales personnel in the State of Texas. Sun (at the time of this complaint) has advertised for sales personnel in the State of Texas.

9. Upon information and belief, Sun is currently advertising for a Director, Professional Relations West, which is to be located in Dallas, TX. The screenshot below is from LinkedIn: visited Dec. 4, 2023 at 1:30 pm CT.

Director, Professional Relations West

SUN PHARMA · Dallas, TX 3 weeks ago · 35 applicants

- Hybrid Full-time Director
- 10,001+ employees · Pharmaceutical Manufacturing
- 23 connections work here · 2 school alumni work here
- View verifications related to this job post.View verifications related to this job post.

Draft a message to the hiring team with AI

Patricia Hart
2nd
Head of Talent Acquisition @ SUN PHARMA | Human Resources
Job poster

10. Per the job posting, the job duties include: "Drive regional engagement strategy for Sun Medical Dermatology Business Unit through enhancing our partnership with assigned customers & its portfolio of products. Build and maintain regional engagement plans for all assigned customers. Attend local, regional & national congresses and serve as a liaison between key customers and the Medical Dermatology leadership team. Member of Regional Leadership Team with key participation in the development and management of key customers and thought leader relationships. Ongoing demonstration of collaboration and pull thru across internal stakeholders (Medical Affairs, Marketing, Sales Leadership and Market Access) to coordinate a consistent company approach to key customers. Reports to Business Unit Head Medical Dermatology. This is a field-based role: Locations

considered are West Coast (California), Arizona or Texas. Interacts at multiple levels inside and outside the company. Tact, diplomacy, and a high level of professionalism are essential".

11. This Director position is in a fixed geographical location. They are "regular" and "established" because they operate in a "steady, uniform, orderly, and methodical manner" and are sufficiently permanent. These locations are "of the defendant" because Defendant Sun has contractual rights with them—as employees of Sun and conduct business on behalf of Sun, and are to interact with "multiple levels inside and outside the company".

12. Defendants, including Sun, are also advertising for a Medical Liaison for the West division, which upon information includes Texas. On Sun's careers website (From: https://careers.sunpharma.com/search/?q=&locationsearch=USA (visited Dec. 4, 2023 at 1:45 pm CT), the Medical Liaison will interact with health care practitioners (such as doctors, physician assistants, nurse practitioners) as follows: "The Medical Science Liaison (MSL) – West Region will represent Sun Pharmaceutical (SUN). The MSL will primarily identify and engage with a targeted group of national and regional thought leaders/healthcare professionals (HCPs) as well as payers and managed care accounts, providing the consistent delivery of educational and compliant scientific information in support of Oncology and Specialty products. The MSLs will engage with HCPs, NPs, & PAs who are in clinical practice caring for their patients. They will be trained to respond to complex inquiries in a scientific, fair-balanced, compliant manner serving as a critical field medical resource to these HCPs and also, internal SUN sales and managed markets

constituents.". This Liaison will undoubtedly interact with health care practitioners (HCP), nurse practitioners (NP), and/or physician assistants (PA) in this State and in this District.

13. A search of LinkedIn also indicated that several other employees of Sun are in Texas and in this district:

Ricky Ballenger · 2nd
Oncology Account Manager at SUN PHARMA
Tyler-Jacksonville Area · Contact info
500+ connections

Debbie Heintz · 2nd
Senior Dermatology Sales Specialist at Sun Dermatology
Plano, Texas, United States · Contact info
500+ connections

Belinda Lawson · 3rd
Medical Assistant/Biologic Coordinator
Denton, Texas, United States · Contact info

Rajendra Kothapally · 3rd
Microsoft Azure devops Senior Engineer
Denton, Texas, United States · Contact info

