

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NEURELIS, INC.,

Plaintiff,

v.

PADAGIS LLC, PADAGIS US LLC, AND
PADAGIS ISRAEL PHARMACEUTICALS LTD.,
et al.,

Defendants.

C.A. No. 24-562 (MN)

(CONSOLIDATED)

DEFENDANTS' PROPOSED CLAIM TERMS AND PHRASES FOR CONSTRUCTION

Pursuant to the April 23, 2026 Second Consolidation Order and Modified Case Schedule (D.I. 132), defendants Padagis LLC, Padagis US LLC, and Padagis Israel Pharmaceuticals Ltd., defendants Lupin Inc., Lupin Pharmaceuticals, Inc., and Lupin Limited, and defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. (collectively, “Defendants”) hereby provide to Neurelis, Inc. (“Plaintiff” or “Neurelis”) the following initial list of claim terms and phrases in need of construction as found in U.S. Patent Nos. 8,895,546 (“the ’546 Patent”); 11,241,414 (“the ’414 Patent”); 11,793,786 (“the ’786 patent”), 12,268,664 (“the ’664 patent”), 12,324,852 (“the ’852 patent”), 12,337,061 (“the ’061 patent”), and 12,521,400 (“the ’400 patent”), collectively the “Asserted Patents.”

I. Introductory Statement and Reservations

This preliminary list of claim terms and phrases and proposed constructions is based upon Defendants’ present understanding of Plaintiff’s infringement contentions, which are broad, vague, conclusory, and inadequate. Defendants reserve all rights to amend or supplement this list in view of Plaintiff’s terms and proposed constructions, in view of Plaintiff supplementing,

amending, or otherwise revising its contentions and Interrogatory Responses to comply with the Federal and Local Rules, in view of positions taken in this case by Plaintiff or its experts, or in view of subsequent disputes that become apparent at a later stage of the case. Defendants expressly reserve the right to add, remove, or revise the proposed terms for construction, or revise or supplement proposed constructions, or supplement Defendants' future identification of intrinsic evidence in light of further discovery, analysis, other disclosures, or developments in the case. Defendants further reserve the right to refine terms or phrases for construction and future cited intrinsic evidence in an effort to resolve any dispute that might arise as to the proper disposition of the listed terms or phrases. Defendants reserve the right to proffer non-infringement and invalidity bases which are alternative to any bases for non-infringement or invalidity based on proposed claim constructions presented in this document.

With respect to the claim terms or phrases that Defendants contend are indefinite under 35 U.S.C. § 112, Defendants submit that they would be more appropriately addressed at a later stage in the case when the parties and the Court have the benefit of full fact and expert discovery. Accordingly, Defendants propose that the parties agree to defer indefiniteness issues so as not to unnecessarily burden the Court, as well as the parties' witnesses during the claim construction phase. Should Plaintiff not agree to such a deferral, Defendants reserve all rights to present any and all arguments and positions with respect to the indefinite terms or phrases set forth below.

II. Claim Terms and Phrases to Construe as Present in Applicable Asserted Patents

Claim Term or Phrase	Claims Reciting Term or Phrase	Proposed Construction/Indefinite
"vitamin E"	'546 Patent, claim 17 '414 Patent, claim 10	"any of the natural or synthetic tocopherols, tocotrienols, any isomers thereof, any esters thereof, any analogs or derivatives"

Claim Term or Phrase	Claims Reciting Term or Phrase	Proposed Construction/Indefinite
	'786 Patent, claims 10, 26-27 '852 Patent, claims 1, 6, 10, 14 '061 Patent, claims 1, 5, 21, 33, 43, 53	thereof, or any combinations thereof"
"treating bouts of intermittent and stereotypic episodes of increased seizure activity in an epilepsy patient that is distinguishable from other seizures suffered by the patient"/ "treating the bouts of intermittent and stereotypic episodes of increased seizure activity in the patient"	'852 Patent, claims 1, 6, 10, 14 '061 Patent, claims 1, 5, 21, 33, 43, 53	Indefinite.
"bioavailability of an equivalent dose of diazepam administered intravenously"	'852 Patent, claims 1, 2, 6, 7, 10, 11, 14, 15, 18, 19 '061 Patent, claims 1, 5, 21, 33, 43, 53	Indefinite.
"stable"	'852 Patent, claims 6, 14 '061 Patent, claims 1, 2, 5, 6, 21, 22, 33, 34, 43, 44, 53, 54	Indefinite.
"treatment selected from the group consisting of a reduction in the severity of the seizure, a reduction in the probability that the patient will experience a repeat seizure, an increase in the interval between a current seizure and a next seizure in the patient, a reduction in the frequency of seizure in the patient and combinations thereof,"	'852 Patent, claims 1, 6, 10, 14 '061 Patent, claims 1, 5, 21, 33, 43, 53	Indefinite.
"safe and effective"	'852 Patent, claims 1, 6, 10, 14	Indefinite.

