UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AERIN MEDICAL INC.

Petitioner,

v.

NEURENT MEDICAL LTD.

Patent Owner.

Case No. IPR2025-01125

U.S. Patent No. 12,089,889

PATENT OWNER'S BRIEF ON DISCRETIONARY DENIAL

TABLE OF CONTENTS

I. INTRODUCTION 1

II. BACKGROUND 2

A. Parallel Litigation 2

B. Prosecution History 3

III. THE OFFICE SHOULD EXERCISE DISCRETION TO DENY THE PETITION 4

A. Institution Should Be Denied Under 35 U.S.C. §325(d) 5

1. *Advanced Bionics* Factor 1 6

2. *Advanced Bionics* Factor 2 7

B. Institution Should Be Denied Under 35 U.S.C. §314(A) 11

1. *Fintiv* Factor 1: Possibility of Stay 11

2. *Fintiv* Factor 2: Proximity of Court's Trial Date 12

3. *Fintiv* Factor 3: Investment in Underlying Litigation 13

4. *Fintiv* Factor 4: Overlap in Issues 14

5. *Fintiv* Factor 5: Overlap in Parties 16

6. *Fintiv* Factor 6: Other Circumstances 16

7. Balancing of *Fintiv* Factors and Other Considerations 20

IV. CONCLUSION 20

TABLE OF AUTHORITIES

Page(s)

Federal Cases

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH,
IPR2019-01469, Paper 6, 8 (P.T.A.B. Feb. 13, 2020).....5, 6, 8

Amneal Pharms., Inc. v. Nivagen Pharms., Inc.,
IPR2025-00731, Paper 15 (Director Sept. 3, 2025) 14

Apple Inc. v. Fintiv, Inc.,
IPR2020-00019, Paper 11, 5-6 (P.T.A.B. Mar. 20, 2020).....*passim*

Becton, Dickinson & Co. v. B. Braun Melsungen AG,
IPR2017-01586, Paper 8, 17-18 (P.T.A.B. Dec. 15, 2017).....6, 8

Charles River Labs., Inc. v. Seikagaku Corp.,
IPR2025-00440, Paper 9, 2 (Director July 10, 2025).....16

Ecto World, LLC v. RAI Strategic Holdings, Inc.,
IPR2024-01280, Paper 13, 4 (Director May 19, 2025) 6

Hulu, LLC v. Piranha Media Distribution, LLC,
IPR2024-1252, Paper 27 (Director Apr. 27, 2025) 14

iRhythm Technologies Inc. v. Welch Allyn Inc.,
IPR2025-00363, Paper 10 (Director June 6, 2025) 17

Ivantis Inc. v. Sight Scis., Inc.,
IPR2022-01533, Paper 14, 19-20 (P.T.A.B. Mar. 27, 2023).....9

In re Kotzab,
217 F.3d 1365 (Fed. Cir. 2000) 18

LifeVac, LLC, v. DCSTAR Inc.,
IPR2025-00454, Paper 11, 2 (Director July 11, 2025).....16

Miltenyi Biomed. GmbH v. The Trustees of the Univ. of Penn.,
IPR2022-00853, Paper 11, 46-48 (P.T.A.B. Oct. 11, 2022) 9

Motorola Sols., Inc. v. Stellar, LLC,
IPR2024-01205, Paper 19, 4 (Director Mar. 28, 2025).....15

NHK Spring Co. Ltd. v. Intri-Plex Techs. Inc.,
IPR2018-00752, Paper 8, 20 (P.T.A.B. Sept. 12, 2018) 5

Nvidia Corp. v. Neural AI, LLC,
IPR2025-00606, Paper 18, 2-3 (Director July 31, 2025) 17

Regeneron Pharms. Inc., v. KYMAB Ltd.,
IPR2019-01580, Paper 9, 14-17, 23-24 (P.T.A.B. March 18, 2020) 10

SAP Am., Inc. v. Cyandia, Inc.,
IPR2024-01496, Paper 13, 8-9 (PTAB Apr. 7, 2025).....15

In re Stepan Co.,
868 F.3d 1342 (Fed. Cir. 2017) 18

Supercell Oy v. Gree, Inc.,
IPR2020-01628, Paper 9, 9-11 (P.T.A.B. Feb. 17, 2021) 14

Therabody Inc. v. Datafeel Inc.,
PGR2025-00026, Paper 10, 2 (Director July 17, 2025) 16