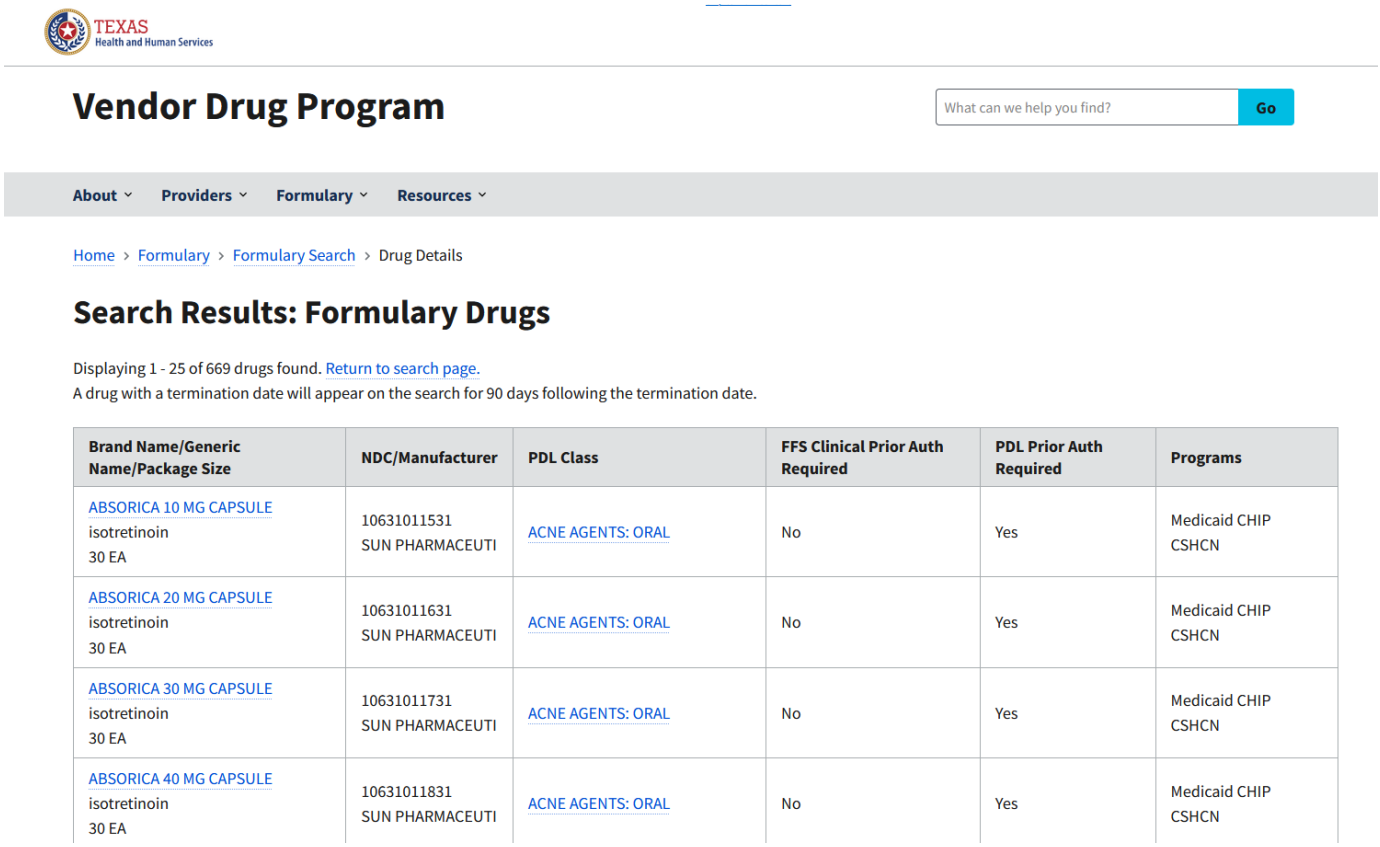
John Riley · 3rd+
Oncology Account Manager
Orange, TX
Current: Oncology Account Manager at **SUN PHARMA**

LinkedIn Member
Executive Director at SUN PHARMA
Plano, TX

Stephanie Le · 3rd+
Account Manager, Specialty Dermatology
Katy, TX
Current: Account Manager at **SUN PHARMA**

Josh Sokolewicz · 3rd+
Specialty Pharmaceutical & Healthcare Sales
McKinney, TX
Current: Ophthalmic Account Manager at **SUN PHARMA**

14. Defendants, including Sun, participate in the Texas Medicare rebate program because it offers to sell drug products across the State, including in this District. Using the Texas Health and Human Services vendor drug program website, and searching for Sun Pharma, the results returned about 669 products in the Texas rebate program. https://www.txvendordrug.com/formulary/formulary-search/drugs?field_drug_ndc_value=&combine=&field_manufacturer_value=sun&field_pdl_drug_class_target_id=All&field_cpa_descr_list_target_id=All&field_clinical_prior_auth_requir_value=All&field_field_pdl_prior_auth_requi_value=All



TEXAS Health and Human Services

Vendor Drug Program

What can we help you find? Go

About Providers Formulary Resources

Home > Formulary > Formulary Search > Drug Details

Search Results: Formulary Drugs

Displaying 1 - 25 of 669 drugs found. Return to search page.
A drug with a termination date will appear on the search for 90 days following the termination date.

Brand Name/Generic Name/Package Size	NDC/Manufacturer	PDL Class	FFS Clinical Prior Auth Required	PDL Prior Auth Required	Programs
ABSORICA 10 MG CAPSULE isotretinoin 30 EA	10631011531 SUN PHARMACEUTI	ACNE AGENTS: ORAL	No	Yes	Medicaid CHIP CSHCN
ABSORICA 20 MG CAPSULE isotretinoin 30 EA	10631011631 SUN PHARMACEUTI	ACNE AGENTS: ORAL	No	Yes	Medicaid CHIP CSHCN
ABSORICA 30 MG CAPSULE isotretinoin 30 EA	10631011731 SUN PHARMACEUTI	ACNE AGENTS: ORAL	No	Yes	Medicaid CHIP CSHCN
ABSORICA 40 MG CAPSULE isotretinoin 30 EA	10631011831 SUN PHARMACEUTI	ACNE AGENTS: ORAL	No	Yes	Medicaid CHIP CSHCN

15. Defendant Sun has regular, physical presences of Defendant Sun employees in this District conducting Defendant Sun's business. Defendant Sun maintains a regular and established place of business at the Defendant Sun defined places and separate areas by the regular, physical presence of its employees.

