IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEURELIS, INC. *Plaintiffs*, v. PADAGIS LLC, PADAGIS US LLC, AND PADAGIS ISRAEL PHARMACEUTICALS LTD. *Defendants*.	)	C.A. No. 24-562-MN

SCHEDULING ORDER

This 28th day of August 2024, ~~the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and~~ the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(l) Initial Disclosures and E-Discovery Default Standard. The parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(l) by **September 6, 2024**. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI"), which is posted at http://www.ded.uscourts.gov (*see* Other Resources, Default Standard for Discovery) and is incorporated herein by reference (the "Default Standard for Discovery"). The parties shall make their initial disclosures pursuant to Paragraph 3 of the Default Standard for Discovery by **September 20, 2024**.

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2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **April 4, 2025**. Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 8(g) and 9.

3. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court by **September 5, 2024**. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 8(g) below.

Any proposed protective order must include the following paragraph:

> Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

4. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

5. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of all briefs and any other document filed in support of any briefs (*i.e.*, appendices, exhibits,

declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

6. ADR Process. This matter is **NOT** referred to a magistrate judge to explore the possibility of alternative dispute resolution.

7. Disclosures. Absent agreement among the parties, and approval of the Court:

(a) By **September 20, 2024**, Plaintiff shall comply with Paragraph 4.a. of the Default Standard for Discovery.

(b) By **October 21, 2024** Defendants shall comply with Paragraph 4.b. of the Default Standard for Discovery.

(c) By **November 21, 2024**, Plaintiff shall comply with Paragraph 4.c. of the Default Standard for Discovery.

(d) By **December 20, 2024**, Defendants shall comply with Paragraph 4.d. of the Default Standard for Discovery.

(e) By **January 16, 2025**, Defendants shall provide their initial response to Plaintiff's initial infringement contentions.

(f) By **February 12, 2025**, Plaintiff shall provide its initial response to Defendants' initial invalidity contentions.

(g) By **April 18, 2025**, Plaintiff shall provide final infringement contentions.

(h) By **April 18, 2025**, Defendants shall provide final invalidity contentions.

(i) By **May 2, 2025**, Defendants shall provide their final response to Plaintiff's final infringement contentions.

(j) By **May 2, 2025**, Plaintiff shall provide its final response to Defendants' final invalidity contentions.

8. Discovery. Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules shall be strictly observed.

(a) Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **April 18, 2025**.

(b) Document Production. Document production shall be substantially complete by **February 14, 2025**.

(c) Requests for Admission. A maximum of fifty (50) requests for admission are permitted for each side.

(d) Interrogatories.

i. A maximum of twenty-five (25) interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides (*i.e.*, the more detail a party provides, the more detail a party shall receive).

(e) Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of fifty (50) hours of taking testimony by deposition upon oral examination of fact witnesses, including depositions noticed pursuant to Fed. R. Civ. P. 30(b)(6) and depositions of third parties pursuant to a subpoena served under Fed. R. Civ. P. 45.

ii. Location of Depositions. The parties consent to conduct depositions in a mutually agreeable location based on witness proximity and ability to travel. Absent agreement

between the parties, any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

(f) Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before **August 29, 2025**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **September 19, 2025**. Reply expert reports from the party with the initial burden of proof are due on or before **October 10, 2025**. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Expert Report Supplementation. The parties agree they **will** permit expert declarations to be filed in connection with motions briefing (including case-dispositive motions).

iii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than **October 28, 2025**, unless otherwise ordered by the Court. Briefing in opposition to *Daubert* motions shall be filed on or before **November 12, 2025**, and

replies to such oppositions shall be filed on or before **November 19, 2025**. Except as otherwise provided, briefing on such motions will be presented pursuant to the Court's Local Rules.

iv. Expert Discovery Cut-Off. All expert discovery in this case shall be initiated so that it will be completed on or before **October 24, 2025**.

(g) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after a reasonable effort pursuant to Local Rule 7.1.1 that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Judicial Administrator to schedule an argument.

iii. On a date to be set by separate order, generally not less than four (4) days prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than three (3) days prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. The parties shall provide to the Court two (2) courtesy copies of its discovery letter and any other document filed in support of any letter (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

v. Should the Court find further briefing necessary upon conclusion of the conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the conference and will, in that event, cancel the conference.

9. Motions to Amend / Motions to Strike.

(a) Any motion to amend (including a motion for leave to amend) a pleading or any motion to strike any pleading or other document shall be made pursuant to the discovery dispute procedure set forth in Paragraph 8(g) above.

(b) Any such motion shall attach the proposed amended pleading as well as a "redline" comparison to the prior pleading or attach the document to be stricken.

10. Technology Tutorials. Although technology tutorials are not required by the Court, they are appreciated and, if any party chooses to file such a tutorial, it shall be submitted on or before the date that the Joint Claim Construction Brief is filed.

11. Claim Construction Issue Identification. On **March 28, 2025** the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be submitted two weeks prior to service of the opening claim construction brief. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. Intrinsic evidence (including copies of the patent(s) at issue) shall NOT be attached to the joint claim construction chart and, instead, the parties shall include a joint appendix with the joint claim construction brief, and the joint appendix shall include a copy

of the patent(s) at issue and portions of all relevant intrinsic evidence that would have otherwise been included with the joint claim construction chart, as well as any additional evidence cited in the parties' briefing.

