

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NYXOAH, INC., and
NYXOAH SA,
Petitioners,

v.

INSPIRE MEDICAL SYSTEMS, INC.,
Patent Owner.

Case No. IPR2026-00092

U.S. Patent 11,850,424

**PETITIONERS' OPPOSITION TO PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL OF INSTITUTION**

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PETITIONERS' LIST OF EXHIBITS

<i>Exhibit #</i>	<i>Description</i>
1001	U.S. Patent No. 11,850,424 (the "'424 Patent")
1002	Select portions of the prosecution history of the '424 Patent ("File History")
1003	Declaration of Petitioners' Expert Dr. Gerald Loeb
1004	Declaration of Petitioners' Expert Dr. Ingrid Hsieh-Yee
1005	International Patent Application Publication No. WO 2016/149344 ("Wagner")
1006	U.S. Patent Application Publication No. 2006/0224211 ("Durand")
1007	U.S. Patent Application Publication No. 2015/0094962 ("Hoegh")
1008	International Patent Application Publication No. WO 2010/006218 ("Headley")
1009	Tran et al., "Development of Asynchronous, Intralingual Electrical Stimulation to Treat Obstructive Sleep Apnea," Proceedings of the 25th Annual International Conference of the IEEE EMBS, Cancun, Mexico (September 17-21, 2003) ("Tran-I")
1010	Tran et al., "First Subject Evaluated with Simulated BION™ Treatment in Posterior Genioglossus to Prevent Obstructive Sleep Apnea," Proceedings of the 26th Annual International Conference of the IEEE EMBS, San Francisco, CA (September 1-5, 2004) ("Tran-II")
1011	U.S. Patent No. 5,944,680 ("Christopherson")
1012	U.S. Patent Application Publication No. 2014/0228905 ("Bolea")
1013	Mortimer, "Electrical Excitation of Nerve," Neural Prostheses – Fundamental Studies, Chapter 3 (1990) ("Mortimer")

<i>Exhibit #</i>	<i>Description</i>
1014	Anagnostopoulos, et al., “Electronic Pacemakers of the Heart, Gastrointestinal Tract, Phrenic Nerve, Bladder, and Carotid Sinus: Current Status,” Surgery 60:2, 480-494 (August 1966) (“Anagnostopoulos”)
1015	Glenn et al., “Electrical Stimulation of Excitable Tissue by Radio-Frequency Transmission,” Annals of Surgery 160:3, 338-350 (1964) (“Glenn”)
1016	Judson et al., “Radio-Frequency Electrophrenic Respiration – Long-Term Application to a Patient with Primary Hypoventilation,” JAMA 203:12, 1033-1037 (March 18, 1968) (“Judson”)
1017	Singh, et al., “Recruitment Properties of Intramuscular and Nerve-Trunk Stimulating Electrodes,” IEEE Transactions on Rehabilitation Engineering, 8:3, 276-285 (September 2000) (“Singh”)
1018	Richmond et al., “Tactical Application of Sensorimotor Prosthetic Technology,” Proceedings of the 25th Annual International Conference of the IEEE EMBS, Cancun, Mexico (September 17-21, 2003) (“Richmond”)
1019	Edmonds, et al., “The Effects of Transcutaneous Electrical Stimulation During Wakefulness and Sleep in Patients with Obstructive Sleep Apnea,” Am Rev Respir Dis, 146:1030-1036 (1992) (“Edmonds”)
1020	Miki et al., “Effects of Submental Electrical Stimulation During Sleep on Upper Airway Patency in Patients with Obstructive Sleep Apnea,” Am Rev Respir Dis 140:1285-1289 (1989) (“Miki”)
1021	Decker et al., “Functional Electrical Stimulation and Respiration During Sleep,” Journal of Applied Physiology, 75(3): 1053-1061 (1993) (“Decker”)
1022	Eisele et al., “Direct Hypoglossal Nerve Stimulation,” Arch. Otolaryngol Head Neck Surg., 123:57-61 (1997) (“Eisele1997”)