Federal Statutes

35 U.S.C. §102.....17

35 U.S.C. §103.....17

35 U.S.C. §112.....1, 3, 17

35 U.S.C. §312(a) 19

35 U.S.C. §314(a) 11, 20

35 U.S.C. §325(d) 5, 17

Regulations

37 C.F.R. §42.104(b)(4).....19

I. INTRODUCTION

The Office should not use Board resources to consider Petitioner's ("Aerin" or "Petitioner") petition for *inter partes* review. Not only was Petitioner's asserted prior art before the examiner during prosecution, but Aerin moved nearly ten months ago for the U.S. District Court to dismiss Patent Owner's infringement suit on the basis of substantively identical art (a product Aerin claims practices the prior art application relied on in the Petition). That fully briefed motion will be decided long before any final written decision could issue based on the Petition. Devoting Board resources to this Petition would therefore be—at best—duplicative of the work the district court will already do (but faster than the Board) and—at worst—could result in conflicting rulings on the merits.

What's more, despite having ample time to do so, Petitioner elected not to avail itself of a Post Grant Review ("PGR"), in which all invalidity issues—including the redundant product prior art on which Petitioner primarily relies in the district court proceeding and Petitioner's Section 112 defenses—could have been adjudicated efficiently together. The Board should not permit Petitioner to purposely cause inefficiency as it has done here. Having foregone PGR, the only forum that can adjudicate all of Petitioner's weak invalidity positions is the district court. The Board should therefore exercise its discretion to defer to that forum rather than

expend its resources adjudicating just a portion of Petitioner's arguments.

II. BACKGROUND

A. Parallel Litigation

Neurent asserted U.S. Patent No. 11,998,262 ("'262 patent") against Aerin as a counterclaim more than one year ago, on July 8, 2024. *See* Ex.2004. On August 5, 2024, Aerin moved to dismiss Neurent's infringement counter-claim, alleging the '262 patent is invalid based on Aerin's prior device, the same device Petitioner claims is covered by the Wolf-003 reference in its IPR Petition. *See* Ex.1023, 8-13; Pet., 42-93 (Grounds II and III relying on Wolf-003).

Neurent also asserted three related patents—U.S. Patent Nos. 12,096,973 ("'973 patent"), 12,096,974 ("'974 patent"), and 12,098,889 ("Challenged Patent")—against Aerin nearly one year ago, on September 24, 2024.[1] *See* Ex.2005. Aerin filed a nearly identical motion to dismiss those three patents on November 15, 2024, similarly alleging the three related patents are invalid based on Aerin's prior device. *See* Ex.2001, 6-15. That motion has been fully briefed since December 23, 2024 and is awaiting the district court's ruling. *See* Ex.2005, 2; Ex.2002; Ex.2003.[2]

[1] Aerin has also filed nearly identical IPR petitions challenging the three related patents asserted by Neurent. *See* Patent Owner's Mandatory Notices, 2.

[2] The court consolidated Neurent's infringement claims March 18, 2025. Ex.2008.

Over the course of the last 14 months, there has been additional substantial investment in the parallel district court litigation: Aerin produced core technical documents, the parties exchanged infringement and invalidity contentions, and the parties have responded to discovery requests. *See* Ex.2004, 7. On August 19, 2025, the Court entered a schedule through trial, with the *Markman* hearing scheduled for May 28, 2026 and trial starting on August 23, 2027. *See* Ex.2007-Schedule, 5.[3]

Aerin's district court invalidity contentions include substantively the same art and arguments as the Petition (with many others). *See* Ex.2009. Those contentions assert invalidity based on Townley (Ex.1004), Wolf-003 (Ex.1005), Wolf-290 (Ex.1006), and Angeles (Ex.1007). *See* Ex.2009, 5, 33-37. They also identify additional publication and patent art, system art similar to the asserted publication art, and written description, enablement, and indefiniteness defenses under 35 U.S.C. §112, all of which could have been raised in PGR. *See, e.g.*, *id.*, 33-37, 56-60.

