

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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EMBODY, INC. AND ZIMMER BIOMET HOLDINGS, INC.,  
Petitioner

v.

LIFENET HEALTH,  
Patent Owner.

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Case No. IPR2025–00249  
U.S. Patent No. 11,318,227

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**PATENT OWNER’S REQUEST FOR DISCRETIONARY DENIAL**  
**37 C.F.R. § 42.20(d)**

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## **LIST OF EXHIBITS**

### **Patent Owner's Exhibits**

| 2001 | U.S. Patent Application Publication No. 2012/0221025, published Aug. 30, 2012 (“Simpson”) |
|------|-------------------------------------------------------------------------------------------|
| 2002 | WO 2012/078472, published June 14, 2012 (“Patel”)                                         |

## I. INTRODUCTION

Patent Owner LifeNet Health (“LifeNet” or “Patent Owner”) submits this Request for Discretionary Denial in response to the Petition for *Inter Partes* Review filed by Embody. Inc. and Zimmer Biomet Holdings, Inc. (“Petitioner”), by which Petitioner challenges claims 1–8 of U.S. Patent Number 11,318,227 (“the ’227 patent”). Paper 2 (“Petition” or “Pet.”). Patent Owner’s Request is filed pursuant to the March 26, 2025, Memorandum entitled “Interim Processes for PTAB Workload Management,” and within two months of the Notice of Filing Date Accorded. *See* Interim Processes for PTAB Workload Management, available at <https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf>; *see also* Paper 5; Paper 6.

Patent Owner will file a Preliminary Response addressing the merits of the Petition pursuant to 37 C.F.R. § 42.107(a) on the schedule set forth by regulation and consistent with the March 26, 2025, Memorandum. *See* 37 C.F.R. § 42.107(b).

As detailed below, Patent Owner respectfully requests that the Director exercise discretion to deny institution under 35 U.S.C. § 325(d) and *Advanced Bionics*.<sup>1</sup> Petitioner presents prior art that is substantially the same as prior art that was previously considered by the U.S. Patent and Trademark Office (“USPTO” or

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<sup>1</sup> *Advanced Bionics, LLC v. MED–EL Elektromedizinische Geräte GmbH*, IPR2019–01469, Paper 6 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).

“Office”) during prosecution of the ’227 patent. Indeed, the Examiner rejected the patent application’s claims over prior art that is substantially the same as the art asserted here. Petitioner fails to even acknowledge these prior art rejections advanced by the Examiner during prosecution. Pet. 16–20, 64–65.

Despite facial similarities in structure, function, and the manner in which Petitioner applied the prior art, Petitioner provides nothing more than the bare and conclusory assertion that the Petition’s prior art is “noncumulative” to that considering during prosecution. Pet. 64. And even though Petitioner foresaw the applicability of § 325(d), Petitioner fails to even *allege* Examiner error in its Petition. *Id.* at 65.

Accordingly, § 325(d) and *Advanced Bionics* favor exercise of discretion to deny institution and Patent Owner respectfully requests that the Petition be denied.

## **II. THE ’227 PATENT**

### **A. The ’227 Patent**

#### **1. A scaffold comprising electrospun fibers**

The ’227 patent is directed to a “scaffold comprising an aligned fiber.” Ex. 1001, Abstract, 13:23–29. This scaffold may be used to facilitate growth of, for example, bone, ligament, or tendon tissue, *id.* at 11:28–57, and may be incorporated into biocompatible implants used for, e.g., “repairing or restoring tissues damaged by disease or trauma.” *Id.* at 16:18–20. “The invention also relates to methods of treating a tissue or organ defect or injury, for example, a musculoskeletal, dental or

soft-tissue defect or injury, in an animal comprising administering ... the aligned fiber, electrospun fiber, scaffold and/or implant described herein to the tissue or organ defect (e.g. osseous defects, defects in cartilage, ligament, tendon, spinal disk, and tendon insertion site to bone).” *Id.* at 18:54–62; *see also id.* at 16:53–17:5 (disclosing nerve repair).