16. Venue is proper in this District as to Defendant pursuant to at least 28 U.S.C. §§1391(c)(2), (3), and 1400(b).

17. Furthermore, venue is proper in this Judicial District pursuant to 28 U.S.C. §§1391(b), 1391(c) and 1400(b) because, among other things, Defendants are subject to personal jurisdiction in this Judicial District, regularly conducted business in this Judicial District, certain of the acts complained of herein occurred in this Judicial District, and that SPIL, SPM, and SPARC are not residents in the United States and may be sued in any judicial district.

BACKGROUND AND PATENTS-IN-SUIT

18. Nivagen is the sole and exclusive owners, by assignment, of U.S. Patent Nos.: 11,878,076 (the '076 patent) and 11,406,598 (the '598 patent) (collectively the "Asserted Patents") relating to phenobarbital injections and methods of manufacturing phenobarbital injections.

19. The Asserted Patents valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code. The '598 patent issued on 09 Aug. 2022. The '076 patent issued on 23 Jan. 2024.

20. The Asserted Patents includes numerous claims defining distinct inventions.

21. The priority date of the '598 patent is 20 Sept. 2019, and the priority date of the '076 patent is also 20 Sept. 2019. As of the priority date, the inventions as claimed were novel, non-obvious, unconventional, and non-routine.

22. Independent Claim 1 of the '598 patent claims: "1. 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."

23. The independent claims of the '076 patent are claims 1 and 7. Independent Claim 1 states: "1. 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." Independent Claim 7 states: "7. A 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, wherein the composition comprises no less than 98% phenobarbital sodium, and wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.1% phenylethylacetylurea (PEAU)."

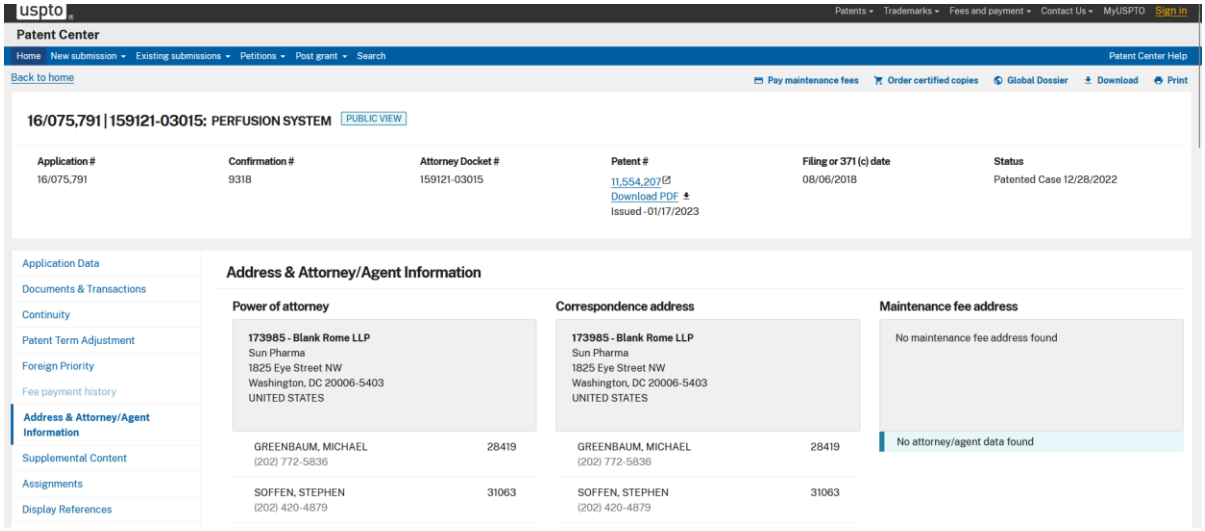
24. Claim 16 of the ‘076 patent also claims: “16. The pharmaceutical product of claim 1, wherein the product comprises the 100 mg dose in the single use dose vial.”

25. Claim 17 of the ‘076 patent also claims: “17. The pharmaceutical product of claim 7, wherein the product comprises the 100 mg dose in the single use dose vial.

26. The claims of the Asserted Patents were all properly issued and are valid and enforceable for the respective terms of their statutory life through expiration and are enforceable for purposes of seeking damages for past infringement even post-expiration.

27. During prosecution of the ‘598 patent (the ‘598 patent has a serial number of 17/025,881), on or about 31 Aug. 2021, an anonymous Third Party submitted (through an attorney at the Blank Rome LLP law firm) ten (10) prior art references to the Patent Office Examiner. The Patent Office acknowledged receipt of the Third Party Submission and notified Nivagen’s representative on 02 Sept. 2021. The identity of the actual Third Party (as opposed to the name of submitting lawyer/law firm) is not disclosed in the Submission. Upon information and belief, the underlying third party is one or more of the Defendants acting individually or jointly.

