

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

NEURELIS, INC.

Plaintiffs,

v.

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

Defendants.

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

JOINT CLAIM CONSTRUCTION CHART

Pursuant to ¶ 2 of the Scheduling Order (D.I. 132, as extended, D.I. 145), Plaintiff Neurelis, Inc. (“Neurelis” or “Plaintiff”) and Defendants Padagis LLC, Padagis US LLC, Padagis Israel Pharmaceuticals Ltd. (collectively, “Padagis”), Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”), Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. (collectively, “Amneal”) (together, “Defendants”) hereby submit this Joint Claim Construction Chart (“Chart”) (Exhibit A) regarding the two (2) claim terms at issue between the parties that appears 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”). Set forth in the Chart below is the disputed claim term, together with the parties’ proposed constructions and citations to the supporting intrinsic evidence.

The parties mutually reserve the right to rely upon any intrinsic evidence cited in the chart to follow in their briefing irrespective of which party has cited it below. During the briefing process and in responding to the arguments advanced by the other party, each party may identify additional

pieces of intrinsic evidence that they may wish to reply upon, and the parties will timely file an Amended Joint Claim Construction Chart if necessary.

* * * *

In addition, Defendants have advanced several indefiniteness arguments for the terms set forth in Exhibit B. During the meet and confer process, the parties agreed that these indefiniteness arguments based on terms for which there is no proposed construction are not proper for handling at Claim Construction. The parties disagree, however, as to whether such terms should be identified in this Joint Claim Construction Chart.

Plaintiff's Position: the Scheduling Order in this matter provides that the "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." (D.I. 111, ¶ 12). Because Defendants are not proposing any construction for the terms set forth in Exhibit B **and** because there is no other provision in the Scheduling Order that would permit Defendants to advance invalidity arguments at this time, Neurelis respectfully submits that Defendants' Exhibit B should be stricken from the record. Neurelis reserves all of its rights to respond to and present evidence that counter Defendants' invalidity arguments, including any claims of indefiniteness, that are properly disclosed and made at the time of trial in this matter.

Defendants' Position: Defendants submit Exhibit B to inform the Court they alleged certain terms are indefinite should the Court require indefiniteness addressed during the claim construction phase. By submitting Exhibit B, Defendants simply wish to preserve their indefiniteness arguments, but Defendants will make a submission to the Court to request the Court's approval to defer indefiniteness until the full fact and expert record is developed. If the

Court does not approve of this approach, Defendants are prepared to address indefiniteness at the Court's convenience, including during claim construction.

No.	Claim Term	Plaintiff's Proposed Construction	Plaintiff's Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
1.	"vitamin E"	The term should be accorded its plain and ordinary meaning. No further construction is necessary.	'786 patent¹ col. 30:1-54; 35:1-37; Table 3-1; 43:31-34; Table 5-1; Table 5-4; Table 5-5; claim 10 '546 patent, claim 17 '414 patent, claim 10 '852 File History: 10/25/2023 Response to Non-Final Office Action, page 8 Rowe et al., editors, Handbook of Pharmaceutical Excipients, Fourth Edition (2003), Monographs, American Pharmaceutical Association, Washington DC (2003), pp. 13-15, 27-29, 53-55, 257-259, 414-416, 454-459, 521-523, 535-537, 659-660 [filed as EX1031 in IPR2019-00451, IPR2019-00450, IPR2019-00449].	"any of the natural or synthetic tocopherols, tocotrienols, any isomers thereof, any esters thereof, any analogs or derivatives thereof, or any combinations thereof"	'546 Patent: Figures 4, 5; 3:1-17; 4:2-18; 5:38-51; 9:56-10:9; 10:18-25; 10:33-49; 12:31-13:34; 13:61-14:53; 15:15-30; 15:51-67; 32:26-33:18; claims 14, 17-21; Original Claims (Neurelis-00013401-7); November 26, 2012 Preliminary Amendment, pg. 4-5 (Neurelis-00013426-7); May 8, 2013 Requirement for Restriction/Election, pg. 2 (Neurelis-00015464); September 6, 2013 Response to Restriction Requirement, pg. 4-5, 8-9 (Neurelis-00015472-3; 00015476-7); October 1, 2013 Non-Final Office Action, pg. 4 (Neurelis-00015562); April 1, 2014 Response to Non-Final Office Action, 4-5, 8-9, 11-

¹ The cited portions of the '786 specification are also contained in the related '414 and '546 patents. For ease of reference, Neurelis's citations are to the specification of the '786 patent unless otherwise noted.