<i>Exhibit #</i>	<i>Description</i>
1023	Fuller et al., “Effect of Co-Activation of Tongue Protrudor and Retractor Muscles on Tongue Movements and Pharyngeal Airflow Mechanics in the Rat,” Journal of Physiology 519, 2, 601-613 (1999) (“Fuller”)
1024	U.S. Patent No. 6,572,543 (“Christopherson ’543”)
1025	Schwartz et al., “Electrical Stimulation of the Lingual Musculature in Obstructive Sleep Apnea,” J Appl Physiol. (81(2):643-652 (1996) (“Schwartz1996”)
1026	Goding et al., “Relief of Upper Airway Obstruction With Hypoglossal Nerve Stimulation in the Canine,” Laryngoscope, 108:162-169 (1998) (“Goding”)
1027	U.S. Patent No. 4,830,008 (“Meer”)
1028	Yoo et al., “Selective Stimulation of the Hypoglossal Nerve: A FINE Approach to Treating Obstructive Sleep Apnea,” Proceedings of the Second Joint EMBS/BMES Conference, 2049-2050 (October 23-26, 2002) (“Yoo”)
1029	Fairbanks et al., “Neurostimulation for Obstructive Sleep Apnea,” ENT Journal (January 1993) (“Fairbanks”)
1030	Schwartz et al., “Therapeutic Electrical Stimulation of the Hypoglossal Nerve in Obstructive Sleep Apnea,” Arch Otolaryngol Head Neck Surg., Vol. 127 (Oct. 2001) (“Schwartz2001”)
1031	Oliven, “Treating Obstructive Sleep Apnea with Hypoglossal Nerve Stimulation,” Current Opinion in Pulmonary Medicine 17:419-424 (2011) (“Oliven”)
1032	Mwenge et al., “Targeted Hypoglossal Neurostimulation for Obstructive Sleep Apnoea: a 1-Year Pilot Study,” Eur Respir J. 41:360-367 (2013) (“Mwenge”)

<i>Exhibit #</i>	<i>Description</i>
1033	Zaidi et al., “Tongue Anatomy and Physiology, the Scientific Basis for a Novel Targeted Neurostimulation System Designed for the Treatment of Obstructive Sleep Apnea,” <i>Neuromodulation</i> ; 16:376-386 (2012) (“Zaidi”)
1034	Steier et al., “Continuous Transcutaneous Submental Electrical Stimulation in Obstructive Sleep Apnea,” <i>Chest</i> 140:998-1007 (2011) (“Steier”)
1035	Agnew et al., “Considerations for Safety with Chronically Implanted Nerve Electrodes,” <i>Epilepsia</i> , 31 (Suppl. 2): S27-32 (1990) (“Agnew”)
1036	U.S. Patent No. 7,277,749 (“Gordon”)
1037	Meadows et al., “Effects of Targeted Activation of Tongue Muscles on Oropharyngeal Patency in the Rat,” <i>Journal of the Neurological Sciences</i> , 346:178-193 (August 2014) (“Meadows”)
1038	Eastwood et al., “Treating Obstructive Sleep Apnea with Hypoglossal Nerve Stimulation,” <i>SLEEP</i> , 34:11, 1479-1486C (2011) (“Eastwood”)
1039	Sinha et al., “Safety of Microstimulator During Radiation Therapy – A Preliminary Study on Head and Neck Cancer Patients,” <i>J. Nucl. Med. Radiat. Ther.</i> 5:4 (2014) (“Sinha”)
1040	Kaplan et al., “Preventing ischial pressure ulcers: III. Clinical pilot study of chronic neuromuscular electrical stimulation,” <i>Applied Bionics and Biomechanics</i> 8, 345359 (2011) (“Kaplan”)
1041	Bailey et al., “Anatomic consequences of intrinsic tongue muscle activation,” <i>J Appl Physiol</i> 101:1377-1385 (2006) (“Bailey”)
1042	Brennick et al., “MRI study of pharyngeal airway changes during stimulation of the hypoglossal nerve branches in rats,” <i>J Appl Physiol</i> 90:1373-1384 (2001) (“Brennick”)

<i>Exhibit #</i>	<i>Description</i>
1043	Oliven et al., “Upper airway response to electrical stimulation of the genioglossus in obstructive sleep apnea,” J Appl Physiol 95:2023-2029 (2003) (“Oliven2003”)
1044	Oliven et al., “Effect of coactivation of tongue protruder and retractor muscles on pharyngeal lumen and airflow in sleep apnea patients,” J Appl Physiol 103:1662-1668 (2007) (“Oliven2007”)
1045	U.S. Patent Application Publication No. 2006/0167523 (“Tehrani”)
1046	Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al., Case No. 1:25-cv-00667-RGA (D. Del.) (D.I. 11)
1047	Stipulation and Order to Stay Certain Deadlines, entered November 21, 2025, Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al., Case No. 1:25-cv-00667-RGA (D. Del.) (D.I. 52)
1048	Joint Stipulation and Order to Extend Stay, entered January 1, 2026, Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al., Case No. 1:25-cv-00667-RGA (D. Del.) (D.I. 61)
1049	Amended Scheduling Order, entered March 6, 2026, Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al., Case No. 1:25-cv-00667-RGA (D. Del.) (D.I. 73)
1050	Order reassigning case, entered March 19, 2026, Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al., Case No. 1:25-cv-00667-RGA (D. Del.) (Text Only Order)

I. INTRODUCTION

The Director should deny Patent Owner’s (“PO”) request for discretionary denial of this proceeding (Paper 6) (“Request” or “Req.”). PO’s Request consists of a volley of arguments, none of which warrant discretionary denial.