28. U.S. Patent No.: 11,554,207 (the ‘207 patent) is assigned to Sun Pharmaceutical Industries, Ltd. (SPIL).



29. The SPIL '207 patent has an underlying serial number of 16/075,791. On 14 July 2022, the exact same attorney filed remarks in the Sun Pharmaceutical Industries Ltd '791 application.

Dated: July 14, 2022

Respectfully submitted,

By /Jay P. Lessler/
Jay P. Lessler
Registration No.: 41,151
BLANK ROME LLP
1271 Avenue of the Americas
New York, NY 10020
(202) 420-2200
Attorney for Applicant

30. The USPTO registration number of the attorney in this '791 application response is the same registration number (and name) of the attorney who filed the anonymous Third Party Submission in the '598 patent/'881 application.

In view of the foregoing, it is respectfully requested that these documents be considered and made of record in the examination of the above-identified application.

Dated: August 31, 2021

Respectfully submitted,

By /Jay P. Lessler/
Jay P. Lessler
Registration No. 41,151
Blank Rome LLP

31. It is undisputed that the underlying party that caused the Third Party Submission in the '881 application (now Nivagen's 598 patent) is one or more of the Defendants acting individually or jointly.

32. In SPIL's '207 patent, the Power of Attorney is signed by the Assoc. VP of IP for Sun Pharmaceutical Industries, Ltd., not Sun Pharmaceuticals Industries, Inc.

Please mail all correspondence to

The address associated with customer number:

173985

Please direct telephone calls to: Jay P. Lessler at (212) 885-5176.

Please direct facsimiles to: Jay P. Lessler at (917) 332-3773.

Signature: _____ Date: 1/11/2021

Name: Craig Kuchii

Title: AVP, Intellectual Property/Authorized Signatory

Sun Pharmaceutical Industries Ltd.

33. This demonstrates that the Defendant entities are inextricably intertwined as it relates to Sezaby infringement.

34. On 23 Sept. 2021, the Patent Examiner issued a rejection of the then-pending claims of the '881 application relying on Parker 2017/01443719 and a FDA document on lyophilization of parenterals. Both Parker and the FDA document were submitted to the Patent Office in the Third Party Submission. The Patent Examiner understood the references cited in the Third Party Submission because the Examiner used two of them in the office action rejection of 23 Sept. 2021.

35. The Patent Office Examiner allowed the '881 application and it issued into the '598 patent.

36. Defendants individually or collectively submitted the Third Party Submission in the '881 application proceedings with the intent to stop the '881 application from

issuing into an issued patent.

37. The Defendants individually or collectively wanted to block the '881 patent application from issuing because the Defendants individually or collectively infringe one or more claims of the '881 patent.

38. Defendants individually or collectively know that products made outside the United States may nonetheless infringe an issued U.S. patent if the product is at least imported into the United States.

DEFENDANTS' INFRINGING PRODUCTS

39. Upon information and belief, Defendants make, sell, advertise, offers for sale, use, or otherwise provide infringing phenobarbital injections, including but not limited to the drug product "Sezaby".

40. Sezaby is a drug product approved by the US FDA under NDA # N215910, and it was FDA approved on 17 Nov. 2022. The Electronic Orange Book, as it is known, indicates that Sezaby contains the active ingredient phenobarbital sodium. The strength is 100 mg/vial. The NDA is owned by Sun Pharmaceutical Industries Inc.

41. Per FDA law and regulations, the Sezaby drug product also includes labeling information that explains the drug product and its use.

42. The Sezaby label states in the Highlights of Prescribing Information section that "SEZABY™ (phenobarbital sodium) for injection, for intravenous use, CIV"

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SEZABY safely and effectively. See full prescribing information for SEZABY.

SEZABY™ (phenobarbital sodium) for injection, for intravenous use, CIV
Initial U.S. Approval: 2022

43. The Sezaby label also states in Section 3 Dosage Forms and Strengths: "For injection: 100 mg of phenobarbital sodium as a white to off-white lyophilized powder in a single dose vial for reconstitution."

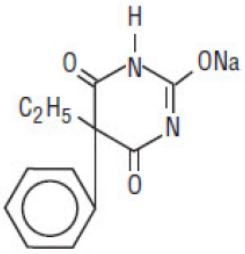
3 DOSAGE FORMS AND STRENGTHS

For injection: 100 mg of phenobarbital sodium as a white to off-white lyophilized powder in a single-dose vial for reconstitution.

44. In Section 11 Description, the Sezaby label also states: "SEZABY (phenobarbital sodium) for injection, for intravenous use, is supplied as sterile white to off white lyophilized powder in a 10 mL tubular glass vial. Each single-dose vial contains 100 mg of phenobarbital sodium (equivalent to 91.35 mg of phenobarbital). The pH range is 9.20-10.00. SEZABY does not contain benzyl alcohol or propylene glycol."