					14 (Neurelis-00015578-9, 00015582-3, 00015585-8). '414 Patent: 2:51-64; 6:46-67; 7:10-17; 7:26-42; 9:57-10:31; 10:58-11:20; 12:13-28; 12:49-65; 29:63-30:54; 34:60-35:2; claim 10; May 27, 2021 Preliminary Amendment, pg. 2-4 (Neurelis-00000038-40); December 13, 2021 Examiner Interview Summary Record, pg. 1 (Neurelis-00000381); December 13, 2021 Notice of Allowance, pg. 6 (Neurelis-00000379). '786 Patent: 2:10-25; 2:49-62; 5:54-6:26; 6:44-65; 7:8-15; 7:24-40; 8:15-9:24; 9:55-11:56; 12:11-26; 12:47-63; 30:2-62; 35:1-10; Original Claims (Neurelis-00178070-5); November 22, 2021 Preliminary Amendment, pg. 2 (Neurelis-00190497); March 21, 2022 Preliminary Amendment, pg. 2-4 (Neurelis-00190517-9); March 16, 2023 Non-Final Office
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					Action, pg. 2, 4-5 (Neurelis-00190590, 190592-3); June 16, 2023 Amendment and Response to Final Office Action, pg. 3, 6-11 (Neurelis-00190679, 00190682-7); July 24, 2023 Notice of Allowance, pg. 6 (Neurelis-00190698). '852 Patent: Figures: 4, 5; 2:21-3:22; 3:28-38; 3:50-56; 4:2-25; 5:45-58; 6:13-23; 7:25-30; 7:49-58; 10:5-11:2; 12:53-14:67; 15:40-55; 16:9-25; 33:32-34:23; 38:29-38; April 15, 2022 Preliminary Amendment, pg. 2-3 (Neurelis-02042529-30) July 20, 2023 Non-Final Office Action, pg. 2-3 (Neurelis-02049649-50); October 25, 2023 Amendment and Response to Non-Final Office Action, pg. 2-3, 5, 7-8, 12 (Neurelis-02049981-2, 02049984, 02049986-7, 02049991); October 25, 2023 Affidavit Traversing Rejections or Objections Under Rule 132, pg. 6-12
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					(Neurelis-02049871-7); December 7, 2023 Final Office Action, pg. 6-8, 12-14 (Neurelis-02052451-3, 02052457-9); March 14, 2024 Amendment entered with Filing of Continued Prosecution Application/Request for Continued Examination, pg. 3-7, 13-22 (Neurelis-02052487-91, 02052497-02052506); August 29, 2024 Non-Final Office Action, pg. 3-6, 10-15 (Neurelis-02052551-4, 02052558-63); November 29, 2024 Amendment and Response to Non-Final Office Action, pg. 2-6, 9-23, 26-28, 31-33 (Neurelis-02052610-14, 02052617-31, 02052634-6, 02052639-41); March 13, 2025 Non-Final Office Action, pg. 2-4 (Neurelis-02053113-5); April 14, 2025 Amendment and Response to Non-Final Office Action, pg. 2-4, 10-13, 16-18, 20-21 (Neurelis-02053155-57, 02053163-66, 02053169-71, 02053173-74); April 14,
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					2025 Affidavit Traversing Rejections or Objections Under Rule 132, pg. 4, 10 (Neurelis-02053145, 02053151). '061 Patent: Figures: 4, 5; 2:24-3:25; 3:31-4:28; 5:9-30; 5:48-61; 6:17-56; 7:33-60; 9:38-57; 10:8-46; 10:55-11:4; 12:55-13:60; 14:60-15:2; 15:42-57; 16:11-27; 33:30-34:21; Original Claims (Neurelis-02053368-70); July 21, 2022 Response to Election/Restriction, pg. 2-5 (Neurelis-02053487-90); August 18, 2022 Non-Final Office Action, pg. 3-9 (Neurelis-02053510-16); November 18, 2022 Amendment and Response to Non-Final Office Action, pg. 2-4, 12, 18 (Neurelis-02053603-5, 02053613, 02053619); December 9, 2022 Final Office Action, pg. 5-13 (Neurelis-02053640-8); February 9, 2023 Amendment and Response to Final Office Action, pg. 2-3, 16-18