Claim Term or Phrase	Claims Reciting Term or Phrase	Proposed Construction/Indefinite
	'061 Patent, claims 1, 5, 21, 33, 43, 53	
"sufficient quantity of ethanol"	'852 Patent, claims 1, 6, 10, 14 '061 Patent, claims 1, 5, 21, 33, 43, 53	Indefinite.

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OF COUNSEL:

POLSINELLI PC

Mark T. Deming
POLSINELLI PC
150 N. Riverside Plaza, Suite 3000
Chicago, IL 60606
(312) 819-1900
mdeming@polsinelli.com

/s/ Stephen J. Kraftschik
Stephen J. Kraftschik (#5623)
222 Delaware Avenue, Suite 1101
Wilmington, DE 19801
(302) 252-0920
skraftschik@polsinelli.com

Dominique E. Smith
POLSINELLI LLP
2049 Century Park East, Suite 2900
Los Angeles, CA 90067
(310) 229-1390
dominique.smith@polsinelli.com

Corey M. Casey
POLSINELLI LLP
900 W. 48th Place, Suite 900
Kansas City, MO 64112
ccasey@polsinelli.com

Chad A. Landmon
POLSINELLI LLP
1401 Eye Street, N.W., Suite 800
Washington, D.C. 20005
clandmon@polsinelli.com

*Attorneys for Defendants Padagis LLC,
Padagis US LLC and Padagis Israel
Pharmaceuticals Ltd.*

OF COUNSEL:

Deepro R. Mukerjee
Lance Soderstrom
KATTEN MUCHIN ROSENMAN LLP
50 Rockefeller Plaza
New York, NY 10020-1605
deepro.mukerjee@katten.com
lance.soderstrom@katten.com

Jitendra Malik Ph.D.
KATTEN MUCHIN ROSENMAN LLP
550 S. Tryon Street, Suite 2900
Charlotte, NC 28202-4213
(704) 444-2000
jitty.malik@katten.com

Matthew M. Holub
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902-5200
matthew.holub@katten.com

OF COUNSEL:

Scott J. Bornstein
Richard C. Pettus
Giancarlo L. Scaccia
Emma Cohen
GREENBERG TRAUIG, LLP
One Vanderbilt Ave.
New York, NY 10017
(212) 801-9200
scott.bornstein@gtlaw.com
pettusr@gtlaw.com
scacciag@gtlaw.com

Jonathan R. Wise
GREENBERG TRAUIG, LLP
1717 Arch Street, Suite 400
Philadelphia, PA 19103
(215) 988-7850
wisej@gtlaw.com

MORRIS JAMES LLP

/s/ Kenneth L. Dorsney
Kenneth L. Dorsney (#3726)
Cortlan S. Hitch (#6720)
3205 Avenue North Boulevard, Suite 100
Wilmington, DE 19803
(302) 888-6800
kdorsney@morrisjames.com
chitch@morrisjames.com

*Attorneys for Defendants
Lupin Inc., Lupin Ltd., and
Lupin Pharmaceuticals, Inc.*

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Anne Shea Gaza
Anne Shea Gaza (No. 4093)
Samantha G. Wilson (No. 5816)
Daniel G. Mackrides (No. 7230)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
swilson@ycst.com
dmackrides@ycst.com

*Attorneys for Defendants
Amneal Pharmaceuticals, Inc. and
Amneal Pharmaceuticals LLC*