B. Prosecution History

The Challenged Patent has a priority date of April 9, 2020, which comes after

[3] Neurent sought IPR of eight patents asserted by Aerin in January 2025, before the Acting Director's March 2025 Memorandum, which resulted in disclaimer or invalidation of all challenged claims. *See* IPR2024-00275 to -00281, -00669.

there had been development and disclosure by both Neurent and Aerin in the art. The Challenged Patent, however, reflects advancements over the prior art, and when Neurent prosecuted the application leading to the Challenged Patent on April 26, 2024, it made Aerin and Neurent's relevant history plain to the examiner. In a May 01, 2024 Information Disclosure Statement ("IDS"), Neurent submitted ***three of the same references*** Petitioner relies on in the grounds of this IPR (Wolf-003, Townley, and Angeles). Ex.1002, 185 (identifying Wolf-003), 186 (identifying Townley), 191 (identifying Angeles). Neurent also submitted the issued patent of the Wolf-290 reference that Petitioner relies on in two grounds of this IPR (Ex.1002, 176 (identifying U.S. Patent No. 10,456,185); Ex.2011-USP185 (issued patent of Wolf-290), as well as hundreds of other references, including references detailing both Neurent's prior development and Aerin's prior product (*see generally* Ex.1002, 165-199). The examiner considered the information in Neurent's IDS and in an July 18, 2024 Notice of Allowance ("NOA") the examiner considered "the prior art both in whole and in part" and concluded that "the claimed invention is not taught." Ex.1002, 15-21, 108-140.

III. THE OFFICE SHOULD EXERCISE DISCRETION TO DENY THE PETITION

The Office has explained that IPRs should "provide an effective and efficient alternative to district court litigation," and that the Board's resources should be

preserved to efficiently resolve non-duplicative proceedings. *NHK Spring Co. Ltd. v. Intri-Plex Techs. Inc.*, IPR2018-00752, Paper 8, 20 (P.T.A.B. Sept. 12, 2018) (quoting *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, 16-17 (P.T.A.B. Sept. 6, 2017)); Interim Processes for PTAB Workload Management (Mar. 26, 2025). There are two independent reasons the Director should exercise discretion to deny institution, either of which would be sufficient: (1) denial is proper under 35 U.S.C. §325(d) because the same and substantively similar art was before the Office during prosecution; and (2) Petitioner does not pursue IPR as a true alternative to litigation, but is duplicating and expanding proceedings by presenting substantively the same prior art in district court, including in a pending dispositive motion and in contentions that raise arguments that could have been, but were not, presented in PGR. Taken together, these reasons for discretionary denial are especially compelling.

A. Institution Should Be Denied Under 35 U.S.C. §325(d)

The Director should deny institution under 35 U.S.C. §325(d). *Advanced Bionics* requires consideration of: (1) "whether the same or substantially the same art [or arguments] previously [were] presented to the Office"; and (2) if so, whether the petitioner has demonstrated that the Office materially erred. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8

(P.T.A.B. Feb. 13, 2020); *see also Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17-18 (P.T.A.B. Dec. 15, 2017) (precedential in part). These factors strongly favor discretionary denial.

1. *Advanced Bionics* Factor 1

When evaluating whether the same or substantially the same prior art or arguments were before the Office, the Office considers *Becton, Dickinson* factors a, b, and d: (a) similarities and material differences between art in the Petition and involved during examination; (b) cumulative nature of the art in the Petition and evaluated during examination; and (d) extent of overlap between how the prior art is used by the Petitioner or distinguished by Patent Owner and arguments made during examination. *Becton, Dickinson*, IPR2017-01586, Paper 8, 17-18; *Advanced Bionics*, IPR2019-01469, Paper 6, 9-10.

As the Director explained in *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13, 4 (Director May 19, 2025) (precedential), "[c]hallenging the claims using the same prior art that was previously presented on an IDS is sufficient to satisfy the first part of the *Advanced Bionics* framework." That is the case here. As discussed above, the primary references raised in the Petition—Wolf-003 and Townley—were presented on an IDS and considered by the Examiner. Ex.1002, 108-140, 185 (identifying Wolf-003), 186 (identifying Townley). The

secondary reference for Ground III—Angeles—was also presented on an IDS and considered by the Examiner. Ex.1002, 108-140, 191 (identifying Angeles).

The Petition also cites Wolf-290 as a secondary reference for Grounds II and III. The Wolf-290 publication was not before the examiner, but the issued patent of Wolf-290 was presented on an IDS and considered by the Examiner. Ex.1002, 108-140, 176 (identifying U.S. Patent No. 10,456,185); Ex.2011-USP185 (issued patent of Wolf-290). Wolf-290 and its issued patent share a substantively identical specification and figures, and each portion of Wolf-290 relied on in the Petition is in the issued patent. *Compare* Ex.1006-Wolf-290, [0009], [0012], [0043], [0053], [0076] *with* Ex.2011-USP185, 2:37-49, 3:20-30, 7:20-38, 9:36-50, 14:40-55. Thus, Wolf-290's teachings cited by Petitioner were considered during prosecution.