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					(Neurelis-02053662-3, 02053676-8); May 9, 2023 Amendment entered with Filing of Continued Prosecution Application/Request for Continued Examination, pg. 2-3, 5-7, 15-18 (Neurelis-02053696-7, 02053699-701, 02053709-12); July 19, 2023 Non-Final Office Action, pg. 3-9 (Neurelis-02053734-40); October 19, 2023 Amendment and Response to Non-Final Office Action, pg. 2-4, 7, 9, 13-17 (Neurelis-02057972-4, 02057977, 02057979, 02057983-7); October 19, 2023 Affidavit Traversing Rejections or Objections Under Rule 132, pg. 6-11 (Neurelis-02054091-02054096); November 24, 2023 Final Office Action, pg. 5, 10-13 (Neurelis-02058121, 02058126-9); December 13, 2023 Amendment entered with Filing of Continued Prosecution Application/Request for Continued Examination, pg.
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					3-6, 13-14 (Neurelis-02058158-61, 02058168-9); February 14, 2024 Non-Final Office Action, pg. 4-5, 9-13 (Neurelis-02058186-7, 02058191-5); March 14, 2024 Amendment and Response to Non-Final Office Action, pg. 2-3, 5, 9-17 (Neurelis-02058210-1, 02058213, 02058217-25); March 28, 2024 Final Office Action, pg. 3-4, 6, 9-14 (Neurelis-02058233-4, 02058236, 02058239-02058244); May 28, 2024 Amendment and Response after Final Action, pg. 2-3, 5, 9, 11-12 (Neurelis-02058265-6, 02058268, 02058272, 02058274-5); June 13, 2024 Amendment and Response after Final Action, pg. 2-3 (Neurelis-02058314-5) ; August 28, 2024 Pre-Appeal Brief Conference Request, pg. 1, 3 (Neurelis-02058329, 02058331); November 20, 2024 Appeal Brief, pg. 2, 5, 7-10, 13, 15-17, 21, 23-25, 27, 29, 31-32, 34-35, 37, 42-43
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					(Neurelis-02058350, 02058353, 02058355-8, 02058361, 02058363-5, 02058369, 02058371-3, 02058375, 02058377, 02058379-80, 02058382-3, 02058385, 02058390-1) ; December 11, 2024 Supplemental Appeal Brief, pg. 2-3 (Neurelis-02058434-5); April 25, 2025 Amendment entered with Filing of Continued Prosecution Application/Request for Continued Examination, pg. 2-3, 6, 8-9, 11 (Neurelis-02058923-4, 02058927, 02058929-30, 02058932).
2.	“vitamin E USP”	The term should be accorded its plain and ordinary meaning. No further construction is necessary	’786 Patent, 43:5-30; Table 3-1; claims 26-27 ’852 Patent: Figure 4; 47:45-48:11 (Example 3); Table 3-1; claims 1, 6, 10, and 14 ’061 Patent: Figure 4; 47:45-48:11 (Example 3); Table 3-1; claims 1, 5, 21, 33, 43, and 53 ’786 File History: 7/24/2023 Notice of Allowance, Claim	The “vitamin E” term is construed as referenced above. The “USP” term should be accorded its plain and ordinary meaning. No further construction necessary.	’546 Patent: Figures 4, 5; 3:1-17; 4:2-18; 5:38-51; 9:56-10:9; 10:18-25; 10:33-49; 12:31-13:34; 13:61-14:53; 15:15-30; 15:51-67; 32:26-33:18; claims 14, 17-21; Original Claims (Neurelis-00013401-7); November 26, 2012 Preliminary Amendment, pg. 4-5 (Neurelis-00013426-7); May 8, 2013 Requirement for

