

**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.,

Defendants.

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

(LEAD CASE)

NEURELIS, INC.,

Plaintiff,

v.

PADAGIS LLC, PADAGIS US LLC, AND
PADAGIS ISRAEL PHARMACEUTICALS LTD.,
LUPIN INC., LUPIN LTD., AND LUPIN
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 25-821 (MN)

NEURELIS, INC.,

Plaintiff,

v.

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

Defendants.

C.A. No. 25-1228 (MN)

**DEFENDANTS' PADAGIS LLC, PADAGIS US LLC, AND PADAGIS ISRAEL
PHARMACEUTICALS LTD. STIPULATION REGARDING CLAIM CONSTRUCTION**

Defendants Padagis LLC, Padagis US LLC, and Padagis Israel Pharmaceuticals Ltd. (collectively, “Padagis”) submit the following stipulation to remove certain claim construction positions related to U.S. Patent Nos. 8,895,546 (“the ’546 patent”), 11,241,414 (“the ’414 patent”), and 11,793,786 (“the ’786 patent”) (collectively, “the Asserted Patents”).¹

WHEREAS, on May 8, 2024, Plaintiff Neurelis, Inc. (“Neurelis”) filed a complaint alleging that Padagis’s Abbreviated New Drug Application for diazepam nasal spray (10 mg/spray) infringes the Asserted Patents. *See* C.A. No. 24-562 at D.I. 1.

WHEREAS, on January 17, 2025, Padagis filed petitions requesting *inter partes* review of the Asserted Patents with the Patent Trial and Appeal Board. *See* IPR2025-00464 at Paper 2; IPR2025-00465 at Paper 2; IPR2025-00466 at Paper 2.

WHEREAS, on August 15, 2025, the parties filed a joint claim construction brief in this Court disputing the meaning of the following claim term from all Asserted Patents:

Term	Neurelis’s Position	Padagis’s Construction
A pharmaceutical solution for nasal administration consisting of	No construction necessary; the scope of “consisting of” is established by law.	“a pharmaceutical solution for nasal administration containing only those elements set forth in the claim and excluding anything else, particularly excluding water and oil” Otherwise indefinite.

See C.A. No. 24-562, D.I. 83 at 20.

WHEREAS, on September 8, 2025, the Court issued an order staying the case and canceling the claim construction hearing so that the parties could negotiate and submit an amended

¹ Padagis submits this stipulation on its own behalf only and not on the behalf of any other parties in these or any related proceedings.

scheduling order to consolidate and coordinate additional related cases filed by Neurelis. *See* C.A. No. 24-562 at D.I. 85.

WHEREAS, on September 17, 2025, the PTAB granted institution of Padagis’s petitions for *inter partes* review of the Asserted Patents. *See* IPR2025-00464 at Paper 13; IPR2025-00465 at Paper 13; IPR2025-00466 at Paper 13. In its institution decisions, the PTAB noted that Padagis “suggests the transitional phrase ‘consisting of’ means the claimed pharmaceutical solutions include only those components recited in the claims . . . [s]uch interpretation tracks the conventional meaning of the ‘consisting of’ transitional phrase in claim drafting.” *See* IPR2025-00464 at Paper 13 at 7, n. 5; IPR2025-00465 at Paper 13 at 9, n. 7; IPR2025-00466 at Paper 13 at 10, n. 9.

WHEREAS, after Padagis’s petitions for *inter partes* review were instituted, the Director of the United States Patent and Trademark Office issued several precedential and informative decisions explaining that Petitioners in *inter partes* review proceedings should generally propose the same constructions of claim terms in both the IPR petitions and any parallel district court proceedings, or otherwise explain why it has proposed different claim constructions in the parallel proceedings.

WHEREAS, in view of the USPTO Director’s recent guidance, Padagis wishes to remove any doubt as to the consistency of its claim construction positions, and Padagis also wishes to streamline the disputed issues in this proceeding;

WHEREAS, on November 13, 2025, the Court issued a Scheduling Order consolidating C.A. No. 24-562; C.A. No. 25-821; C.A. No. 25-1228; and C.A. No. 25-1443.²

² The now consolidated cases involve three additional patents that Neurelis has asserted against Padagis (U.S. Patent Nos. 12,268,664; 12,324,852; and 12,337,061) and an additional defendant unrelated to Padagis: Lupin Inc., Lupin Pharmaceuticals, Inc., and Lupin Limited (collectively, “Lupin”).

WHEREAS, the Court's consolidated Scheduling Order preserves the prior claim construction briefing and dispute filed by Padagis and Neurelis. *See* C.A. No. 24-562, D.I. 111 at 10 ("On July 22, 2026 at 10:00 a.m., the Court will hear argument on claim construction (including matters raised in briefing submitted in C.A. 1:24-cv-00562 (D.I. 83)").

WHEREAS, the parties have not yet begun the claim construction process in the consolidated cases.

NOW THEREFORE, Padagis hereby stipulates and agrees as follows:

1. Padagis withdraws the claim construction positions it raised in the parties' joint claim construction brief with respect to the Asserted Patents, including both the proposed construction and indefiniteness position and the supporting Declaration of Maureen Donovan, Ph.D. *See* C.A. No. 24-562 at D.I. 83 and 84 (Exhibit 30).

2. Padagis agrees to adopt Neurelis's proposed construction with respect to the disputed claim term (i.e., "no construction necessary; the scope of 'consisting of' is established by law"), which is consistent with the construction proposed by Padagis in its petitions for *inter partes* review of the Asserted Patents. *See* C.A. No. 24-562, D.I. 83 at 20; *see also* IPR2025-00464 at Paper 13 at 7, n. 5; IPR2025-00465 at Paper 13 at 9, n. 7; IPR2025-00466 at Paper 13 at 10, n. 9.

3. Nothing in this stipulation affects Padagis's right to propose constructions of claim terms from U.S. Patent Nos. 12,268,664; 12,324,852; 12,337,061; or any other patent that Neurelis later asserts against Padagis.

OF COUNSEL:

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

POLSINELLI PC

/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

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

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

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

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