The ’227 patent discloses that scaffolds comprising aligned fibers may be formed by electrospinning. *Id.* at 13:23–25. Through electrospinning techniques, fibers may be formed “as small as one nanometer.” *Id.* at 2:42–44. The ’227 patent discloses embodiments in which the electrospun fibers are aligned in one direction and formed into an elongated roll, elongated sheets, a composite of multiple layers of sheets, or a combination thereof. *Id.* at 8:26–35. The ’227 patent further explains that these scaffolds may comprise collagen. *Id.* at 13:50–14:2.

Finally, the ’227 patent discloses that cells may be seeded and cultured on the disclosed scaffolds. *Id.* at 10:56–57, 16:26–27. “In some embodiments, the cells are selected from ... stem cells, adipose derived stem cells, dental pulp stem cells, fibroblasts, and dorsal root ganglia.” *Id.* at 16:27–30; *see also id.* at 16:43–52 (describing conditions). The ’227 explains that “differentiation of stem cells into osteoblasts, chondrocytes, ligament or tendon” may be promoted by “culturing the cells on the scaffold or aligned fiber described herein in conditions suitable for the cell differentiation.” *Id.* at 1:31–35; *see also id.* at 16:54–18:17.

## 2. Fast Fourier transform analysis

To measure alignment of the scaffold's fibers, the '227 patent employs a fast Fourier transform ("FFT") analysis. *Id.* at 13:38–49. This technique is further described in a 2008 publication, to which Petitioner states that its declarant, Dr. David G. Simpson, is the senior author, and which the '227 patent incorporates by reference. *Id.*; Pet. 11; Ex. 1003 ¶ 62.<sup>2</sup>

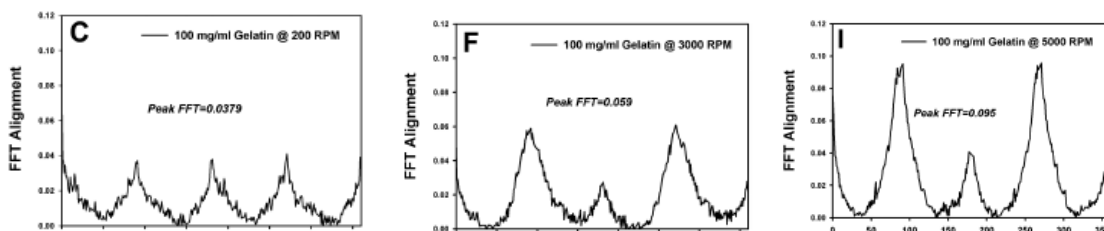
Dr. Simpson's 2008 paper describes using FFT analysis "to measure fiber alignment in electrospun materials." Ex. 1010, Abstract. With this approach, "[t]he 2D FFT function converts spatial information in an optical data image into a mathematically defined frequency domain," which "maps the rate at which pixel intensities change in the spatial domain." *Id.* at 608.<sup>3</sup>

Dr. Simpson's 2008 paper provides three examples of the results of an FFT analysis, shown below in Figures 1C, 1F, and 1I.

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<sup>2</sup> Petitioner refers to two of Dr. Simpson's papers as the "Ayres" papers because Chantal E. Ayres is the first-named author. Ex. 1010; Ex. 1013; *see, e.g.*, Pet. 11. However, Dr. Simpson is listed as a co-author on each paper, and Petitioner states that Dr. Simpson is the "senior author" of the 2008 paper. Pet. 11; Ex. 1003 ¶ 62. For clarity in recognizing the relationship between Petitioner's declarant and these papers, Patent Owner refers to them as Dr. Simpson's papers.

<sup>3</sup> For consistency with Petitioner's briefing, Patent Owner cites to the native page numbering in the exhibits.



Ex. 1010, 608 at Figs. 1C, 1F, 1I. Consistent with the figures shown above, Dr. Simpson’s 2008 paper explains that the FFT analysis result for “a random matrix will exhibit 4 peaks that occur every 90°. Peaks of nearly uniform height are a hallmark of a scaffold composed of random elements.” *Id.* at 609, Fig. 1C. By contrast, “plots generated from sample scaffolds containing aligned elements exhibit asymmetrical peaks, two larger peaks at 90 and 270° and two smaller peaks at 0 and 360° (Fig. 1F and I).” *Id.* at 610.