11 DESCRIPTION

Phenobarbital is a barbiturate. Chemically, phenobarbital sodium is 2,4,6(1H,3H,5H)-Pyrimidinetrione, 5-ethyl-5-phenyl-, monosodium salt and has the following structural formula:



$C_{12}H_{11}N_2NaO_3$ MW 254.22

The sodium salt of phenobarbital occurs as a white, slightly bitter powder, crystalline granules or flaky crystals; it is very soluble in water, soluble in alcohol and practically insoluble in ether or chloroform.

SEZABY (phenobarbital sodium) for injection, for intravenous use, is supplied as sterile white to off white lyophilized powder in a 10 mL tubular glass vial. Each single-dose vial contains 100 mg of phenobarbital sodium (equivalent to 91.35 mg of phenobarbital). The pH range is 9.20-10.00. SEZABY does not contain benzyl alcohol or propylene glycol.

45. The Sezaby label in Section 16.1 indicates that Sezaby is supplied as a sterile 100 mg phenobarbital dose in a single unit vial.

16.1 How Supplied

SEZABY (phenobarbital sodium) for injection is supplied as a sterile white to off-white, lyophilized powder in single-dose clear glass vials containing 100 mg of phenobarbital sodium.

Carton Contents	NDC
One 100 mg single-dose vial	NDC 62756-301-01

The vial stopper is not made with natural rubber latex.

46. The Sezaby label also indicates the relevant relationship of the Defendants, which further demonstrates that at least Defendants SPM, Sun, and SPARC are engaged in a mutual enterprise to manufacture, export from India for import into the United States, and for commercial sale of the Sezaby product:

Manufactured by: Sun Pharmaceutical Medicare Ltd., Baska Ujeti Road, Ujeti Halol -389350, Gujarat, India

rence ID: 5079438

Distributed by: Sun PharmaceuticalIndustries, Inc., Cranbury, NJ 08512
SEZABY is a trademark of Sun Pharma Advanced Research Company Ltd., used under license

47. As shown above, Defendants' Sezaby product includes 100 mg of phenobarbital sodium in a single use vial, as a sterile and lyophilized drug product. Upon information and belief, the Sezaby product will contain no less than 98% phenobarbital sodium. Upon information and belief, the Sezaby product will upon reconstitution also contain no more than 0.1% phenylethylacetylurea (PEAU).

48. Upon information and belief, the Defendants individually or jointly will manufacture the Sezaby product that will infringe the claims of the '598 and '076 patents. Upon information and belief, the Defendants individually or jointly will

import or cause the importation of the Sezaby product into the United States that will infringe the claims of the '598 and '076 patents.

49. Defendants individually or jointly have had notice of the '598 patent and the '076 patent.

50. SPARC is pursuing its own U.S. patent application under Serial No.: 17/715,491 to generally phenobarbital injections, which is now SPARC's US Patent No.: 11,857,683 (issued 02 Jan. 2024).

51. In the file history of SPARC's '491 application, the Patent Office Examiner on 15 Sept. 2022 rejected the then-pending claims of the SPARC '491 application in view of the Chodavarapu 2021/0085608 publication. The Chodavarapu '608 publication is based on serial no.: 17/025,881 application, which is now Nivagen's '598 patent. On 17 Nov. 2022, SPARC's patent attorney representative emailed Examiner Vu suggesting an agenda for an Applicant-Examiner interview wherein the Chodavarapu reference was to be discussed. The interview took place on 18 Nov. 2022. On or about 14 Dec. 2022, SPARC's attorney filed a response to the outstanding rejection by, among other things, reiterating the contents of the previous interview and also providing a discussion about the Chodavarapu '608 publication. On 30 Jan. 2023, the Examiner issued a Final Office Action that again rejected SPARC's then pending claims in view of the Chodavarapu '608 publication. On or about 01 May 2023, SPARC's attorney submitted among other things a portion of a response derived from the Chodavarapu '881 application, namely a response filed by Nivagen's counsel dated 13 May 2021. The Nivagen '881 document was appended as Exhibit 4 to a SPARC inventor declaration.

52. SPARC's repeated referencing of the Chodavarapu '608 publication, which is now Nivagen's '598 patent, in its own '491 application demonstrates that at least SPARC is on notice of the '598 patent. Further, the face of SPARC's now Patent No.: 11,857,683 specifically references the Chodavarapu '608 publication:

(21) Appl. No.: **17/715,491**

(22) Filed: **Apr. 7, 2022**

(65) **Prior Publication Data**

US 2023/0031957 A1 Feb. 2, 2023

Related U.S. Application Data

(60) Provisional application No. 63/319,918, filed on Mar. 15, 2022.

