UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NYXOAH, INC., and
NYXOAH SA,
Petitioner,

v.

INSPIRE MEDICAL SYSTEMS, INC.,
Patent Owner.

_____

IPR2026-00091
Patent 11,806,526

_____

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

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Exhibit No.	Description
2001	Complaint, *Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al.*, Case No. 1:25-cv-00667-RGA (D. Del.)
2002	Answer, *Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al.*, Case No. 1:25-cv-00667-RGA (D. Del.)
2003	Letter to The Honorable Richard G. Andrews regarding proposed revised case schedules (D.I. 70)
2004	Order Lifting Stay, entered March 2, 2026 (D.I. 71)

Nyxoah, Inc. and Nyxoah SA ("Petitioners" or "Nyxoah") have concurrently filed three IPR petitions, including the instant Petition, challenging the three patents asserted against them by Patent Owner Inspire Medical Systems, Inc. ("Inspire"), in the District of Delaware. The challenged patents are US Patent Nos. 10,898,709 (IPR2026-00090), 11,806,526 (IPR2026-00091), and 11,850,424 (IPR2026-00092). All three patents are titled "Stimulation for Treating Sleep Disordered Breathing" and have the same specification. All three IPR petitions include the same references used in two invalidity grounds: **Ground I**: Durand (Ex. 1006) in view of Hoegh (Ex. 1007); and **Ground II**: Headley (Ex. 1008) in view of Tran-I (Ex. 1009) and Tran-II (Ex. 1010).

I. INTRODUCTION

The Director should exercise his discretion to deny institution of the Petition for four independent reasons. ***First***, as discussed in Section III, two of the challenged patents have claims that recite "means for" elements. *See*, '526 Patent claims 1, 16, 22 ("*non-cardiac (stimulation) means for stimulating*"), and '424 Patent claims 1, 18, 20 ("*means for stimulating*"). Their respective petitions assert a "plain and ordinary meaning" construction without explaining why these terms are not means-plus-function limitations or, alternatively, identifying the corresponding structure in the specification. This violates 37 C.F.R. § 42.104(b)(3) and warrants denial. If even one petition is deficient, all three should be denied to

avoid duplicative PTAB and district court proceedings that waste resources and risk inconsistent outcomes.

Second, the Director should reject the instant Petition under 35 U.S.C. § 325(d). As discussed in Section IV, the Petition merely raises the same issues that the Office has already considered and rejected. For Ground 1, Petitioners admit that Durand was already considered during prosecution and cite Hoegh as if it were new art, but Hoegh reproduces almost verbatim the teachings of Bolea (Ex. 1012)—which the Examiner extensively considered in multiple Office Actions. Ground 2 is cumulative, relying on a set of Tran references to allegedly disclose timing parameters already disclosed in Bolea/Hoegh and considered by the Examiner.

Third, as discussed in Section V, the Petition relies on improper expert testimony. Petitioners' expert, Dr. Loeb, is a co-author of the two Tran references, and attempts to fill in factual gaps of the deficient Tran references with testimonial evidence.

Fourth, as discussed in Section VI, the District of Delaware is the superior forum. The same parties are litigating the same patents and raising the same validity issues. The District of Delaware can comprehensively resolve the disputes between the parties while properly handling the complex expert testimony issues presented here and eliminating the risk of inconsistent outcomes.

II. BACKGROUND

Inspire, based in Minneapolis, Minnesota, is a medical device company focused on treating obstructive sleep apnea ("OSA"). Inspire's neurostimulation technology for OSA treatment began with work at Medtronic in the 1990s. In 2007, Inspire's CEO, Tim Herbert, founded Inspire as a start-up company focused on continued research and development of the technology originally developed at Medtronic. Inspire has invested hundreds of millions of dollars in research and development.

In 2014, the FDA approved Inspire's implant, making it the first FDA-approved OSA neurostimulation therapy of its kind. Inspire's device has reportedly been implanted in over 100,000 patients.