Similarly, the ’227 patent explains that the FFT analysis result of the claimed scaffold with aligned fibers shows “adjacent major peaks with about 180° apart from each other,” where “major peaks” “refer to peaks higher than the average of the peaks in the result.” Ex. 1001, 13:25–29. This is depicted in Figure 8A of the ’227 patent, reproduced below alongside Figure 8B.

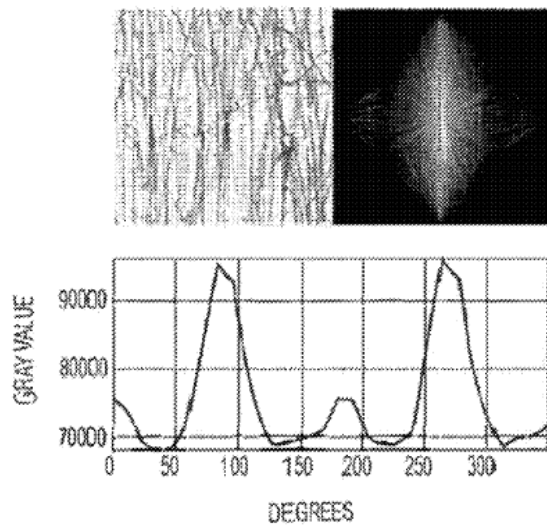


**FIG. 8A**

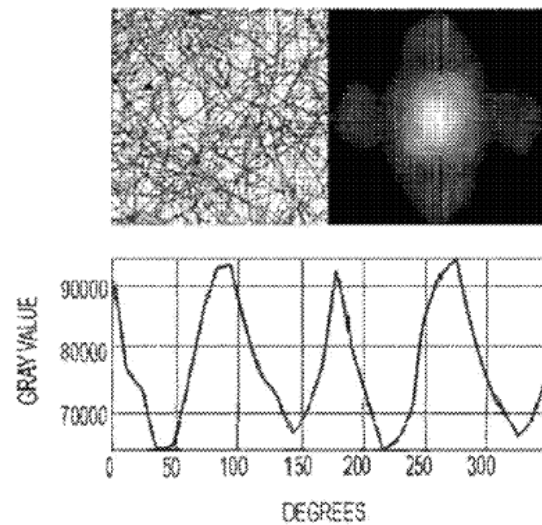


**FIG. 8B**

*Id.* at 13:46–49. “FIG. 8A depicts exemplary FFT analysis results of the [aligned] fibers described herein . . . Fig. 8B depicts an FFT analysis of a control sample.”

*Id.* at 2:10–12. As shown, the FFT analysis result for aligned fibers in the ’227 patent shows adjacent major peaks with about 180° apart from each other (Figure 8A), while non-aligned fibers do not (Figure 8B). *Id.* at 13:46–49.

## **B. The ’227 Patent Claims**

Of the ’227 patent’s 14 issued claims, only claims 1–8 are challenged in the Petition. Pet. 1, Ex. 1001, 23:29–24:14; Pet. 1. Of the challenged claims, claims 1 and 7 are independent and recite:

1. A method of treating a tissue defect in a subject comprising[:]  
implanting at the tissue defect a scaffold comprising crosslinked fibers comprising collagen, wherein a result of a fast Fourier transform (FFT) analysis of the fibers demonstrates that the fibers have major adjacent peaks that are about 180° apart from each other, and

applying the scaffold to the tissue defect to repair a tendon, a ligament or a nerve defect.

7. A method of cell culture comprising[:]

placing cells on a scaffold comprising aligned fibers, wherein a result of a FFT analysis of the fibers demonstrates that the fibers have major adjacent peaks that are about 180° apart from each other, and growing the cells in conditions suitable for the cell culture.

Ex. 1001, 23:29–37, 24:5–11.