First, there has been no violation of 37 C.F.R. § 42.104(b)(3) because no challenged claim in this proceeding recites limitations that invoke 35 U.S.C. § 112(f) under any reasoned construction. Petitioners have not taken a claim construction position in district court to the contrary.

Second, institution is warranted under 35 U.S.C. § 325(d) to cure the material errors committed by the Examiner during prosecution of the ’424 Patent. For Ground 1, the primary reference (Durand (Ex. 1006)) was before the Examiner—buried in one of four IDSs along with over 350 other references. The Examiner did not apply Durand during examination, and PO neglected to identify Durand as being of particular relevance, despite its plain disclosure of every key feature that PO told the Examiner was missing from the art he did apply (*i.e.*, Bolea (Ex. 1012)). The Request ignores Durand’s disclosures and does not dispute that Durand teaches everything PO said Bolea lacks during prosecution.

Ground 2 applies prior art not before the Examiner, including Tran (EX-1009 and EX-1010). Ground 2 is not cumulative given that Tran differs in material part from Bolea in that it discloses the limitations PO argued were missing from Bolea

during prosecution and that led to the erroneous issuance of the '424 Patent.

Third, there also is no basis to give the unpatentability of the '424 Patent a pass under *Fintiv*. The parallel litigation is in its early stages and is not set for trial until December 2027—six months after the statutory deadline for the final written decision for this Petition. Moreover, the district court has indicated that it will consider a stay if IPR is instituted. Thus, the *Fintiv* factors favor institution.

Fourth, the Petition provides persuasive evidence of unpatentability and is supported by reasoned expert testimony from Dr. Loeb. His declaration provides extensive citations to documentary factual support in the Tran references, properly complying with requirements to be given significant weight. 37 C.F.R. § 42.65(a).

II. PROCEDURAL BACKGROUND

Petitioner Nyxoah SA is a medical device developer located in Belgium. One of its products is the Genio® device for treating obstructive sleep apnea (“OSA”), which Nyxoah SA originally launched and sold throughout Europe. Petitioner Nyxoah, Inc., is a publicly-traded Delaware corporation based in New Jersey. Nyxoah, Inc. has obtained FDA approval for the Genio® device and launched it in the U.S. The U.S. Genio® devices are manufactured in Minnesota. Together, Petitioners (including any subsidiaries) (“Nyxoah”) have fewer than 500 employees.

On May 30, 2025, PO filed a complaint against Nyxoah, asserting that the Genio® device infringes three patents, including the '424 Patent. EX-2001. Nyxoah

answered on August 25, 2025, denying infringement and asserting counterclaims for non-infringement and invalidity of each asserted patent. EX-2002. Prior to answering, Nyxoah filed a motion to disqualify PO's litigation counsel. EX-1046. The motion was granted and a stay of all litigation deadlines was entered on November 20, 2025, prior to production of technical documents and service of contentions. EX-1047, EX-1048.

IPR petitions challenging all claims of U.S. Pat. No. 10,898,709 (PTAB-IPR2026-00090) ("the '709 Petition"); U.S. Pat. No. 11,806,526 (PTAB-IPR2026-00091) ("the '526 Petition"); and U.S. Pat. No. 11,850,424 (PTAB-IPR2026-00092) ("the '424 Petition) were filed December 18, 2025, while the litigation was stayed.

On March 2, 2026, nearly three months after the Petitions were filed, new litigation counsel appeared, and the court lifted the stay. EX-2004. A scheduling order was entered on March 6, 2026, setting trial for December 13, 2027. EX-1049. The parties will exchange initial infringement and invalidity contentions in April 2026; and the joint claim construction brief is not due until September 18, 2026. *Id.* On March 19, 2026, the case was reassigned to a different judge. EX-1050.

III. STIPULATION

Petitioners stipulate that if the Board grants the Petition and institutes an *inter partes* review in IPR2026-00092, unless institution is later vacated, reversed, or otherwise withdrawn by rehearing or Director Review, Petitioners will not pursue in

the district court litigation the specific grounds asserted in the Petition, or any other invalidity ground that Petitioners raised or could have reasonably raised in the Petition under §§ 102 or 103 against the asserted claims of the '424 Patent

IV. THE '424 PETITION SATISFIES RULE 104(B)(3)

A. The Challenged Claims in the Petition Do Not Invoke 35 U.S.C. § 112(f)

The '424 Petition satisfies Rule 104(b)(3)'s requirement to identify how the challenged claims are to be construed. The Rule requires:

Where the claim to be construed contains a means-plus-function or step-plus-function limitation as permitted under 35 U.S.C. § 112(f), the construction of the claim must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function;

37 C.F.R. § 42.104(b)(3). However, none of the challenged claims in the '424 Petition “contains a means-plus-function... limitation ... under § 112(f)” under any reasoned construction.

The use of “means” in a claim does not necessarily mean that § 112(f) applies. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc in relevant part). Where “the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure,” the presumption that the word “means” invokes 112(f) is overcome. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348-49 (Fed. Cir. 2015) (en banc in relevant part).