(30) **Foreign Application Priority Data**

Jul. 7, 2021 (IN) 202121030559

(51) **Int. Cl.**

A61K 9/19	(2006.01)
A61P 25/08	(2006.01)
A61K 9/08	(2006.01)
A61K 31/515	(2006.01)
A61K 47/10	(2017.01)

(52) **U.S. Cl.**

CPC ***A61K 9/19*** (2013.01); ***A61K 9/08*** (2013.01); ***A61K 31/515*** (2013.01); ***A61K 47/10*** (2013.01); ***A61P 25/08*** (2018.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

9,901,576	B2	2/2018	Parker et al.	
2021/0085608	A1 *	3/2021	Chodavarapu	A61K 9/0019

FOREIGN PATENT DOCUMENTS

AU	495261	B2	3/1977

53. On or about 11 Apr. 2022, SPARC's representative patent attorney filed a Power of Attorney that permits that patent attorney to represent SPARC in the SPARC '491 application process. The Power of Attorney was signed by Sun Pharma's US-based

Associate Vice President of Intellectual Property. This Associate VP of IP is employed by Sun. Accordingly Sun is also on notice of the issuance of the '598 patent.

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

SUN PHARMA ADVANCED RESEARCH COMPANY LTD.

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	4/11/2022
Name	Craig Kuchii		
Title	Associate VP, Intellectual Property/Authorized Signatory		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

54. Upon information and belief, a jointly issued press release dated 09 Nov. 2022 by Sun and SPARC states that SPARC developed the Sezaby drug product and owns the intellectual property rights to the Sezaby product. The press release also states that SPARC initially submitted the NDA for Sezaby. It also states that Sun will pay SPARC an upfront milestone fee of $10 million USD and that SPARC will continue to receive certain milestone payments tied to the FDA approval (which is now approved) and sales of Sezaby. This further demonstrates that Defendant Sun and Defendant SPARC have joint mutual interest in the future sales of Sezaby in the United States, including in this District.

55. SPARC also owns the SPARC '491 application. SPARC licenses the Sezaby rights to either Sun or SPIL, of which now Sun owns the Sezaby approved NDA. Sun markets the Sezaby product throughout the United States, including in the State of Texas and in this District. SPM manufacturers the commercial product on behalf of SPIL or Sun. One or more of the Defendants also had notice of the '598 patent

because the Third Party Submission was done on behalf of one or more of the Defendants. Because the '076 patent is related to the '598 patent, one or more of the Defendants are also on notice of the '076 patent.

56. The Defendants acted individually or jointly to meddle with Nivagen's patent application process by among other things filing Third Party Submissions; by having the Sun Assoc. VP of IP sign patent application powers of attorney on behalf of SPARC, and that non-US entities assist in the infringement of the patents by manufacturing, packaging, and exporting Sezaby into the United States, and Sun imports and commits acts of infringement by at least importing and selling Sezaby in the United States.

57. Nivagen reserves the right to assert additional claims and to assert infringement under the doctrine of equivalents in light of information learned during discovery or in view of this Court's claim construction order.

58. SPARC, individually or collectively with the other Defendants, filed a Citizen Petition to the US FDA on or about 24 July 2023. The FDA assigned the Citizen Petition a docket number of FDA-2023-P-3078. The Citizen Petition requests that FDA take enforcement action to request that all marketers of unapproved phenobarbital injectable product be pulled from the market (i.e., a product recall) and prohibited from selling phenobarbital injectable products.

59. If FDA takes such enforcement action by removing all other phenobarbital injectable products from the market with only Sezaby remaining in the market, then Defendants infringement of the Nivagen patents will continue and Defendants will be unjustly rewarded because Sezaby will be the only product on the market for

patients. Upon information and belief, Sezaby's price will also increase because of the monopolistic position Sezaby would be in.

COUNT 1 – All Defendants
Infringement of U.S. Patent No. 11,406,598

60. Nivagen incorporates the above paragraphs by reference.

61. Defendants, acting individually or jointly, without authority, made, used, sold, offered to sell, and/or imported into the United States the Sezaby product.

62. Defendants thus have infringed at least one claim of the '598 Patent literally and/or under the doctrine of equivalents.

63. Defendants have also actively induced the infringement of at least one claim of the '598 Patent, in violation of 35 U.S.C. §271(b), by, among other things, actively and knowingly aiding and abetting infringement of others through activities such as inducing another party to manufacturer the Sezaby product, marketing Sezaby to health care practitioners, by advertising Sezaby and its availability, creating and/or distributing marketing and therapeutic materials, brochures, manuals, instructional documents, and/or similar materials with instructions on how to purchase Sezaby, apply for reimbursement of it, and how to use it, with the specific intent to induce others to directly make, use, offer for sale, sell, and/or import into the United States products that fall within the scope of the '598 patent, without license or authority from Nivagen. On information and belief, Defendants know that the induced acts constitute infringement of the '598 Patent.

64. Defendants individually, collectively, or through others or intermediaries, have contributorily infringed in violation of 35 U.S.C. §271(c), at least one claim of the '598 Patent by making, using, offering for sale, selling, and/or importing, material parts

of the inventions claimed in the '598 Patent, which are not a staple article or commodity of commerce suitable for substantial non-infringing use, and knowing the accused parts to be especially made or especially adapted for use in an infringement of the '598 claims.