### **C. Prosecution of the '227 Patent**

U.S. Patent Application No. 16/045,159 (the “'159 application”) was filed on July 25, 2018, and ultimately issued as the '227 patent. Ex. 1001, codes 21–22. The '159 application is a divisional of U.S. Patent Application No. 14/776,106 (“the '106 application”), now U.S. Patent No. 10,137,223,<sup>4</sup> which is the national stage of PCT Application No. US2014/025636, filed March 13, 2014, and which claims priority to U.S. Provisional Patent Application No. 61/785,031, filed on March 14, 2013. *Id.* at codes 60, 62. The '159 application was filed with 24 application claims, which were cancelled in a preliminary amendment and replaced with new claims 25–35. Ex. 1002–1, 1–4.

Notably, Petitioner’s summary of the prosecution history of the '159 application is incomplete. *See* Pet. 16–20. Petitioner alleges that prosecution

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<sup>4</sup> U.S. Patent No. 10,137,223 is challenged by Petitioner in IPR2025-00248.

“focused primarily on 35 U.S.C. § 112, with the Examiner rejecting the presented claims as both indefinite and non-enabled.” Pet. 19. The Examiner did indeed issue rejections based on § 112, on December 24, 2020 (*see* Ex. 1002–2, 491–497) and on July 19, 2021 (*id.* at 532–537). However, as part of the Examiner’s July 19, 2021, Office Action, the Examiner also rejected pending application claim 26 under 35 U.S.C. § 102(b) as anticipated by two pieces of prior art that are substantially the same as that presented in the Petition. *Id.* at 537–538.<sup>5</sup> These prior art rejections, which Petitioner does not discuss, bear directly on the Director’s discretion to deny institution under 35 U.S.C. § 325(d).

Specifically, with respect to the prior art, and as pertinent to Patent Owner’s request for discretionary denial under 35 U.S.C. § 325(d), the Examiner rejected application claim 26 as anticipated under 35 U.S.C. § 102(b) by Simpson,<sup>6</sup> which the Examiner found taught “construction of fibrous scaffolds (see e.g. ¶0035) which is anisotropic (see e.g. ¶0011). The fibers comprise collagen (see e.g. 0049). These

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<sup>5</sup> The Examiner also issued an obviousness-type double patenting rejection over pending U.S. patent application 16/989,307 as part of that Office Action. Ex. 1002–2, 538–539.

<sup>6</sup> U.S. Patent Application Publication No. 2012/0221025, published Aug. 30, 2012 (“Simpson,” Ex. 2001). The first-named inventor appears to be the same David Simpson that submitted an expert declaration for Petitioner in this proceeding.

are used to repair nerve damage (see e.g. abstract). The fiber anisotropy is measured using Transform analysis (see e.g. ¶0100).” *Id.* at 538.

The Examiner also rejected application claim 26 as anticipated by Patel,<sup>7</sup> which the Examiner found taught “construction of fibrous scaffolds with collagen (see e.g. ¶0189) which is anisotropic (see e.g. ¶0323). These are used to repair tendon, ligament or nerve damage (see e.g. ¶0168). As evidenced above, the fiber anisotropy is measured using Fourier Transform analysis.”<sup>8</sup> *Id.*

After the Examiner’s rejections, the applicant cancelled application claim 26, among others, and amended several pending claims. *Id.* at 648–650 (claims), 651. The applicant also provided argument against the Examiner’s enablement rejection. *Id.* at 652–653.

The applicant and Examiner conducted an interview on February 8, 2022, *id.* at 662–663, and the Office allowed the ’159 application thereafter, which issued as the ’227 patent, on February 28, 2022. Ex. 1002–2, 664–670.<sup>9</sup>

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<sup>7</sup> WO 2012/078472, published June 14, 2012 (“Patel,” Ex. 2002).

<sup>8</sup> The Examiner’s rejection mistakenly referred to Patel as “Yeo et al.” Ex. 1002–2, 538. During an interview, the Examiner clarified that the reference to “Yeo” was incorrect. *Id.* at 636.

<sup>9</sup> Minor amendments were made after allowance to correct a minor typographical error. Ex. 1002–2, 685–691 (deleting “and ,” and adding --and-- from application claim 25).