Accordingly, *Advanced Bionics* Factor 1 and *Becton Dickinson Factors* (a), (b), and (d) are met and favor denying institution.

2. *Advanced Bionics* Factor 2

Advanced Bionics factor 2 requires consideration of whether Petitioner "has demonstrated that the Office erred in a manner material to the patentability of challenged claims," and *Becton, Dickinson* factors (c), (e), and (f): (c) the extent the asserted art was evaluated during examination, including whether it was the basis for rejection; (e) whether Petitioner has pointed out sufficiently how the Examiner

erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts in the petition warrant reconsideration of the prior art or arguments. *See Becton, Dickinson*, IPR2017-01586, Paper 8, 17-18, *Advanced Bionics*, IPR2019-01469, Paper 6, 9-10.

Here, the examiner considered the art and did not commit material error. Examiners Linda Dvorak (primary examiner) and Abigail Bock (assistant examiner) examined both the present application and an application preceding the Challenged Patent, No. 17/225,560 (now U.S. Patent No. 11,883,091 ("'091 patent")). Ex.1001-USP889, Cover; Ex.1008-USP091, Cover.[4] Examination of the '091 patent was extensive and included multiple rejections based on, among others, the ***same Townley reference asserted by Petitioner*** here. *E.g.*, Ex.1009, 70-88 (anticipation and obviousness over Townley), 129-149 (same), 445-450 (restriction requirement).

During prosecution of the '091 patent, the Examiners acknowledged the disclosures of Townley (and other Townley references), including its multi-electrode device for treating rhinitis/rhinorrhea, its use, and its outcomes, just like Petitioner relies on here. *E.g.*, Ex.1009, 132-140 (rejection based on Townley), 144-148

[4] Another primary examiner, Examiner Daniel Fowler, was also involved in the prosecution of the '091 patent. *E.g.*, Ex.1009, 88.

(same); Pet., 13-26 (obviousness based on Townley). Applicant overcame each of those rejections, and the claims of the '091 patent were allowed. *See* Ex.1009, 19-21 (Notice of Allowance). Yet Petitioner relies on substantially the same disclosures here. For example, the Examiners evaluated Townley's discussion of Figure 2 and paragraph [0042], and the Petition relies on that same discussion for multiple limitations. Ex.1009, 132-140; Pet., 14-17, 24-32, 40. And the Examiners also evaluated Townley's discussion of Figure 4 and its corresponding descriptions in paragraph [0066], and the Petition similarly relies on that same discussion for multiple limitations. Ex.1009, 132-140; Pet., 17-24, 30-32. Indeed, overall, the Petition relies on many of the same paragraphs the Examiners did. *Compare* Pet., 13-42 (citing Townley Fig. 2, Figs. 3A-E, Fig. 4, Fig. 5A-G, [0003], [0042], [0045], [0055], [0058], [0066], [0067]) *with* Ex.1009, 132-140 (citing the same).

Thus, although the asserted prior art was not the basis for a rejection in the application leading to the Challenged Patent, the fact that the examiners issued multiple rejections in a family application, including based on Townley, and then had the asserted prior art during prosecution of the Challenged Patent supports denial. *E.g.*, *Ivantis Inc. v. Sight Scis., Inc.*, IPR2022-01533, Paper 14, 19-20 (P.T.A.B. Mar. 27, 2023) (examiner's silence not enough for material error where examiner made arguments for parent patent); *Miltenyi Biomed. GmbH v. The*

Trustees of the Univ. of Penn., IPR2022-00853, Paper 11, 46-48 (P.T.A.B. Oct. 11, 2022) (no material error where same Examiner lodged rejections based on substantially similar art in related application); *Regeneron Pharms. Inc., v. KYMAB Ltd.*, IPR2019-01580, Paper 9, 14-17, 23-24 (P.T.A.B. March 18, 2020) (same).