65. Defendants have been on actual notice of the '598 Patent at least as early as its issuance on 09 Aug. 2022 and as early as 31 Aug. 2021 when the Defendants (acting individually or jointly) filed (or caused the filing of) the Third Party Submission in the '598 patent proceedings. Defendants also have notice of the '598 patent by virtue of it (or its underlying application) being cited in SPARC's '491 application. Defendants direct and indirect infringement of the '598 Patent have thus been committed with knowledge of the '598 Patent, making Defendants liable for direct, indirect, and willful infringement.

66. Defendants attempted to block the issuance of the '598 patent by filing or causing to be filed the Third Party Submission. If Defendants were not infringing the '598 patent, then there would not be any reason to block the issuance of the '598 patent. Defendants are infringing the '598 patent.

67. Nivagen has been damaged because of the infringing conduct by Defendants alleged above. Thus, Defendants are liable to Nivagen in an amount that adequately compensates it for such infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. §284, and enhanced damages for willful infringement.

68. Nivagen has satisfied all statutory obligations required to collect pre-filing damages

for the full period allowed by law.

COUNT 2 – All Defendants
Infringement of U.S. Patent No. 11,878,076

69. Nivagen incorporates the above paragraphs by reference.

70. Defendants without authority, made, used, sold, offered to sell, and/or imported into the United States the Sezaby product.

71. Defendants thus have infringed at least one claim of the '076 patent literally and/or under the doctrine of equivalents.

72. Defendants have also actively induced the infringement of at least one claim of the '076 patent, in violation of 35 U.S.C. §271(b), by, among other things, actively and knowingly aiding and abetting infringement of others through activities such as inducing another party to manufacturer the Sezaby product, marketing Sezaby to health care practitioners, by advertising Sezaby and its availability, creating and/or distributing marketing and therapeutic materials, brochures, manuals, instructional documents, and/or similar materials with instructions on how to purchase Sezaby, apply for reimbursement of it, and how to use it, with the specific intent to induce others to directly make, use, offer for sale, sell, and/or import into the United States products that fall within the scope of the '076 Patent, without license or authority from Plaintiff. On information and belief, Defendants know that the induced acts constitute infringement of the '076 Patent.

73. Defendants individually, collectively, or through others or intermediaries, have contributorily infringed, and/or is contributorily infringing, in violation of 35 U.S.C. §271(c), at least one claim of the '076 Patent by making, using, offering for sale, selling, and/or importing, material parts of the inventions claimed in the '076

Patent, which are not a staple article or commodity of commerce suitable for substantial non-infringing use, and knowing the accused parts to be especially made or especially adapted for use in an infringement of the '076 claims.

74. Defendants have been on actual notice of the '076 Patent at least as early as its issue date and as early as 31 Aug. 2021 when the Defendants (acting individually or jointly) filed (or caused the filing of) the Third Party Submission in the '598 patent proceedings, and further that Defendants are charged with the knowledge of the subsequent events including the prosecution history of the '076 patent and its issuance. Defendants also have notice of the '076 patent by virtue of it (or its underlying application) being cited in SPARC's '491 application. Defendants' direct and indirect infringement of the '076 Patent has thus been committed with knowledge of the '076 Patent, making Defendants jointly and severally liable for direct, indirect, and willful infringement.

75. Nivagen has been damaged because of the infringing conduct by Defendants alleged above. Thus, Defendants are liable to Nivagen in an amount that adequately compensates it for such infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. §284, and enhanced damages for willful infringement.

76. Nivagen has all statutory obligations required to collect pre-filing damages for the full period allowed by law.

COUNT 3 – Sun Pharmaceuticals Industries Inc.
Infringement of U.S. Patent No. 11,406,598

77. Nivagen incorporates the above paragraphs by reference.

78. Defendant Sun, acting individually or jointly with the other Defendants, without authority, made, used, sold, offered to sell, and/or imported into the United States the Sezaby product.

79. Defendant Sun imports (or causes to be imported) into the United States the Sezaby product knowing that the Sezaby product is made outside of the United States in a manner that infringes one or more claims of the '598 patent.

80. Defendant Sun owns the NDA for Sezaby and that NDA identifies the manufacturer of the Sezaby product and the manner in which it is made.

81. Defendant Sun thus has infringed at least one claim of the '598 Patent literally and/or under the doctrine of equivalents.

82. Defendant Sun has also actively induced the infringement of at least one claim of the '598 Patent, in violation of 35 U.S.C. §271(b), by, among other things, actively and knowingly aiding and abetting infringement of others through activities such as inducing another party to manufacturer the Sezaby product, marketing Sezaby to health care practitioners, by advertising Sezaby and its availability, creating and/or distributing marketing and therapeutic materials, brochures, manuals, instructional documents, and/or similar materials with instructions on how to purchase Sezaby, apply for reimbursement of it, and how to use it, with the specific intent to induce others to directly make, use, offer for sale, sell, and/or import into the United States products that fall within the scope of the '598 Patent, without license or authority from Nivagen. On information and belief, Defendant Sun knows that the induced acts constitute infringement of the '598 Patent.