### III. LEVEL OF SKILL IN THE ART

At this stage of the proceeding, Patent Owner does not raise a dispute regarding Petitioner’s identified level of skill possessed by a person of ordinary skill in the art (“POSITA”). Pet. 20–21.

### IV. CLAIM CONSTRUCTION

At this stage of the proceeding, Patent Owner does not raise a dispute regarding Petitioner’s assertion that claim construction is not necessary. Pet. 21.

### V. PETITIONER’S ASSERTED GROUNDS AND EVIDENCE

#### A. The Asserted Grounds of Unpatentability

Petitioner alleges that:

- 1) claims 1–6 are obvious under 35 U.S.C. § 103 over Huang<sup>10</sup> and Kuo,<sup>11</sup>
- 2) claims 1–6 are obvious under 35 U.S.C. § 103 over Lee<sup>12</sup> alone, or over Lee and Kuo,
- 3) claims 7–8 are anticipated under 35 U.S.C. § 102 by Huang<sup>2</sup>.

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<sup>10</sup> Huang et al., *The involvement of integrin  $\beta$ 1 signaling in the migration and myofibroblastic differentiation of skin fibroblasts on anisotropic collagen-containing nanofibers*, 33 *Biomaterials* 1791–1800 (Feb. 2012) (“Huang2,” Ex. 1005).

<sup>11</sup> Kuo et al., U.S. Patent Application No. US 2011/0293685 A1, published Dec. 1, 2011 (“Kuo,” Ex. 1018).

<sup>12</sup> Lee et al., U.S. Patent Application No. US 2010/0331980 A1, published Dec. 30, 2010 (“Lee,” Ex. 1011).

Pet. 4 (identifying § 103 over “Lee in view of Kuo”), 45 (identifying § 103 over “Lee alone or in view of Kuo”).

## **B. The Asserted Prior Art**

Each of Petitioner’s asserted grounds relies upon prior art that is substantially the same as prior art that was previously considered by the Office. Specifically, the primary references asserted by Petitioner – Huang<sup>2</sup> and Lee – are substantially the same as, and cumulative to, Simpson and Patel, over which the Examiner rejected pending application claim 26.<sup>13</sup> *See supra* Section II.C.

The Petition also relies heavily upon the testimony of Petitioner’s expert, Dr. David G. Simpson, in support of the asserted grounds. *See, e.g.*, Pet. 7. However, the Examiner already considered *four* of Dr. Simpson’s publications during prosecution and nonetheless determined to allow the claims. *See, e.g.*, Ex. 1001, code (56) (listing U.S. Patent Application Publications Numbers 2002/0090725, 2004/0037813, 2012/0221025, and Simpson’s 2008 paper); *see supra* Section II.A.2 n.2.

The Director need not revisit the Examiner’s conclusions in view of these cumulative materials. Institution should be denied given (1) the substantial similarity between the prior art applied by the Examiner and that asserted in the

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<sup>13</sup> Petitioner relies upon Kuo primarily for its teaching of repairing specific tissues, e.g., ligaments, tendons, and nerves. *See, e.g.*, Pet. 22–23.

Petition, (2) Petitioner's failure to identify Examiner error, and (3) the redundant nature of Petitioner's proffered expert testimony.