Nyxoah is a medical device company based in Belgium. In July 2020, six years after Inspire introduced its revolutionary device, Nyxoah began selling its "Genio" device in Europe. Ex. 2001, ¶32. Nyxoah has publicly characterized itself as a "smart follower" of Inspire. Ex. 2001, ¶37. Indeed, in its May 2025 earnings call, Nyxoah stated: "It's always nice to be second, meaning that there was a lot of heavy lifting done by competition." *Id*.

On May 30, 2025, Inspire filed suit against Nyxoah in the District of Delaware, asserting infringement of three patents. *See Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al.*, Case No. 1:25-cv-00667-RGA (D. Del.). On August 25,

2025, Nyxoah answered the Complaint and asserted counterclaims seeking declaratory judgments of invalidity of all three Inspire patents. On December 18, 2025, Nyxoah filed these three IPR petitions challenging the same three patents.

On September 15, 2025, Nyxoah filed its own offensive patent infringement action against Inspire, asserting three Nyxoah patents, in the same District of Delaware. *See Nyxoah, Inc. et al. v. Inspire Medical Systems, Inc.*, Case No. 1:25-cv-01147-RGA (D. Del). Both cases are before the same Judge.

III. PETITIONS' FAILURE TO CONSTRUE "MEANS" WARRANTS DENIAL OF ALL PETITIONS TO AVOID INCONSISTENT DETERMINATIONS

The Petition asserts that "[e]ach claim term in the Challenged Claims should be given its plain and ordinary meaning in this proceeding." Pet. at 13. However, all claims of the '526 patent (and '424 patent) recite "means for" elements, and the Petition offers no further explanation of plain and ordinary meaning of the elements or why these elements should not be construed as means-plus-function terms, despite 37 C.F.R. § 42.104(b)(3). *See*, '526 Patent claim 1 ("*non-cardiac stimulation means for stimulating*") and claims 16, 22 ("*non-cardiac means for stimulating*"); *see also* '424 Patent claims 1, 18, 20 ("*means for stimulating*"). The Petition should be denied: (1) for failure to identify why such terms are not means-plus-function limitations, or in the alternative, (2) for failure to "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); PTAB Trial Practice Guide, Section II.B.6 ("A petitioner who chooses not to address construction under § 112(f) risks failing to satisfy the requirement of 37 C.F.R. § 42.104(b)(3).").

Petitioners have averred their products do not have the "means for stimulating" elements in the '526 patent, likely involving additional claim construction in the parallel district court case. Ex. 2002 at 52. Petitions posturing different constructions to the Board than in district court have been discretionarily denied. *Apple Inc. v. HBCU Messaging US LP,* IPR2025-01493, Paper 15, fn. 1 (Director Feb. 18, 2026) (citing *Revvo Technologies, Inc. v. Cerebrum Sensor Technologies, Inc.,* IPR2025-00632, Paper 20 (Director Nov. 3, 2025) (precedential)).

All three petitions involve intrinsically similar issues and should be denied for an efficient use of Office resources as these issues will be addressed by the district court. *Apple Inc. v. HBCU*, Paper 15, fn. 2.

IV. THE DIRECTOR SHOULD DECLINE INSTITUTION UNDER § 325(D)

Ground 1 relies on Durand—admittedly cited during prosecution—in combination with Hoegh (Ex. 1007). But Hoegh is the very same prior art that was already before the Examiner in the form of Bolea (Ex. 1012).

Hoegh and Bolea share the same listed assignee, Cyberonics, Inc., and both

applications share common subject matter. Critically, ***all*** portions of Hoegh that Petitioners rely upon are reproduced ***almost verbatim*** from Bolea.