83. Defendant Sun individually, collectively, or through others or intermediaries, have

contributorily infringed in violation of 35 U.S.C. §271(c), at least one claim of the '598 Patent by making, using, offering for sale, selling, and/or importing, material parts of the inventions claimed in the '598 Patent, which are not a staple article or commodity of commerce suitable for substantial non-infringing use, and knowing the accused parts to be especially made or especially adapted for use in an infringement of the '598 claims.

84. Defendant Sun has been on actual notice of the '598 Patent at least as early as its issuance on 09 Aug. 2022 and as early as 31 Aug. 2021 when the Defendant Sun (acting individually or jointly) filed (or caused the filing of) the Third Party Submission in the '598 patent proceedings. Defendant Sun also has notice of the '598 patent by virtue of it (or its underlying application) being cited in SPARC's '491 application. Defendant Sun's direct and indirect infringement of the '598 Patent have thus been committed with knowledge of the '598 Patent, making Defendant Sun jointly or severally liable for direct, indirect, and willful infringement.

85. Defendant Sun attempted to block the issuance of the '598 patent by filing or causing to be filed the Third Party Submission. If Defendant Sun was not infringing the '598 patent, then there would not be any reason to block the issuance of the '598 patent. Defendant Sun is infringing the '598 patent.

86. Nivagen has been damaged because of the infringing conduct by Defendant Sun alleged above. Thus, Defendant Sun is liable to Nivagen in an amount that adequately compensates it for such infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under

35 U.S.C. §284, and enhanced damages for willful infringement.

87. Nivagen has all statutory obligations required to collect pre-filing damages for the full period allowed by law.

COUNT 4 – Sun Pharmaceutical Industries Inc.
Infringement of U.S. Patent No. 11,878,076

88. Nivagen incorporates the above paragraphs by reference.

89. Defendant Sun without authority, made, used, sold, offered to sell, and/or imported into the United States the Sezaby product.

90. Defendant Sun has infringed at least one claim of the '076 patent literally and/or under the doctrine of equivalents.

91. Defendant Sun has also actively induced the infringement of at least one claim of the '076 patent, in violation of 35 U.S.C. §271(b), by, among other things, actively and knowingly aiding and abetting infringement of others through activities such as inducing another party to manufacturer the Sezaby product, marketing Sezaby to health care practitioners, by advertising Sezaby and its availability, creating and/or distributing marketing and therapeutic materials, brochures, manuals, instructional documents, and/or similar materials with instructions on how to purchase Sezaby, apply for reimbursement of it, and how to use it, with the specific intent to induce others to directly make, use, offer for sale, sell, and/or import into the United States products that fall within the scope of the '076 patent, without license or authority from Plaintiff. On information and belief, Defendant Sun knows that the induced acts constitute infringement of the '076 Patent.

92. Defendant Sun individually, collectively, or through others or intermediaries, have contributorily infringed, and/or is contributorily infringing, in violation of 35 U.S.C.

§271(c), at least one claim of the '076 Patent by making, using, offering for sale, selling, and/or importing, material parts of the inventions claimed in the '076 Patent, which are not a staple article or commodity of commerce suitable for substantial non-infringing use, and knowing the accused parts to be especially made or especially adapted for use in an infringement of the '076 claims.

93. Defendant Sun has been on actual notice of the '076 Patent at least as early as its issue date and as early as 31 Aug. 2021 when the Defendant Sun (acting individually or jointly) filed (or caused the filing of) the Third Party Submission in the ''598 patent proceedings, and further that Defendants are charged with the knowledge of the subsequent events including the prosecution history of the '076 patent and its issuance. Defendant Sun also has notice of the '076 patent by virtue of it (or its underlying application) being cited in SPARC's '491 application. Defendant Sun's direct and indirect infringement of the '076 Patent has thus been committed with knowledge of the '076 Patent, making Defendant jointly or severally liable for direct, indirect, and willful infringement.

94. Nivagen has been damaged because of the infringing conduct by Defendant Sun alleged above. Thus, Defendant Sun is liable to Nivagen in an amount that adequately compensates it for such infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. §284, and enhanced damages for willful infringement.

95. Nivagen and/or its predecessors-in-interest have satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law.

PRAYER FOR RELIEF

WHEREFORE, Nivagen respectfully requests the Court enter judgment against Defendants as follows:

1. Declaring that Defendants have individually or collectively infringed the Asserted Patents;
2. Awarding Nivagen its damages suffered because of Defendants infringement of the Asserted Patents;
3. Awarding Nivagen its costs, reasonable attorneys' fees, expenses, and interest;
4. An award to Nivagen of enhanced damages, up to and including trebling of Nivagen's damages pursuant to 35 U.S.C. §284 for Defendants' willful infringement of the Asserted Patents;
5. Awarding any injunctive relief, including removal of Sezaby from the market by enjoining its importation, sale, and distribution in the United States; and
6. Granting Nivagen such further relief as the Court finds appropriate.

JURY DEMAND

Plaintiff demands trial by jury, under Fed. R. Civ. P. 38.

Dated: January 23, 2024

Respectfully Submitted

/s/ Melissa R. Smith

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