			Interpretation, page 2 (Neurelis-00013236) '852 File History: 10/25/2023 RCE, Amendment, and Response to Final Office Action, Amendments to the Claims; Declaration Under 35 C.F.R. § 1.132, page 7 n.21 (Neurelis-02049872); 11/29/2024 Amendment and Response to Non-Final Office Action, Remarks, pages 15, 17, 23, 28 (Neurelis-02052623-37) '061 File History: 10/19/2023 Amendment and Response to Non-Final Office Action, Summary of Examiner Interview, page 9 (Neurelis-02057979), 35 U.S.C. § 112, page 13 (Neurelis-02057983); 10/19/2023 Declaration Under 35 C.F.R. § 1.132, page 6 n.21 (Neurelis-02054091) Rowe et al., editors, Handbook of Pharmaceutical Excipients, Fourth Edition (2003), Monographs, American Pharmaceutical Association, Washington DC (2003), pp. 13-15, 27-29, 53-55, 257-259,		Restriction/Election, pg. 2 (Neurelis-00015464); September 6, 2013 Response to Restriction Requirement, pg. 4-5, 8-9 (Neurelis-00015472-3; 00015476-7); October 1, 2013 Non-Final Office Action, pg. 4 (Neurelis-00015562); April 1, 2014 Response to Non-Final Office Action, 4-5, 8-9, 11-14 (Neurelis-00015578-9, 00015582-3, 00015585-8). '414 Patent: 2:51-64; 6:46-67; 7:10-17; 7:26-42; 9:57-10:31; 10:58-11:20; 12:13-28; 12:49-65; 29:63-30:54; 34:60-35:2; claim 10; May 27, 2021 Preliminary Amendment, pg. 2-4 (Neurelis-00000038-40); December 13, 2021 Examiner Interview Summary Record, pg. 1 (Neurelis-00000381); December 13, 2021 Notice of Allowance, pg. 6 (Neurelis-00000379). '786 Patent: 2:10-25; 2:49-62; 5:54-6:26; 6:44-65; 7:8-15; 7:24-40; 8:15-9:24;
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			414-416, 454-459, 521-523, 535-537, 659-660 [filed as EX1031 in IPR2019-00451, IPR2019-00450, IPR2019-00449].		9:55-11:56; 12:11-26; 12:47-63; 30:2-62; 35:1-10; Original Claims (Neurelis-00178070-5); November 22, 2021 Preliminary Amendment, pg. 2 (Neurelis-00190497); March 21, 2022 Preliminary Amendment, pg. 2-4 (Neurelis-00190517-9); March 16, 2023 Non-Final Office Action, pg. 2, 4-5 (Neurelis-00190590, 190592-3); June 16, 2023 Amendment and Response to Final Office Action, pg. 3, 6-11 (Neurelis-00190679, 00190682-7); July 24, 2023 Notice of Allowance, pg. 6 (Neurelis-00190698). '852 Patent: Figures: 4, 5; 2:21-3:22; 3:28-38; 3:50-56; 4:2-25; 5:45-58; 6:13-23; 7:25-30; 7:49-58; 10:5-11:2; 12:53-14:67; 15:40-55; 16:9-25; 33:32-34:23; 38:29-38; April 15, 2022 Preliminary Amendment, pg. 2-3 (Neurelis-02042529-30) July 20,
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					2023 Non-Final Office Action, pg. 2-3 (Neurelis-02049649-50); October 25, 2023 Amendment and Response to Non-Final Office Action, pg. 2-3, 5, 7-8, 12 (Neurelis-02049981-2, 02049984, 02049986-7, 02049991); October 25, 2023 Affidavit Traversing Rejections or Objections Under Rule 132, pg. 6-12 (Neurelis-02049871-7); December 7, 2023 Final Office Action, pg. 6-8, 12-14 (Neurelis-02052451-3, 02052457-9); March 14, 2024 Amendment entered with Filing of Continued Prosecution Application/Request for Continued Examination, pg. 3-7, 13-22 (Neurelis-02052487-91, 02052497-02052506); August 29, 2024 Non-Final Office Action, pg. 3-6, 10-15 (Neurelis-02052551-4, 02052558-63); November 29, 2024 Amendment and Response to Non-Final Office Action, pg. 2-6, 9-23, 26-28, 31-33 (Neurelis-