“The ultimate question is whether ‘the claim language, read in light of the specification, recites sufficiently definite structure to avoid § 112, 6.’” *MTD Prod. Inc. v. Iancu*, 933 F.3d 1336, 1342 (Fed. Cir. 2019) (quoting *Media Rights Techs. Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1372 (Fed. Cir. 2015)). “Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure.” *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259-60 (Fed. Cir. 2008).

Here, the ’424 independent claims recite a “means for stimulating a . . . nerve.” Importantly, however, the claims also include a “wherein” clause that expressly defines the exact structure for performing the stimulating function:

wherein, the ... means for stimulating **comprises an implantable electrode and/or an implantable pulse generator electrically connectable to the implantable electrode.**

EX-1001 (Claims 1, 18, 20). Given the plain language of the “wherein clause,” a reasoned claim construction that invokes § 112(f) is not plausible. The Petition therefore satisfied Rule 104(b)(3) by stating that the “plain and ordinary” meaning applies. Pet. at §VI.

To the extent there is any dispute whether the structure defined in the “wherein” clauses is sufficient to perform the stimulating function, the Petition lays

that issue to rest. The Petition identifies the implantable electrode and/or the electrically connected implantable pulse generator as the structure for stimulating the nerve and cites to the corresponding description in the specification for support. Pet., §IV (citing EX-1001, Fig. 2A (annotated), 9:58-10:31, 11:66-12:29).

In short, the Petition complies with Rule 104(b)(3).

B. Rule 104(b)(3) Does Not Require an Explanation for Why § 112(f) Does Not Apply

PO can find no support in PTAB decisions for its argument that Rule 104(b)(3) necessarily is violated if the Petition does not explain why § 112(f) does not apply. Req. at 4. Decisions addressing Rule 104(b)(3) have discretionarily denied institution on that basis only in the limited circumstance where the petitioner took inconsistent positions regarding the applicability of § 112(f) before the PTAB and in district court. *See 10X Genomics, Inc. v. President & Fellows of Harvard Coll.*, IPR2023-01299, Paper 15 at 13 (PTAB Mar. 7, 2024); *Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-01546, Paper 10 at 11 (PTAB Feb. 14, 2019). *See also Revvo Techs. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 at 3-4 (Director Nov. 3, 2025) (precedential) (when taking different claim construction positions, petitioner “should, at a minimum, explain why alternative positions are warranted”).

Here, Nyxoah has not advanced any inconsistent positions. Any argument that terms in the challenged claims invoke § 112(f) is not reasonable. The claim construction gamesmanship that led to discretionary denial in *10X Genomics* and

Orthopediatrics will not occur here. *See also Samsung Elecs. Co. Ltd. v. Wilus Inst. of Standards & Tech. Inc.*, IPR2025-01069, Paper 16 at 7 (Dec. 10, 2025) (“the record does not show inconsistent claim construction positions that warrant denial under PTAB precedent”).

Nonetheless, PO speculates that Nyxoah will take an inconsistent claim construction position in district court because Nyxoah’s counterclaims of noninfringement state that the accused Genio® device does not have “‘a means for stimulating a ... nerve,’ and does not utilize a stimulation period whose ‘duration . . . is based on a reference respiratory-related parameter.’” EX-2002, ¶46. PO does not explain why this statement demonstrates that Nyxoah will take a claim construction position that is at odds with the “plain and ordinary” meaning advanced in the Petition. The statement does not address claim construction at all. By contrast, *10X Genomics* and *Orthopediatrics* denied institution based on evidence of actual inconsistent positions, and not unsupported conjecture about actions the petitioner might take in the future. Applying a different standard here would be manifestly unfair, particularly in view of the strong invalidity grounds set forth in the Petition.

PO’s reliance on *Apple Inc. v HBCU*, IPR2025-1493, Paper 15 (Feb. 18, 2026) to urge a blanket denial of the three petitions is misplaced. There, the underlying litigation involving multiple patents had advanced well into claim construction, and PO had filed discretionary denial briefing showing that petitioner had taken different

claim construction positions in the litigation than it had in IPRs challenging those patents. *Apple*, Paper 7 at 6-8. As a consequence, the Director discretionarily denied two IPRs in view of *Revvo*, and a third IPR involving a related patent because of “intrinsically similar issues.” *Apple*, Paper 15 at n.1 & n.2. The circumstances in *Apple* are not present here. Nyxoah has not taken any claim construction position in district court relating to either the ’526, ’424, or ’709 Petitions.