Advanced Bionics, LLC v. Med-El Elektromedizinsche Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB. Feb. 13, 2020) provides a two-part framework when evaluating discretionary denial under 35 U.S.C. § 325(d): (1) whether the same or substantially the same art or arguments previously were presented to the Office; and (2) whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

The Petition uses portions of Hoegh that are substantially the same as the portions of Bolea used in prosecution. Petitioners provide no reasons why the Office erred in a matter of patentability material to Bolea or why Hoegh provides better evidence of the prior art than Bolea. The grounds are redundant with past prosecution.

A. Ground 1 Relies on Substantially the Same Prior Art Previously Presented to the Office

1. Durand Was Expressly Considered During Prosecution

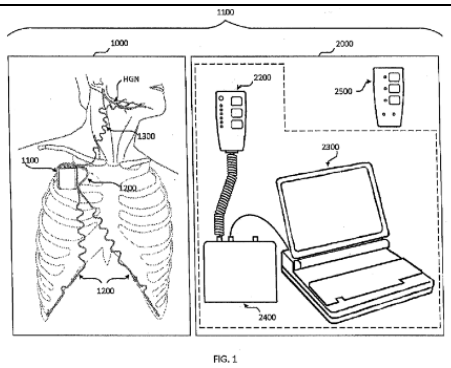
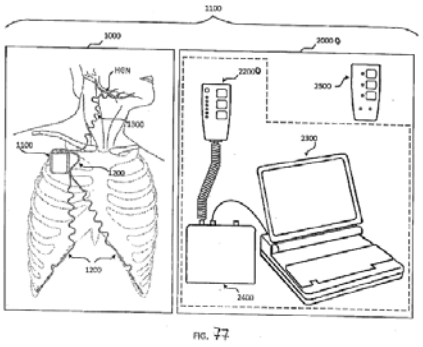
Petitioners admit that Durand, a published patent application, was considered during prosecution of the ’526 Patent because the patent corresponding to Durand (US 7,680,538) was cited in an IDS and considered by the Examiner. Pet. at 19. “Previously presented art includes … art provided to the Office by an applicant, such as on an Information Disclosure Sheet (IDS).” *Advanced Bionics*,

Paper 6 at 7–8.[1]

2. Hoegh Is The Same as Bolea, Which Was Extensively Considered During Prosecution

As cited in the Petition, Hoegh is the same as Bolea (U.S. Patent Application Publication No. 2014/0228905, Ex. 1012), which was extensively applied by the Examiner in at least two Office Actions. Critically, ***all*** portions of Hoegh relied upon by Petitioners in this Petition are found ***almost verbatim*** in Bolea.

Hoegh's relevant discussion of stimulation techniques was reproduced entirely from Bolea. The Petition cites FIG. 1 from Hoegh; which is taken directly from Bolea (even the reference numbers are the same):

 Hoegh's FIG. 1 (cited in Pet. at 23, 26)	 Bolea's FIG. 77

The Petition quotes Hoegh for various claim elements. Each of these quotes are found verbatim or near verbatim in Bolea. For example, the Petition quotes paragraph 97 of Hoegh for element 1.b, Pet. at 30; however, paragraph 97 of

[1] In addition, the Durand patent subsequently appeared in the Examiner's PE2E search history, *see* Ex. 1002 at 104.

Hoegh is a near verbatim copy of paragraph 498 of Bolea with only minor stylistic difference:

The stimulation duty cycle may be fixed or adaptive. In the fixed mode, *the stimulation duty cycle may be set* using the programmer system 2100 to designate a fixed percentage value. This fixed value may be increased when the respiratory period signal is lost, increasing the likelihood of aligning with actual inspiration… Thus, in some instances, the stimulation duty cycle may run above normal (e.g., above 50% to 60%) to achieve a better likelihood of covering the inspiratory phase.	The stimulation duty cycle may be fixed or adaptive. In the fixed mode, *the stimulation duty cycle is set* using to programmer system 2100 to a fixed percentage value. This fixed value may be increased when the respiratory signal is lost, increasing the likelihood of aligning with actual inspiration… Thus, in some instances, the stimulation duty cycle may run above normal (e.g., above 50% to 60%) to achieve a better likelihood of covering the inspiratory phase.
Pet. at 30 quoting Hoegh ¶97 (original emphasis removed; emphasis added)	Bolea at ¶498