The Petition alleges the challenged claims and the '091 patent are different and baldly claims the "Examiner did not meaningfully consider the prior art." Pet., 7. The mere fact of difference between the Challenged Claims and other allowed claims does not mean the Examiners did not consider the prior art or committed material error. The record reflects the Examiners were familiar and engaged with the prior art during prosecution of this family, and did meaningfully consider it. Indeed, the Examiners noted in prosecution of the Challenged Patent that "the information disclosure statement [including the three primary references here] is being considered by the examiner," Ex.1002, 82, and noted in the list of references considered that they considered every reference not lined through, and did not line through any of the references at issue here. *See* Ex.1002, 108-140. As Neurent's forthcoming Preliminary Response will explain (and as discussed below), the Petition is also weak, as it suffers from several fatal deficiencies.

Accordingly *Advanced Bionics* Factor 2 and *Becton Dickinson Factors* (c), (e), and (f) favor denying institution.

B. Institution Should Be Denied Under 35 U.S.C. §314(a)

The Director should also deny institution because of the substantial investment in parallel litigation and Petitioner's choices to pursue duplicative arguments in that litigation while delaying its request for Patent Office review. Particularly in such circumstances, IPR will not provide an effective alternative to litigation, but will duplicate effort and result in an inefficient use of Board resources. The factors in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 5-6 (P.T.A.B. Mar. 20, 2020) and additional considerations strongly favor denial.

1. *Fintiv* Factor 1: Possibility of Stay

Fintiv Factor 1 requires consideration of "whether the court granted a stay or evidence exists that one may be granted" upon institution. *Fintiv*, Paper 11, 5-6.

On February 28, 2025, the district court rejected Aerin's request for a stay as to the Challenged Patent and ordered that discovery proceed through contentions on the Challenged Patent and other Neurent patents. *See* Ex.2008; Ex.2010, 15-18. On August 19, 2025, the district court entered a schedule setting Markman in May 2026 and trial in August 2027. Ex.2007-Schedule, 4-5.

Petitioner has not sought a stay in the district court since filing this IPR. Such a stay based on Petitioner's IPR filings is unlikely, as the parallel litigation has been pending for over two years, is between competitors, was already previously stayed

for over six months, and the case has made significant progress through fact discovery, contentions, and substantive briefing. *See* Ex.2004; Ex.2007-Schedule, 2-3. Accordingly, this factor favors denying institution.

2. *Fintiv* Factor 2: Proximity of Court's Trial Date

Fintiv Factor 2 requires consideration of "[the] proximity of the court's trial date to the Board's projected statutory deadline for final written decision." *Fintiv*, Paper 11, 6. Trial in the district court is set for August 2027. Although this is after the expected Final Written Decision date, all other factors strongly favor denial.

Further, while trial is expected to occur after the expected Final Written Decision date, a district court determination regarding Aerin's prior art will occur long before any such decision could issue. Aerin has already raised substantially similar prior art arguments to the district court in a fully briefed dispositive motion. As discussed for Factor 3, Aerin's motion in district court seeks invalidity based on the same prior art product Aerin claims is covered by the prior art in its Petition. The Court is likely to resolve that motion well before the expected January 2027 Final Written Decision date, as average time to resolution of motions to dismiss before Judge Hall in the District of Delaware (who is presiding over the parallel case) is only 8 months and briefing was complete in December 2024. Ex.2006 (motion to dismiss statistics for Judge Hall); *see also* Ex.2004; Ex.2005.

3. *Fintiv* Factor 3: Investment in Underlying Litigation

Fintiv Factor 3 requires consideration of "investment in the parallel proceeding by the court and the parties" as of the institution date. *Fintiv*, Paper 11, 9-10. Investment in the parallel district court litigation has been substantial. The parties have exchanged initial disclosures and contentions and responded to discovery, including 256 requests for production and 30 interrogatories. Aerin has produced core technical documents. Ex.2004, 7. Markman is scheduled for May 2026, with exchanges beginning in January 2026. Ex.2007-Schedule, 4-5.

Most importantly, there has been substantial investment in the litigation regarding specific invalidity issues Petitioner raises in this IPR. Petitioner's IPR alleges in Grounds 2-3 that the challenged claims are unpatentable over art it claims is related to Aerin's prior device.[5] Aerin has advanced a substantially similar argument in motions to dismiss it filed in district court, where it also alleges (wrongly) that Aerin's prior device invalidates the Challenged Claims. *See* Ex.1023,

[5] The Petition relies on Wolf-003, which is a publication of the application leading to U.S. Patent No. 9,415,194 ("'194 patent"). Aerin lists the '194 patent as covering RhinAer, the product it relies on in its motion to dismiss. Ex.2012 (identifying '194 patent for RhinAer); Ex.1023, 8-13 (alleging invalidity based on RhinAer).