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					02052610-14, 02052617-31, 02052634-6, 02052639-41); March 13, 2025 Non-Final Office Action, pg. 2-4 (Neurelis-02053113-5); April 14, 2025 Amendment and Response to Non-Final Office Action, pg. 2-4, 10-13, 16-18, 20-21 (Neurelis-02053155-57, 02053163-66, 02053169-71, 02053173-74); April 14, 2025 Affidavit Traversing Rejections or Objections Under Rule 132, pg. 4, 10 (Neurelis-02053145, 02053151). '061 Patent: Figures: 4, 5; 2:24-3:25; 3:31-4:28; 5:9-30; 5:48-61; 6:17-56; 7:33-60; 9:38-57; 10:8-46; 10:55-11:4; 12:55-13:60; 14:60-15:2; 15:42-57; 16:11-27; 33:30-34:21; Original Claims (Neurelis-02053368-70); July 21, 2022 Response to Election/Restriction, pg. 2-5 (Neurelis-02053487-90); August 18, 2022 Non-Final Office Action, pg. 3-9 (Neurelis-02053510-16);
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					November 18, 2022 Amendment and Response to Non-Final Office Action, pg. 2-4, 12, 18 (Neurelis- 02053603-5, 02053613, 02053619); December 9, 2022 Final Office Action, pg. 5-13 (Neurelis- 02053640-8); February 9, 2023 Amendment and Response to Final Office Action, pg. 2-3, 16-18 (Neurelis-02053662-3, 02053676-8); May 9, 2023 Amendment entered with Filing of Continued Prosecution Application/Request for Continued Examination, pg. 2-3, 5-7, 15-18 (Neurelis- 02053696-7, 02053699- 701, 02053709-12); July 19, 2023 Non-Final Office Action, pg. 3-9 (Neurelis- 02053734-40); October 19, 2023 Amendment and Response to Non-Final Office Action, pg. 2-4, 7, 9, 13-17 (Neurelis-02057972- 4, 02057977, 02057979, 02057983-7); October 19, 2023 Affidavit Traversing Rejections or Objections
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					Under Rule 132, pg. 6-11 (Neurelis-02054091-02054096); November 24, 2023 Final Office Action, pg. 5, 10-13 (Neurelis-02058121, 02058126-9); December 13, 2023 Amendment entered with Filing of Continued Prosecution Application/Request for Continued Examination, pg. 3-6, 13-14 (Neurelis-02058158-61, 02058168-9); February 14, 2024 Non-Final Office Action, pg. 4-5, 9-13 (Neurelis-02058186-7, 02058191-5); March 14, 2024 Amendment and Response to Non-Final Office Action, pg. 2-3, 5, 9-17 (Neurelis-02058210-1, 02058213, 02058217-25); March 28, 2024 Final Office Action, pg. 3-4, 6, 9-14 (Neurelis-02058233-4, 02058236, 02058239-02058244); May 28, 2024 Amendment and Response after Final Action, pg. 2-3, 5, 9, 11-12 (Neurelis-02058265-6, 02058268, 02058272,
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					02058274-5); June 13, 2024 Amendment and Response after Final Action, pg. 2-3 (Neurelis-02058314-5) ; August 28, 2024 Pre-Appeal Brief Conference Request, pg. 1, 3 (Neurelis-02058329, 02058331); November 20, 2024 Appeal Brief, pg. 2, 5, 7-10, 13, 15-17, 21, 23-25, 27, 29, 31-32, 34-35, 37, 42-43 (Neurelis-02058350, 02058353, 02058355-8, 02058361, 02058363-5, 02058369, 02058371-3, 02058375, 02058377, 02058379-80, 02058382-3, 02058385, 02058390-1) ; December 11, 2024 Supplemental Appeal Brief, pg. 2-3 (Neurelis-02058434-5); April 25, 2025 Amendment entered with Filing of Continued Prosecution Application/Request for Continued Examination, pg. 2-3, 6, 8-9, 11 (Neurelis-02058923-4, 02058927, 02058929-30, 02058932).
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Exhibit B – Defendants’ Terms Subject to Defendants’ Indefiniteness Arguments

Claim Term or Phrase	Claims Reciting Term of Phrase
“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
“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
“stable”	’852 Patent, claims 6, 14 ’061 Patent, claims 1, 2, 5, 6, 21, 22, 33, 34, 43, 44, 53, 54
“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
“safe and effective”	’852 Patent, claims 1, 6, 10, 14 ’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

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