As another example, consider paragraph 92 of Hoegh, which was quoted by the Petition for element 1.b, Pet. at 30, and the corresponding near verbatim disclosure in Bolea with only a minor stylistic difference:

To mimic this natural physiology, *stimulation may be delivered* to the hypoglossal nerve during the	To mimic this natural physiology, *it is desirable to deliver stimulation* to the hypoglossal nerve during the

inspiratory phase plus a brief pre-inspiratory period of about 300 ms.	inspiratory phase plus a brief pre-inspiratory period of about 300 ms.
Pet. at 30 quoting Hoegh ¶92 (original emphasis removed; emphasis added)	Bolea at ¶493 (emphasis added)

Indeed, ***every citation to Hoegh in the Petition is found in Bolea***:

Hoegh (Ex. 1007) citations	Bolea (Ex. 1012) matching disclosure	Hoegh (Ex. 1007) citations	Bolea (Ex. 1012) matching disclosure
FIG. 1 (Pet. at 25 and 28)	FIG. 77	¶92 (Pet. at 5, 25, 26, 30, 32, 37, 39, 46, 48 and 49)	¶493
¶50 (Pet. at 23 and 26)	¶423, 657	¶93 (Pet. at 32 and 38)	¶494
¶51 (Pet. at 26)	¶424, 658	¶96 (Pet. at 25, 41, 43, 46, 47, and 49)	¶497
¶53–59 (Pet. at 24)	¶427–433	¶97 (Pet. at 31, 37 and 40)	¶473, 498
¶69 (Pet. at 41)	¶450	¶98 (Pet. at 5, 25, 26, 41, 43, 46, and 52)	¶474, 499
¶82 (Pet. at 44)	¶483	¶114 (Pet. at 5, 23, 25, 32, 39, 40, 46, 49, 51 and 52)	¶515
¶85 (Pet. at 44)	¶486	¶134-137 (Pet. at 26)	¶589–592

That is, the ***Petition cites no portion of Hoegh which cannot also be found in Bolea***. Importantly, as described in more detail below, the Examiner specifically applied the cited subject matter of Bolea/Hoegh during prosecution.

3. Petitioners Have Not Even Attempted to Demonstrate Material Error by the Office

"If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review." *Advanced Bionics*, Paper 6

at 8–9.

Here, Petitioners have made no showing that the Examiner erred in evaluating Bolea/Hoegh. The Petition includes a single, conclusory sentence in the description of the prosecution history regarding Bolea:

> The Examiner, having been incorrectly persuaded by Applicant's arguments and apparently misapprehending or overlooking certain disclosures in Bolea, issued a Notice of Allowance ("NOA_1") on July 6, 2025.

Pet. at 12.[2]

Petitioners do not identify any specific finding or analysis by the Examiner that was erroneous. Nor do they point to any specific teaching that the Examiner misapprehended or overlooked.

4. The Office Applied the Same Passages of Hoegh/Bolea in Multiple Office Actions

More fundamentally, Petitioners cannot make such a showing because even

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[2] The Petition cites to Dr. Loeb's expert declaration, which includes some analysis of Bolea, but, critically, Dr. Loeb fails to explain why Hoegh provides a more compelling case of unpatentability than Bolea. Additionally, the Petition must contain all necessary arguments and cannot merely reference Dr. Loeb's expert declaration for them. *Cisco Systems, Inc. v. C-Cation Technologies, LLC,* IPR2014-00454, Paper 12 at 9–10 (PTAB Aug. 29, 2014).