V. INSTITUTION IS WARRANTED TO CORRECT THE ERRONEOUS ISSUANCE OF THE ’424 PATENT

Inter partes review is particularly important because the pre-grant examination by the Patent Office failed to consider or uncover the art and grounds of this Petition, which are neither cumulative nor redundant to the examination upon which the patent rests for its validity. *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (Feb. 13, 2020) (March 24, 2020) (precedential). Indeed, the grounds in the Petition show that the original examination’s failure to appreciate the disclosures of cited art (Ground 1) and to uncover other pertinent prior art (Ground 2) directly led to the erroneous issuance of invalid claims in the ’424 Patent.

A. Ground 1 Demonstrates the Examiner Materially Erred

Ground 1 presents a compelling case of unpatentability of all claims based on the combination of Durand and Hoegh (EX-1007). Although cited, Durand was buried in one of four IDSs, along with an unusually large volume of over 350 other

references. EX-1002 at 0137-139, 0216-218, 0234-244, 0246-275; Pet. at 19. *See Ecto World, LLC v. Rai Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 7 & n.3 (May 19, 2025) (precedential) (“Most IDS submissions contain fewer than 25 references.”) (*Becton Dickinson* factor (c)). The Examiner “did not issue any prior art rejections during examination” based on Durand or even discuss the reference. *Id.* at 5-6 (*Becton Dickinson* factor (c)). It is easy to understand how the Examiner may have overlooked Durand in the sea of prior art that was submitted, but, as set forth below, overlooking Durand’s third disclosed embodiment was material error.

Durand expressly discloses the key limitations that PO convinced the Examiner were missing from the art applied during prosecution and thus Durand “is not substantially the same art.” *Id.* at 5 (*Becton Dickinson* factor (a)). Specifically, during prosecution, the Examiner applied Bolea extensively in his rejections. EX-1003 ¶¶56-57, 68-70 (citing EX-1002 0060-78, 0119-122, 0142-0149). To convince the Examiner that his application of Bolea was wrong, PO argued:

- (1) Bolea only discloses asynchronous stimulation during daytime familiarization and not as nighttime therapy [EX-1002 at 0119-122];
- (2) Bolea’s protocol “depend[s] on stimulation timing synchronized relative to a detected peak of the respiration signal,” and thus conflicts with the claims’ requirement for a **“therapy protocol ... in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation”**

[*Id.* at 0119-120 (underline and bold emphasis original); *see also id.* at 0060-61 (distinguishing Bolea and Tehrani (EX-1045))]; and

(3) neither Bolea nor other art applied by the Examiner (Tehrani) disclosed “wherein the duration of each respective stimulation period is based on a reference respiration-related parameter” [*Id.* at 0062-61, 0064, 0066].

Persuaded by PO’s arguments, the Examiner mistakenly concluded that none of the cited prior art disclosed an implantable electrode and/or an implantable pulse generator for stimulating a hypoglossal nerve “wherein the duration of each respective stimulation period is based on a reference respiration-related parameter.” EX-1002 0020; Pet. at 12 (citing EX-1003 ¶¶59-65).

But, as set out in the Petition, Durand plainly teaches each of features **(1)-(3)**. That is, Durand “includes specific teachings that ‘impact patentability of the challenged claims.’” *Ecto World*, Paper 13 at 5 (citing *Advanced Bionics*, Paper 6 at 8 n.9). Specifically, with respect to features **(1)-(2)**, Durand discloses treating OSA using an asynchronous stimulation protocol, whereby “the controller can be programmed to provide stimulation at a predetermined interval **without either detecting a physical process or requiring feedback from the nerve being stimulated.**” EX-1006 ¶ 25 (emph. added); *id.* at ¶13; Pet. at §X.A.4.a.iii [1.a2].

With respect to feature **(3)**, Durand also plainly teaches that the stimulation cycle duration and rate are based on a reference respiration-related parameter: “In

this method, **the stimulation interval can be determined from the patient's nighttime basal metabolism, e.g., based on the patient's observed nighttime resting respiratory rate. The resultant timing of the stimulation pulse trains will closely simulate the patient's normal nighttime respiration cycle.**" EX-1006 ¶ 25 (emphasis added); Pet. at §X.A.4.a.v [1.c].

Had the Examiner thoroughly reviewed each of the 350+ cited references, he reasonably could not have concluded that the cited art, and Durand in particular, failed to disclose features **(1)-(3)**. *Ecto World*, Paper 13 at 5-6 (*Becton Dickinson* factor (e)). Overlooking Durand's key disclosures therefore was material error. And given that Durand discloses every feature PO said (and the Examiner was led to believe) was missing from the cited prior art (including Bolea), Durand also is not substantially the same as the art the Examiner applied.

Notably, despite Durand's clear disclosures, PO did not identify Durand as relevant to the claims or even attempt to correct the Examiner's mistaken belief about the content of the cited prior art in his Reasons for Allowance. *Ecto World*, Paper 13 at 6 ("the Board should consider ... any applicant information or assistance regarding the relevance of the references.") (*Becton Dickinson* factor (f)). Had PO been forthcoming, the resources of the Patent Office would not now be required to correct the material error that led to issuance of invalid claims.