Ex.2001 (motions to dismiss). Aerin thus argues in both places—this IPR and the district court motion to dismiss—that its prior device invalidates. The district court motion to dismiss has been fully briefed since December 2024, and the parties' substantial investment in that briefing, along with the overall advancement of the case, favors denial. *See, e.g., Supercell Oy v. Gree, Inc.*, IPR2020-01628, Paper 9, 9-11 (P.T.A.B. Feb. 17, 2021) (parties' filing of dispositive motions in parallel proceeding, in addition to other factors, showed substantial investments in parallel proceeding); *see also Amneal Pharms., Inc. v. Nivagen Pharms., Inc.*, IPR2025-00731, Paper 15 (Director Sept. 3, 2025) (discretionary denial where district court considered invalidity and priority arguments in preliminary injunction motion and Board "essentially would be taking up the same preliminary issues as the district court"); *Cf. Hulu, LLC v. Piranha Media Distribution, LLC,* IPR2024-01252, Paper 27 (Director Apr. 17, 2025) (informative) (discretionary denial where district court separately evaluated eligibility at motion to dismiss).

4. *Fintiv* Factor 4: Overlap in Issues

Fintiv Factor 4 requires evaluation of "overlap between issues raised in the petition and in the parallel proceeding," including overlap in claims, grounds, arguments, and evidence. *Fintiv*, Paper 11, 5-6. This factor favors denial.

First, all claims of the Challenged Patent asserted in district court are

challenged here.

Second, Petitioner presents substantially the same grounds in this petition and its district court invalidity contentions. Aerin's contentions rely on Townley, Wolf-003, Wolf-290, and Angeles (the four references in the Grounds). Ex.2009, 33-37. As discussed for Factor 3, the issues in Aerin's motion to dismiss also substantially overlap with those in its Petition.

Third, despite Petitioner's *Sotera* stipulation, estoppel will not substantially reduce overlap between the proceedings since "Petitioner's invalidity arguments in the district court are more expansive and include combinations of the prior art asserted in these proceedings with unpublished system prior art." *Motorola Sols., Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19, 4 (Director Mar. 28, 2025). The Petitioner's district court invalidity contentions rely, in part, on unpublished system art, including combinations of unpublished system art and the prior art asserted in these proceedings. Ex.2009, 33-37. Accordingly, despite the Petitioner's *Sotera* stipulation, there is a substantial risk of duplication between the parallel proceeding and this one, and Petitioner's *Sotera* stipulation should be given little weight. *See SAP Am., Inc. v. Cyandia, Inc.,* IPR2024-01496, Paper 13, 8-9 (P.T.A.B. Apr. 7, 2025) ("*Sotera* stipulation would not prevent Petitioner from asserting an invalidity defense in the district court based on the public use or sale of the [system-based prior

art]" and concluding IPR "would [not] be a 'true alternative' to the Litigation.").

Therefore, this factor strongly weighs in favor of denying institution.

5. *Fintiv* Factor 5: Overlap in Parties

Fintiv Factor 5 looks at "whether the petitioner and the defendant in the parallel proceedings are the same party." *Fintiv*, Paper 11, 5-6. The parties overlap, and this factor weighs in favor of denying institution.

6. *Fintiv* Factor 6: Other Circumstances

a) Settled Expectations of Patent Owner and Petitioner's Delay

This Office has made clear that post-grant review is favored because it must be filed no later than nine months from the grant of the patent, is close in time to examination, and occurs before expectations in patent rights are strongly settled. *See, e.g.*, *LifeVac, LLC, v. DCSTAR Inc.*, IPR2025-00454, Paper 11, 2 (Director July 11, 2025); *Therabody Inc. v. Datafeel Inc.*, PGR2025-00026, Paper 10, 2 (Director July 17, 2025) (same). This is because "[e]arly challenges favor robust, predictable patent rights." *Charles River Lab'ys, Inc. v. Seikagaku Corp.*, IPR2025-00440, Paper 9, 2 (Director July 10, 2025).