their conclusory statement is wrong. The Examiner did not overlook or misapprehend Bolea/Hoegh. Just the opposite, the Examiner applied the very same passages from Hoegh in two Office Actions in the prosecution of the parent '709 patent and in yet another Office Action in the prosecution of the instant patent in the same manner as Petitioners now apply in the Petition. Ex. 1002 at 157–163. In the Final Office Action mailed November 2, 2022, the Examiner applied Bolea in a 103 rejection. *Id.* Notably, the Examiner cited the same passages of Bolea, including paragraph 473, that corresponds to a cited portion of Hoegh in the Petition:

> 5. Claims 1-18 and 20-24 are rejected under 35 U.S.C. 103 as being unpatentable over multiple embodiments of Bolea (US 2014/0228905 A1).
>
> 6. Regarding claim 1, Bolea discloses a device for treating obstructive sleep apnea (eg. Abstract, Para. 2-4), comprising: a non-cardiac stimulation element to stimulate an upper airway patency-related nerve (Eg. Abstract, Para. 361), according to a first stimulation protocol including alternating stimulation periods and non-stimulation periods in which a timing of the stimulation periods is asynchronous relative to patient breathing in multiple embodiments (eg. Para. 473 and 514, asynchronous stimulation), wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period (eg. Para. 460, 473-474, duty cycle values are non-limiting examples), and wherein the duration of each respective stimulation period is based on a reference respiratory-related parameter (eg. Para. 473-474).

Ex. 1002 at 157–158 (highlighting added); *see also* Table, *supra.*

The Examiner further applied Bolea in a §103 rejection in combination with another reference, Nakata. Ex 1002 at 162.

Even the Examiner's characterization of these passages considers specific features described in the Petition. *Compare* Pet. at 5 "Hoegh further discloses 'the maximum stimulation duty cycle may be set from 41% to 69%'" *with* OA (Ex. 1002 at 160) citing Bolea ("Para. 474 and 481, prior art lists the 69% duty cycle as a non-limiting example").

The Applicant submitted arguments and amended the claims, and the Examiner allowed the claims. That is, the Examiner ultimately determined that the cited teachings in Bolea/Hoegh, even in combination with other references, did not render the claims obvious.

In the "Reasons for Allowance," the Examiner stated that Bolea was the "closest prior art" but disclosed that "asynchronous is used for familiarization (e.g., Para. 514–515), but does not use it as therapy for sleep apnea." Ex. 1002 at 16. Notably, Petitioners cite the same passage (Hoegh ¶114/Bolea ¶515) repeatedly for allegedly disclosing asynchronous therapy for sleep apnea. *See* Table, *supra*. Hence, Petitioners simply reargue what the Examiner already rejected.[3]

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[3] Petitioners cannot claim that the use of Durand makes the combination with Hoegh/Bolea not cumulative. First, the Petition does not describe what Office

As *Advanced Bionics* instructs: "[I]f the alleged error is a disagreement with a specific finding of record by the Office, then ordinarily the petitioner's required showing of material error must overcome persuasively that specific finding of record." *Advanced Bionics*, Paper 6 at 10–11 (emphasis added). Here, the record is not silent. The Examiner made specific findings regarding the disclosure of Bolea/Hoegh with respect to the same features relied upon by the Petition. The Examiner then allowed the claims. These are specific findings of record that Petitioners must "overcome persuasively." *Id*. at 11. Petitioners have not done so. They simply present Bolea/Hoegh and argue invalidity as if the Examiner had not already considered that same subject matter.