12. Claim Construction Briefing. The Plaintiff shall serve, but not file, their opening brief, not to exceed 20 pages, on **May 23, 2025.** The Defendants shall serve, but not file, its answering brief, not to exceed 30 pages, on **June 13, 2025**. The Plaintiffs shall serve, but not file, their reply brief, not to exceed 20 pages, on **June 27, 2025**. The Defendant shall serve, but not file, its sur-reply brief, not to exceed 10 pages, on **July 11, 2025**. No later than **July 18, 2025**, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below. If the joint brief as submitted is more than 80 pages, the parties must certify that the page limits (or equivalent word counts) in the Scheduling Order have been complied with and provide a brief explanation (*e.g.*, formatting issues, listing of agreed-upon terms) as to why the brief is longer than 80 pages.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Plaintiffs' Opening Position
2. Defendant's Answering Position
3. Plaintiffs' Reply Position
4. Defendant's Sur-Reply Position

[TERM 2]

1. Plaintiffs' Opening Position

2. Defendant's Answering Position

3. Plaintiffs' Reply Position

4. Defendant's Sur-Reply Position

The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

13. Hearing on Claim Construction. Beginning at **10:00 a.m.** on **August 8, 2025**, the Court will hear argument on claim construction. The parties need not include any general summaries of the law relating to claim construction in their presentations to the Court. The parties shall notify the Court, by joint letter submission, no later than the date on which their joint claim construction brief is filed: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

14. Supplementation. Absent agreement among the parties, and approval of the Court, no later than **April 18, 2025** the parties must finally supplement, *inter alia*, the identification of all accused products and of all invalidity references.

15. Case Dispositive Motions. Absent agreement between the parties, and prior approval from the Court, the Court will not hear case dispositive motions in ANDA cases.

16. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

17. Motions in *Limine*. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each ***SIDE*** shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (l) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

18. Pretrial Conference. On **February 2, 2026**, the Court will hold a pretrial conference in Court with counsel beginning at **4:30 p.m**. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than seven (7) days before the pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) double-sided courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents and the paragraphs shall be numbered.

19. Trial. This matter is scheduled for a 5 day bench trial beginning at 9:30 a.m. on **February 9, 2026**, with the subsequent trial days beginning at 9:00 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

20. Post-Trial Briefing. The parties will address the post-trial briefing schedule and page limits in the proposed final pretrial order.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

Counsel Shall Provide a Chart of All Relevant Deadlines

Event	Deadline
FRCP 26 Initial Disclosures	**Friday, September 6, 2024**
Protective Order	**Thursday, September 5, 2024**
D. Del. Initial Paragraph 3 Disclosures	**Friday, September 20, 2024**
Plaintiff's ID of Accused Products and Production of Patent and File History	**Friday, September 20, 2024**
Defendants' Core Technical Production	**Monday, October 21, 2024**
Plaintiff's Preliminary Infringement Contentions	**Thursday, November 21, 2024**
Defendants' Preliminary Invalidity Contentions	**Friday, December 20, 2024**
Defendants' Response to Preliminary Infringement Contentions	**Thursday, January 16, 2025**
Plaintiff's Response to Preliminary Invalidity Contentions	**Wednesday, February 12, 2025**
Substantial Completion of Document Production	**Friday, February 14, 2025**
Exchange of Claim Terms and Constructions	**Friday, March 28, 2025**
Deadline to Move to Join Parties and/or Amend Pleadings	**Friday, April 4, 2025**
Defendants' Final Invalidity Contentions	**Friday, April 18, 2025**
Plaintiff's Final Infringement Contentions	**Friday, April 18, 2025**
Supplementation of Accused Products	**Friday, April 18, 2025**
Supplementation of Invalidity References	**Friday, April 18, 2025**
Fact Discovery Cutoff	**Friday, April 18, 2025**
Defendants' Final Non-Infringement Contentions	**Friday, May 2, 2025**
Plaintiff's Final Validity Contentions	**Friday, May 2, 2025**
Joint Claim Construction Chart (includes citations to intrinsic evidence only)	**Friday, May 9, 2025**
Plaintiff's Opening Claim Construction Brief (serve not file), not to exceed 20 pages	**Friday, May 23, 2025**
Defendants' Answering Claim Construction Brief (serve, not file), not to exceed 30 pages	**Friday, June 13, 2025**
Plaintiff's Reply Claim Construction Brief (serve, not file), not to exceed 20 pages	**Friday, June 27, 2025**
Defendants' Sur-Reply Claim Construction Brief (serve, not file), not to exceed 10 pages	**Friday, July 11, 2025**

Event	Deadline
Joint Claim Construction Brief (file) and optional Tech Tutorial	**Friday, July 18, 2025**
Claim Construction Hearing	**Friday, August 8, 2025 at 10:00 a.m.**
Opening Expert Reports	**Friday, August 29, 2025**
Rebuttal Expert Reports	**Friday, September 19, 2025**
Reply Expert Reports	**Friday, October 10, 2025**
Expert Discovery Cutoff	**Friday, October 24, 2025**
Daubert Opening Motions	**Tuesday, October 28, 2025**
Daubert Oppositions	**Wednesday, November 12, 2025**
Replies to Daubert Oppositions	**Wednesday, November 19, 2025**
Joint Proposed Pretrial Order and MILs	**Monday, January 26, 2026**
Pretrial Conference	**Monday, February 2, 2026 at 4:30 p.m.**
Trial Begins (5 day bench trial)	**Monday, February 9, 2026**