Here, although the Challenged Patent was asserted against Petitioner in the district court litigation a year ago, in September 2024, Petitioner elected not to file a PGR petition, instead delaying for nine months to file this IPR. While it waited, it

pursued overlapping invalidity arguments in the district court. It filed dispositive motions, including one that was fully briefed over six months before this petition. It also prepared invalidity contentions that not only alleged invalidity under 35 U.S.C. §§102 and 103, but under §112—grounds that could have been raised in PGR. As the Director found in *NVIDIA Corp. v. Neural AI, LLC*, IPR2025-00606, Paper 18, 2-3 (Director July 31, 2025), where a Petitioner has actual notice of the challenged patent but fails to seek early review, that favors denial. *See also iRhythm Technologies Inc. v. Welch Allyn Inc.,* IPR2025-00363, Paper 10, 2-3 (Director June 6, 2025) (lack of challenge after knowledge of patent weighed against institution).

As discussed above with respect to §325(d), having fully disclosed the relevant prior art to the Office during prosecution—including the ***same or substantively the same*** references relied on in the Petition—Neurent had the settled expectation that the challenged patent would not be subject to a duplicative challenge before this Office in IPR. There has been no change in law or precedent that should upset that expectation in view of the scope of relevant prosecution.

Given Aerin's choice to delay and Neurent's resulting expectations, the Director should deny institution and allow Aerin to more efficiently present its arguments in district court.

b) The Merits of the Petition Are Weak and Rely on Improper Expert Testimony

For reasons that will be identified in Neurent's forthcoming Patent Owner Preliminary Response, the Petition merits are weak. Three examples are illustrative.

First, the Petition's motivation to combine and reasonable expectation of success analyses are conclusory and insufficient. For Ground I, Petitioner argues obviousness based on Townley combined with knowledge of a POSITA. *E.g.*, Pet., 13 (admitting Townley "does not specifically state…improv[ing] a patient's nasal breathability" but arguing obviousness to a POSITA). The Petition is deficient because despite arguing this combination, it ***nowhere*** argues motivation to modify Townley or reasonable expectation of success specific to Townley's disclosure. Further, the Petition relies on different Townley figures, without providing reasoning as to why or how a POSITA would have been motivated to combine them or have a reasonable expectation in doing so. *See, e.g.*, Pet., 17-19 (citing Townley Figures 4, 5D, and 11B), 20-21 (same), 23-24 (same). This is also insufficient. *In re Stepan Co.*, 868 F.3d 1342, 1346 (Fed. Cir. 2017) ("there must be a motivation to [combine multiple embodiments from a single reference] and a reasonable expectation [of success], otherwise a skilled artisan would not arrive at the claimed combination."); *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000) ("[e]ven when obviousness is based on a single prior art reference, there must be a showing of a suggestion or

motivation to modify the teachings of that reference.").

Petitioner's motivation and expectation analysis is likewise insufficient for Grounds II-III. There, for example, Petitioner fails to articulate why or how a POSITA would have been motivated to modify Wolf-003's device specifically or why or how it would be expected to achieve the claimed results. *See* Pet., 49-51.

Second, Petitioner improperly relies on expert testimony to gap-fill the prior art, which it ***admits*** does not disclose the claimed nasal breathability. Pet., 12-13, 27. The Petition merely makes conclusory statements this limitation would allegedly have been understood by a POSITA. *See id.*, 12-13, 27. This is insufficient and improper. *See* 35 U.S.C. §312(a); 37 C.F.R. §42.104(b)(4).

Third, the Petition fails to identify where several limitations are even allegedly present in the prior art. For example, though each claim requires electrodes that "extend" from the axis of the shift (Ex.1001, cl. 1), Ground I does not identify how electrodes extend from the device. Pet., 20-25.

As a result, and as further discussed in Neurent's POPR, the merits are weak.

c) Economic Interests Related to the Patented Product

The Challenged Patent relates to novel devices to treat chronic rhinitis and other nasal conditions, diseases that affect millions of Americans and people world-wide. Neurent's technology has helped patients treat symptoms that can

significantly decrease quality of life, impact sleep quality, daily activities, and mental health. *See* Ex.2013; Ex.2014. Neurent has made substantial investments to develop these life-changing methods, investments that have not only successfully brought Neurent's Neuromark system to market in the United States, but secured insurance coverage for many users. *See* Ex.2015. Particularly in view of the other factors and considerations that strongly favor discretionary denial, the Office should exercise its discretion to deny institution in view of Neurent's substantial investment in improving people's lives through its medical device development.

7. Balancing of *Fintiv* Factors and Other Considerations

As shown above, all *Fintiv* factors and the Director's additional considerations favor denial and the petition should be denied under § 314(a).