B. Ground 2 Relies on Substantially the Same Alleged Timing Parameters as Hoegh/Bolea and Is Therefore Cumulative

In Ground 2, for the limitations regarding the relationship between the stimulation period, non-stimulation period, and reference respiratory cycle, Petitioners rely on the Tran references, but these allegedly disclose substantially the same information already considered by the Office in Bolea/Hoegh. Petitioners cite Tran for allegedly disclosing a "'**5 second respiration period**'" with "an ON

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error, if any, Durand purportedly corrects. Second, Durand is primarily relied on for basic structural features, such as implantable electrode and pulse generator, which the Petition also claims Hoegh/Bolea discloses. Petition at 26.

period [***stimulation period***] **of approximately 2.5 seconds**," which is "'followed by no stimulation during an OFF period…repeated in continuous cycles at approximately the natural respiratory rhythm.'" Pet. at 67–68 (citing Ex. 1009, p.377 and Ex. 1010, p.4288) (emphasis added).

Compare this to what Petitioners cite from Bolea/Hoegh for the same limitations in Ground 1: "Hoegh discloses that a patient's **respiratory cycle is about five seconds**." Pet. at 39 (citing Hoegh ¶114) (emphasis added).

As demonstrated above, Hoegh ¶114 is identical to Bolea ¶515, which the Examiner specifically applied in multiple office actions. This is analogous to *Advanced Bionics*, where the Board found that even though the petitioner cited multiple references, if the key limitations are disclosed by references presenting substantially the same information as previously considered, the ground as a whole is cumulative. *Advanced Bionics*, Paper 6 at 19.

Petitioners' reliance on Headley as the primary reference in Ground 2 does not change the cumulative nature of the ground. Petitioners admit that Headley "does not elaborate on these [treatment period] characteristics and parameters." Pet. at 56.

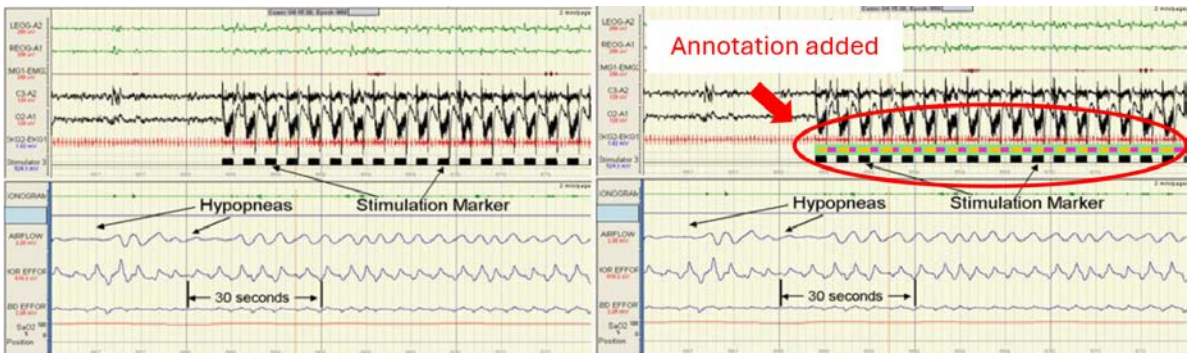
"[B]ased on the totality of the evidence presented," Ground 2, like Ground 1, "includes only 'the same or substantially the same prior art that was previously presented to the Office.'" *Advanced Bionics*, Paper 6 at 19.

V. DISCRETIONARY DENIAL WARRANTED WHEN EXPERT TESTIMONY ATTEMPTS TO FILL GAPS IN PRINTED PUBLICATION EVIDENCE

In support of Ground 2, Dr. Loeb has offered an expert declaration (Ex. 1003) regarding references that Dr. Loeb himself authored, Tran-I (Ex. 1009) and Tran-II (Ex. 1010)—a material fact not mentioned in the Petition or Dr. Loeb's declaration. Ex. 1009, Ex. 1010 (listing "G.E. Loeb" as the second author); *see also* Ex. 1003 at 253, 254 (listing Tran-I and Tran-II in article list). As a co-author, Dr. Loeb's declaration improperly attempts to fill factual omissions in the Tran references, and that testimony is not a printed publication, as required for IPR proceedings.