PO is not forthcoming even now. PO does not address Durand's disclosures,

much less dispute that Durand discloses each of key limitations **(1)-(3)**. PO merely asserts that Durand was before the Examiner and then devotes the majority of its brief arguing that Ground 1's secondary reference—Hoegh—is duplicative of Bolea. Critically, however, the Petition applies Hoegh in a different manner than the Examiner applied Bolea during examination so that Hoegh is not duplicative “in relevant part.” *Advanced Bionics*, Paper 6 at 15, 19.

Specifically, the Petition relies on Hoegh for its disclosure of specific stimulation timing parameters (*i.e.*, the duration of stimulation relative to the inspiratory phase) and presents compelling reasons why a POSITA would have used Hoegh's timing parameters with Durand's asynchronous stimulation protocol. Pet. at §X.A.3. PO does not assert that the Examiner cited to Bolea only for its timing parameters, and PO has never disputed that Bolea (and thus corresponding paragraphs of Hoegh) discloses these timing parameters. Instead, as set forth above, PO took issue with the Examiner's application of Bolea to satisfy the claims' requirement for a stimulation treatment protocol that is asynchronous relative to patient breathing and wherein the duration of each stimulation period is based on a reference respiration-related parameter. But, as set forth above, the Petition relies on Durand for those limitations, and not Hoegh.

Thus, as to Ground 1, PO's focus on the overlap between Hoegh and Bolea misses the mark. The arguments presented in the Petition applying Hoegh differ in

material part from the way that the Examiner applied Bolea during prosecution. Thus, substantially the same arguments regarding Hoegh were not previously presented to the Examiner. The material error made by the Examiner was overlooking Durand's express disclosures of the key limitations he was led to mistakenly believe the cited art lacked.

B. Ground 2 is Not Cumulative

Ground 2, which is based on references not before the Examiner (Headley and Tran), also presents compelling evidence of unpatentability. Headley and Tran both disclose stimulation electrodes implantable in a patient's tongue and that employ asynchronous stimulation to treat OSA. Pet. at §X.B.1-2. Tran is more detailed, with Tran-II illustrating clinical results achieved with a stimulation cycle that has timing parameters based on the patient's typical nighttime respiratory rate, i.e., a "reference respiratory-related parameter." *Id.*; EX-1010, p. 4288, FIG. 4.

PO asserts that Ground 2 is cumulative of Ground 1, because Ground 2 relies "on substantially the same alleged timing parameters as Hoegh/Bolea." Req. at 14. But PO's comparison of the Grounds merely points out that Hoegh (Ground 1) and Tran (Ground 2) each disclose that a patient's "natural respiratory rhythm" is about 5 seconds and that the stimulation cycle closely mimics that natural rhythm. *Id.* This is a shallow similarity that any relevant prior art reference would have. The challenged claims require stimulation to be based on a reference respiratory-related

parameter, such as stable respiration. Thus, any relevant reference would be expected to disclose the typical respiratory timing parameters for humans.

That unremarkable similarity between Tran and Hoegh does not render them cumulative. Importantly, PO does not show how Tran and Hoegh are alike in “relevant part,” *i.e.*, with respect to whether they both disclose the purported key limitations that distinguished the challenged claims from the prior art. *Advanced Bionics*, Paper 6 at 15, 19. The references are not alike in relevant part. As set forth above, PO explicitly argued to the Examiner that Bolea (and Hoegh’s corresponding paragraphs) lacked a stimulation treatment protocol that is asynchronous relative to patient breathing, where the timing of the simulation cycle is based on a reference respiration-related parameter. Tran, however, plainly discloses those features:

In this method, we applied a brief train of electrical pulses during an ON period followed by no stimulation during an OFF period. This method of stimulation is repeated in continuous cycles at approximately the natural respiratory rhythm of the sleeping participant, obviating the need for a sensor to synchronize stimulation with breathing.

EX-1010, p.4288; Pet. at §X.B.2. The Petition applies Tran’s disclosure of these key features in Ground 2. Pet. at §X.B.4.a.v [1.c]. Given that they are the same limitations that PO persuaded the Examiner were missing from Bolea, Tran contributes at least this material difference in disclosure when compared to Bolea/Hoegh. Tran and Bolea/Hoegh therefore are not cumulative in relevant part,

and Ground 2 is not cumulative of Ground 1.

As to Ground 2’s primary reference—Headley, which was never considered by the Office—PO does not address its disclosures at all. Req. at 15. The Petition applies Headley’s disclosures extensively, including with respect to claim elements relating to the duration and rate of stimulation. *E.g.*, Pet. at §X.B.4.a.iii [1.b] & §X.B.4.f.ii [6.b]. As set forth in the Petition, the combination of Headley and Tran discloses the limitations that were key to patentability, further demonstrating that Ground 2 is not cumulative.

