

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Petitioner

v.

NIVAGEN PHARMACEUTICALS, INC.,
Patent Owner

Case IPR2025-00893
U.S. Patent No. 11,878,076

Declaration of Justin T. Oakland

I, Justin T. Oakland, hereby declare as follows:

1. I am an attorney at Carlson, Caspers, Vandenburg & Lindquist P.A., counsel for Sun Pharmaceutical Industries, Inc. (“Sun”). I have personal knowledge of the following facts.

2. Ex-1055 is a true and correct copy of a document that I obtained from the U.S. Food & Drug Administration (“FDA”) via this url:

<https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=703819>. I downloaded Ex-1055 by searching the FDA’s Orphan Drug Designations and Approvals database by product name for “phenobarbital sodium.”

3. Ex-1056 is a true and correct copy of a document that I obtained from the FDA via this url: <https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=725819>. I downloaded Ex-1056 by searching the FDA’s Orphan Drug Designations and Approvals database by product name for “phenobarbital sodium.”

4. Ex-1058 is a true and correct copy of a press release dated January 25, 2023, available at <https://sunpharma.com/wp-content/uploads/2023/01/Press-Release-Sun-Pharma-launch-of-SEZABY%E2%84%A2-in-the-US.pdf>.

5. Ex-1059 is a true and correct copy of Patent Owner Nivagen’s supplemental responses and objections to Petitioner Sun’s second set of

interrogatories that Patent Owner Nivagen served on May 16, 2025, in *Nivagen, Inc. v. Sun Pharmaceutical Industries, Inc.*, No. 2:24-cv-36-RWS-RSP (E.D. Tex.).

6. Ex-1060 is a true and correct copy of an article published by IPLaw360 and dated March 7, 2022, that I obtained via this link:

<https://www.law360.com/articles/1470979>.

7. Ex-1061 is a true and correct copy of a letter from the FDA to Petitioner Sun that I obtained from the Drugs@FDA: FDA-Approved Drugs database at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215910Orig1s000ltr.pdf. I downloaded Ex-1061 via this url by searching for “Sezaby” in the Drugs@FDA database and navigating to “Original Approvals or Tentative Approvals.”

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 25, 2025

s/Justin T. Oakland
Justin T. Oakland