A. Petition's Use of Dr. Loeb's Personal Fact Testimony Is Not Statutory Printed Publication Prior Art

Tran-II is a short three-page article missing many technical details. The Petition repeatedly cites Tran-II's FIG. 4 (and an annotated version of FIG. 4) for allegedly disclosing timing parameters for stimulation and respiratory durations. Pet. at 6, 7, 55, 56, 64, 68, 71.



Tran-II FIG. 4 (left) and Annotated FIG. 4 (right) (Pet. at 7, 56)

Tran-II does not state the numerical values for the timing parameters for FIG. 4 used in the Petition; nor are these values evident from FIG. 4 itself. Nonetheless, Dr. Loeb states, in a conclusory manner, detailed numerical values without providing any underlying rationale for how he deduced these values from Tran-II. *See*, *e.g.*, Ex. 1003, ¶ 271. The annotations made to FIG. 4 are also not explained using underlying facts or data. *See, e.g.,* Pet. at 7, 56. These numerical values are central to Petitioner's argument. To the extent they are Dr. Loeb's approximation or interpretation of FIG. 4, such unexplained interpolation is improper expert testimony. 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.") In fact, annotated FIG. 4 in the instant Petition is not even found in the Declaration of Dr. Loeb submitted in this IPR proceeding.

And to the extent they are information that Dr. Loeb, as co-author, may recall from his direct research, but which is not stated in Tran-II, such personal, subjective experience is improper fact testimony. It is not the printed publication evidence required for use in IPRs. This warrants director denial of this IPR. District court litigation is a better forum for resolving Dr. Loeb's fact testimony than IPRs, which rely on printed publication evidence. 35 U.S.C. § 311(b).

B. The Petitions and Dr. Loeb Provide Inconsistent Assertions About What Tran-II Discloses

More telling, the Petition and Declaration make inconsistent statements

about the purported timing parameters of FIG. 4, which, again, are nowhere stated in Tran-II. For example, the Petition first asserts that the stimulation period in FIG. 4 is "approximately 3 seconds" and later asserts that the same stimulation period is "approximately 2.5 seconds". *Compare* Pet. at 6 ("Annotated **FIG. 4 of Tran-II** below illustrates an asynchronous stimulation cycle with **a stimulation period (ON period) of 3 seconds** and a non-stimulation period (OFF period) of 2 seconds."), *with* Pet. at 68 ("**FIG. 4 of Tran-II** … shows a two-second inspiratory phase and the stimulation markers indicating an **ON period [stimulation period] of approximately 2.5 seconds**.") (emphasis added).[4]

Further confusing the situation, Dr. Loeb's Declaration states that the stimulation period in FIG. 4 is "approximately 2.5 seconds," and not "approximately 3 seconds" as first asserted in the Petition. Ex. 1003, ¶ 271. Nowhere does Dr. Loeb's Declaration equate "approximately 2.5 seconds" to

[4] As another example of inconsistent statements, the instant Petition states that the inspiratory phase in FIG. 4 is 2 seconds, but the petition for IPR2026-0092 states that the same inspiratory phase is approximately 2.5 seconds. *Compare* Pet. at 68 ("FIG. 4 of Tran-II … shows a **two-second inspiratory phase**."), *with* IPR2026-0092 Pet. at 71 ("with **the inspiratory phase** illustrated in FIG. 4 of Tran-II **lasting approximately 2.5 seconds**") (emphasis added).

"approximately 3 seconds" for the stimulation period in Tran-II.

Thus, the Declaration and Petition provide contradictory statements that cast doubt on the reliability of the expert testimony. Contradictory and unreliable testimony has been found to be grounds for Director review and vacatur of IPR proceedings. *Interactive Commc'ns Int'l, Inc. v. Blackhawk Network Inc.*, IPR2024-00465, Paper 40 at 4 (Dir. Squires Oct. 9, 2025).