IV. CONCLUSION

For the reasons set forth above, the Director should exercise discretion to deny the Petition for *Inter Partes* Review.

Respectfully submitted,

By: /David L. Cavanaugh/
David L. Cavanaugh
Registration No. 36,476
Counsel for Patent Owner

CERTIFICATE OF SERVICE

I hereby certify that, on September 8, 2025, I caused a true and correct copy of the following materials:

- Patent Owner's Brief on Discretionary Denial
- Patent Owner's Table of Exhibits
- Exhibits 2001-2015

to be served on Petitioner via electronic mail to:

Heath J. Briggs, BriggsH@gtlaw.com

Benjamin P. Gilford, GilfordB@gtlaw.com

Trenton Ward, Trenton.Ward@gtlaw.com

Elana Araj, Elana.Araj@gtlaw.com

Declan Stone-Murphy, Declan.StoneMurphy@gtlaw.com

Emma Cohen, Emma.Cohen@gtlaw.com

AerinMed-IPRs@gtlaw.com

/Gilbert T. Smolenski/
Gilbert T. Smolenski
Registration No. 78,549

Petitioner's Table of Exhibits

No.	Description
2001	Opening Brief in Support of Defendant's Motion to Dismiss Plaintiff's Complaint of Patent Infringement, *Neurent Medical Ltd. v. Aerin Medical Inc.*, Case No. 1:24-cv-01070-JLH, Dkt. 20 (D. Del. Nov. 15, 2024)
2002	Opposition Brief to Defendant's Motion to Dismiss Plaintiff's Complaint of Patent Infringement, *Neurent Medical Ltd. v. Aerin Medical Inc.*, Case No. 1:24-cv-01070-JLH, Dkt. 31 (D. Del. Dec. 09, 2024)
2003	Reply Brief in Support of Defendant's Motion to Dismiss Plaintiff's Complaint of Patent Infringement, *Neurent Medical Ltd. v. Aerin Medical Inc.*, Case No. 1:24-cv-01070-JLH, Dkt. 34 (D. Del. Dec. 23, 2024)
2004	Docket Sheet for *Aerin Medical Inc. v. Neurent Medical Inc.*, Case No. 1:23-cv-00756-JLH (D. Del.) (dated Sept. 1, 2025)
2005	Docket Sheet for *Neurent Medical Ltd. v. Aerin Medical Inc.*, Case No. 1:24-cv-01070-JLH (D. Del.) (dated Sept. 1, 2025)
2006	Motion to Dismiss Statistics from Docket Navigator for Judge Hall (dated Sept. 1, 2025)
2007	So Ordered Joint Status Report Regarding Stipulated Schedule for Further Proceedings, *Aerin Medical Inc. v. Neurent Medical Inc.*, Case No. 1:23-cv-00756-JLH, Dkt. 129 (D. Del. Aug. 19, 2025)
2008	Stipulation and Order to Consolidate, *Neurent Medical Ltd. v. Aerin Medical Inc.*, Case No. 1:24-cv-01070-JLH, Dkt. 41 (D. Del. Mar. 18, 2025)
2009	Aerin's Initial Invalidity Contentions (July 2, 2025)
2010	Feb. 28, 2025 Hearing Transcript in *Aerin Medical Inc. v. Neurent Medical Inc.*, Case No. 1:23-cv-00756-JLH (D. Del.) and *Neurent Medical Ltd. v. Aerin Medical Inc.*, Case No. 1:24-cv-01070-JLH (D. Del.)
2011	U.S. Patent No. 10,456,185
2012	Aerin Medical Patents, https://aerinmedical.com/patents/ (last visited Sept. 1, 2025)
2013	Douglas D. Reh et al., *Long-term outcomes following impedance-controlled radiofrequency ablation for the treatment*

No.	Description
	of chronic rhinitis, Laryngoscope Investigative Otolaryngology (2024)
2014	Douglas D. Reh et al., *Clinical evaluation of a novel multipoint radiofrequency ablation device to treat chronic rhinitis*, Laryngoscope Investigative Otolaryngology (2023)
2015	Neurent Medical Announces Expanded Access Following Cigna Policy Update for NEUROMARK®, https://neuromark.com/resource/cigna-policy-update-expands-access-for-posterior-nasal-nerve-ablation-using-neuromark-r (last visited Sept. 1, 2025)