VI. THE *FINTIV* FACTORS WARRANT INSTITUTION

The *Fintiv* factors also warrant institution of review. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (March 20, 2020) (precedential) (“*Fintiv*”).

A. Factor 1: The District Court is Inclined to Consider a Stay

Factor 1 favors institution. Due to the previous stay in the litigation, substantive progress in district court remains in its early stages such that institution would occur at the beginning of fact discovery and prior to claim construction. Further, the district court has advised that it would consider a stay if the IPR is instituted. EX-2004. Thus, the litigation would be in prime position for another stay to limit issues and receive the benefit of the PTAB’s expertise in resolving the complex technological issues of prior art invalidity.

B. Factor 2: The court’s trial date is months after the Board’s statutory deadline

Factor 2 favors institution. The statutory deadline for the final written decision (“FWD”) is June 18, 2027—some six months earlier than the December 2027 trial. *American Airlines, Inc. et al. v. Intellectual Ventures I LLC*, IPR2025-00786 Paper 12 (Aug. 29, 2025) (denying request for discretionary denial where FWD would precede trial by nine months).

C. Factor 3: The Parties have Limited Investment in the District Court Litigation

Factor 3 favors institution. As held by the Board in *Fintiv*, “[i]f, at the time of the institution decision, the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution under *NHK*.” *Fintiv*, 10. No *Markman* or prior art invalidity orders have been issued or are expected before institution in the underlying litigation. Fact discovery has only just begun. EX-1049. No contentions have been exchanged. *Id.* PO has not identified its asserted claims. *Id.* At institution, much invalidity work would remain in that case. The *Markman* process will just be starting with the claim construction hearing still four months in the future. *Id.*

Moreover, Petitioners exercised significant diligence in bringing the IPR petitions, filing the petitions before any substantive progress in the litigation.

D. Factor 4: Overlap between issues raised in the petition and in the parallel proceeding.

Factor 4 favors institution. There has been no overlap between issues to date.

Contentions have not been exchanged. Furthermore, this IPR is so far out ahead of the litigation that the IPR will naturally streamline—not duplicate—efforts in the litigation, as Petitioners will face the prospect of statutory estoppel very early on. Indeed, in view of Petitioners’ *Sotera* stipulation (§III), there will be no overlap between the issues raised in the petition and issues to be adjudicated in the litigation.

E. Factor 5: Petitioners Being the District Court Defendants Does Not Outweigh the Factors Weighing Against Denial

Factor 5 is neutral. The Board has long recognized that it is commonplace for petitioners to be defendants and that does *not* weigh in favor of denial. *See HP Inc. v. Slingshot Printing LLC*, IPR2020-01084, Paper 13 at 9 (Jan. 14, 2021) (having the “same parties as parallel proceeding” makes factor 5 “neutral”).

F. Factor 6: The Merits of the Petition are Strong

Factor 6 strongly favors institution. As explained above, the Petition presents overwhelming evidence of invalidity. Both Grounds apply art that discloses the exact features the Examiner mistakenly believed were missing from the prior art. Integrity of the patent system counsels that the Director should not exercise discretion to prevent considering the strong merits of the Petition. *Fintiv*, 14-15.

VII. THE SETTLED EXPECTATIONS DOCTRINE DOES NOT WARRANT SHIELDING THE ’424 PATENT FROM REVIEW

The ’424 Patent issued on December 26, 2023, just two years before the Petition was filed. EX-1001 (cover (45)). Thus, the Patent is too young for the

Petition to be denied on that basis. *Shenzen Tuozhu Tech. Co., LTD v. Stratasys, Inc.*, IPR2025-00611, Paper 10 (Jul. 17, 2025) (rejecting settled expectations argument for denial because patents issued in 2020 had “not been in force for a significant period of time”).

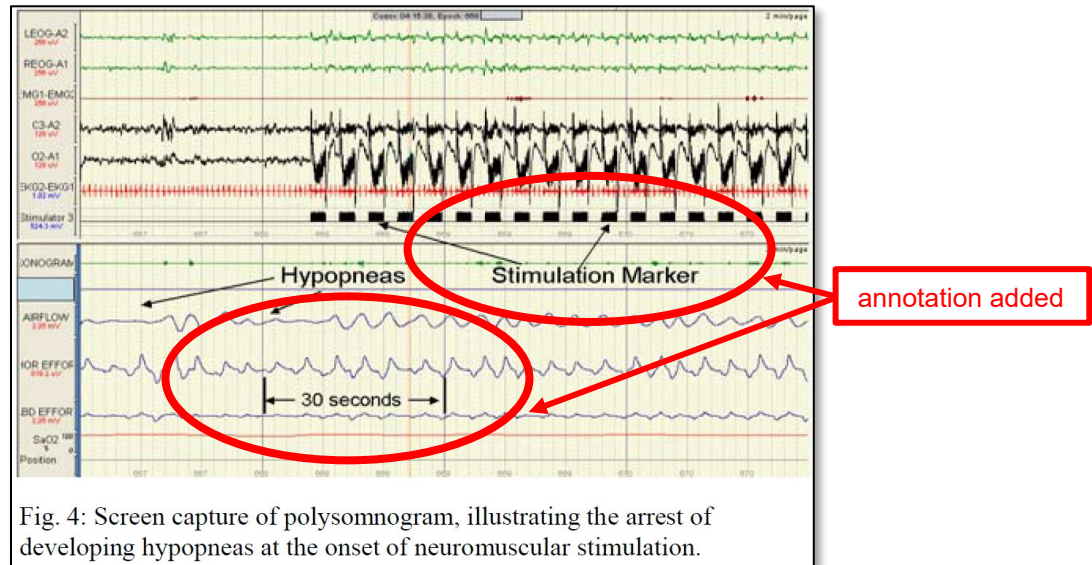
VIII. THE PETITION IS SUPPORTED BY REASONED EXPERT TESTIMONY CORROBORATED BY DOCUMENTARY SUPPORT