VI. DISTRICT COURT IS THE BETTER FORUM

A holistic application of the *Fintiv* framework strongly favors denying institution.

A. Risk of Inconsistent Outcomes and Duplication of Resources (Fintiv Factors 1, 2, 3)

The district court and the Board will simultaneously address claim construction. As of the date this brief is submitted, the parties contemplate claim construction briefing in September 2026 with a trial set to start December 13, 2027. Ex. 2003 at 5; Ex. 2004 at 1. Thus, the district court will be handling claim construction shortly after the expected institution decision (June 30, 2026). Certainly, by the time the Board would issue a final written decision, both the district court and the Board will be deeply invested in resolving the same issues.

In these petitions, Nyxoah asserts a "plain and ordinary" construction without explaining what that means to a POSITA or addressing the "means for" recitations in certain of the challenged patents. Section III, *supra*. Yet in district

court, Nyxoah argued that the same "means for" recitations are not present in its own accused product. Ex. 2002 at 52, 54. Nyxoah thus advances a broad construction to challenge validity in IPR while simultaneously reserving a narrower and unspecified construction to avoid infringement in district court. Gamesmanship of this nature risks inconsistent outcomes and wastes both district court and Board resources. Discretionary denial would eliminate such risks.

B. Identity of Parties and Complete Overlap of Issues (Fintiv Factors 4, 5)

The Petitioners are the same defendants in the district court case, and all three asserted patents are being challenged in the three IPR petitions, respectively. This identity of parties and complete overlap of patents at issue eliminates any efficiency justification based on non-overlapping issues, or non-parties seeking IPR review.

C. Grounds Based on Factual Testimony Better Suited for District Court (Fintiv Factor 6)

Both asserted grounds are obviousness grounds—not anticipation—and rely heavily on disputed expert testimony. Ground 1 combines two references already considered by the Office. Section IV.A, *supra*. Ground 2 combines three references supplemented by Dr. Loeb's fact testimony, which is not printed publication evidence required for IPR proceedings. Sections IV.B, V, *supra*.

VII. CONCLUSION

For the foregoing reasons, Inspire respectfully requests that the Director

exercise his discretion under 35 U.S.C. § 314(a) to deny institution.

Date: March 2, 2026

Respectfully submitted,
/Timothy Bianchi/
Timothy Bianchi
Reg. No. 39,610

Tyler Nasiedlak (Reg. No. 40,099)
Adeel Haroon (Reg. No. 64,938)

Schwegman, Lundberg & Woessner P.A.
Counsel for Patent Owner

CERTIFICATE OF SERVICE

I hereby certify that on March 2, 2026, I caused a true and correct copy of the following materials:

- Patent Owners Request for Discretionary Denial
- Ex. 2001 – Complaint, *Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al.*, Case No. 1:25-cv-00667-RGA (D. Del.)
- Ex. 2002 – Answer, *Inspire Medical Systems, Inc. v. Nyxoah, Inc. et al.*, Case No. 1:25-cv-00667-RGA (D. Del.)
- Ex. 2003 – Letter to The Honorable Richard G. Andrews regarding proposed revised case schedules (D.I. 70)
- Ex. 2004 – Order Lifting Stay, entered March 2, 2026 (D.I. 71)

To be served on Petitioner via electronic mail to

Jared Gunther
Monte Squire
Patrick McPherson
Daniel Tarr
Diana Sangalli
DUANE MORRIS LLP
jmgunther@duanemorris.com
mtsquire@duanemorris.com
pdmcpherson@duanemorris.com

dtarr@duanemorris.com

dmsangalli@duanmorris.com

Date: March 2, 2026

Respectfully submitted,
/Timothy Bianchi/
Timothy Bianchi
Reg. No. 39,610

Tyler Nasiedlak (Reg. No. 40,099)
Adeel Haroon (Reg. No. 64,938)

Schwegman, Lundberg & Woessner P.A.
Counsel for Patent Owner