PO’s attack on the Petition’s reliance on Dr. Loeb’s expert testimony (EX-1003) fails for multiple reasons. As an initial matter, PO’s assertion that Dr. Loeb’s testimony is offered “to fill gaps in printed publication evidence” is without factual support, and ignores binding precedent regarding the allowable use of expert testimony. Req. at 15. Dr. Loeb’s testimony is factually supported by the prior art, demonstrates how a POSITA would have understood the references used in the Grounds, and should properly be considered by the Board. *Unification Techs. LLC v. Micron Technology Inc.*, 2024 WL 3738401, *5-6 (Fed. Cir. Aug. 9, 2024).

Further, PO’s allegations are factually accurate. First, as to the so-called “detailed numerical values” in his declaration, Dr. Loeb expressed those values as “approximately [X] seconds” and provided descriptions of and citations to the Tran references for support. EX-1003, ¶¶256, 273, 275, 296, 342, 356.

Second, PO incorrectly argues that the exact values of Dr. Loeb’s approximations are “central” to the Petition. Req. at 16. The challenged claims do not recite numerical values, but instead define the timing parameters in relative terms

(e.g., durations “based on,” “greater than,” “less than”). EX-1001, claims 1, 4, 6, 7, 18, 20. But even if Dr. Loeb’s approximations were “central” to the Petition, Tran-II’s FIG. 4 expressly discloses the relative timing parameters (including stimulation length via the “stimulation markers”) and their approximate values:



EX-1010 (Tran-II), FIG. 4 (red annotation added here to highlight 30 second time scale with two-second intervals that are shown in original document); EX-1003 ¶¶255-256 (“FIG. 4 of Tran-II is a screen capture of a polysomnogram of a patient, which shows the patient’s inspiratory phase to be approximately 2 seconds and the stimulation markers indicating an ON period [*stimulation period*] of approximately 2.5 seconds.”) (citing EX-1009 (Tran-I), p. 377; EX-1010 (Tran-II), FIG. 4).

In short, Dr. Loeb’s opinions do not rely on his personal knowledge to fill in purported missing information. He provides extensive citations to express factual support in Tran and explains the technical reasoning for his opinions, properly

complying with requirements to be given significant weight. 37 C.F.R. § 42.65(a).

Third, PO's attack on Dr. Loeb's credibility on the basis that the Petition states a value ("approximately 3 seconds") that is not exactly the same as reported by Dr. Loeb in his declaration ("approximately 2.5 seconds") is unfounded. A minor difference between the Petition (which Dr. Loeb did not author) and Dr. Loeb's sworn declaration does not render Dr. Loeb's testimony unreliable. PO does not dispute that Dr. Loeb's sworn declaration is consistent throughout.

Finally, PO's reliance on *Interactive Commc'ns Int'l, Inc. v. Blackhawk Network Inc.*, IPR2024-00465, Paper 40 (Dir. Oct. 9, 2025) to urge discretionary denial is misplaced. The problem there was not a minor difference between the Petition and the expert's declaration, but instead that the expert's deposition testimony on a material issue (*i.e.*, how a POSITA would have combined the prior art) conflicted with his prior sworn declaration. *Id.* at 4. Here, Dr. Loeb has not provided conflicting testimony on a material issue. Moreover, his declaration has not been tested through a deposition and, thus, any conclusions as to Dr. Loeb's credibility are premature. Discretionary denial is not warranted on that basis.

IX. CONCLUSION

Patent Owner has identified no legitimate basis for the Director to deny institution on any discretionary factors. Institution should be granted.

Date: March 31, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on March 31, 2026, a copy of the foregoing Petitioners' Opposition to Patent Owner's Request for Discretionary Denial of Institution and all supporting exhibits were served by electronic means to counsel of record in the present IPR:

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