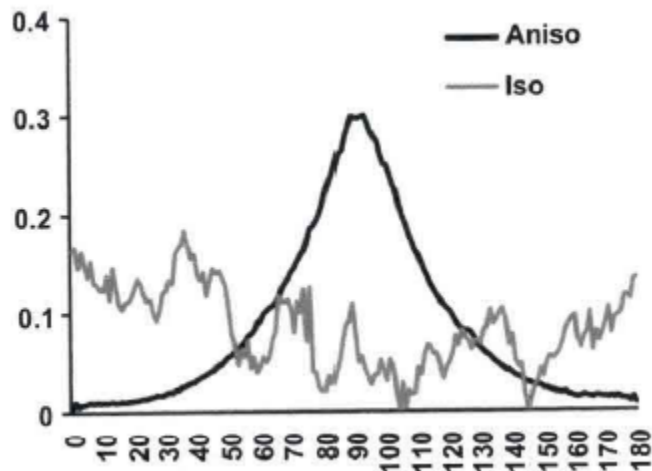
### **1. Huang2**

Huang2 discloses scaffolds for skin tissue repair. Ex. 1005, Abstract ("skin wound repair"). Huang2 explains that, "[t]o better support and facilitate skin cells to form skin-like tissues, it is necessary for the temporary scaffolds not only to provide a surface for the cells to reside, but also to define a cell-friendly microenvironment that maximally recaptures the native extracellular matrix (ECM)." *Id.* at 1791. To best mimic the ECM, Huang2 provides an electrospun scaffold made from a blend of collagen and polycaprolactone (PCL). *Id.*

Huang2 discloses that "[t]he orientation of electrospun nanofibers was determined by using the ImageJ program (NIH) along with the Oval Profile Plot plugin ... These cropped images were then processed with a fast Fourier transform (FFT)." *Id.* at 1792. Huang2's Figure 1C is reproduced below, depicting "[n]ormalized intensity plots against the angle of acquisition for isotropic and anisotropic nanofibrous matrices."<sup>14</sup> *Id.* at 1793, Fig. 1C.

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<sup>14</sup> Huang2 defines "isotropic" as "fibers collected randomly with no alignment" and "anisotropic" as "fibers collected with alignment." Ex. 1005, Abstract.



*Id.* Huang2 explains that “[t]he narrow peak of the normalized intensity values in anisotropic matrices (Fig. 1C) indicated that PCL/Coll nanofibers aligned along a single axis (Fig. 1B). In contrast, the lack of significant peak for the fibers collected on a stationary surface demonstrated no preferred fiber orientation in the isotropic matrices (Fig. 1C).” *Id.* at 1794.

To facilitate skin repair, Huang2 discloses that fibroblast cells are “seeded on the nanofibrous matrices” and cultured for up to 7 days. *Id.* at 1792. Huang2 concludes that its scaffold was successful in repairing skin tissue, reporting that “NHDFs [normal human dermal fibroblasts] cultured on anisotropic PCL/collagen nanofibers showed elongated cell morphology, distinct distribution of focal adhesions, accelerated cell migration and promoted fibroblast-to-myofibroblast differentiation.” *Id.* at 1799.

## 2. Lee

Lee discloses scaffolds for muscle tissue repair. *See, e.g.*, Ex. 1011 ¶ 2 (“The present invention ... involves the engineering of muscle tissues.”). Lee explains that “it is preferable to mimic native skeletal muscle construction, with its highly-oriented fibers of fused mononucleated muscle cells.” *Id.* ¶ 4. To that end, Lee discloses “muscle implants including: a biodegradable scaffold comprising a plurality of fibers oriented along a longitudinal axis of the fibers; and mammalian myotubes in said scaffold and oriented along said longitudinal axis of the fibers.” *Id.* ¶ 5. Lee also discloses that the scaffold may be formed by electrospinning collagen, optionally with other synthetic polymers like PCL. *Id.* ¶ 6.

Lee does not disclose FFT analysis of the scaffolds. *See generally id.* Lee examines the scaffolds, e.g., with scanning electron microscopy and by performing tensile testing. *Id.* ¶¶ 65, 67.

To facilitate muscle tissue repair, Lee also discloses that human skeletal muscle cells (hSkMCs) were seeded on Lee’s scaffold. *Id.* ¶¶ 72–73; *see also id.* ¶¶ 60. After being cultured on the scaffold, “[t]he cells fused and formed myotubes.” *Id.* ¶ 82.

## **VI. THE DIRECTOR SHOULD EXERCISE DISCRETION TO DENY INSTITUTION UNDER 35 U.S.C. § 325(d)**

### **A. 35 U.S.C. § 325(d) Favors Discretionary Denial**

35 U.S.C. § 325(d) permits the Director to deny institution of a proceeding where “the same or substantially the same prior art or arguments previously were presented to the Office.” This statutory discretion “reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 9.

In evaluating this discretion, the Office applies a “two-part framework” considering (1) whether the same or substantially the same prior art or arguments previously were presented to the Office; and (2) if so, “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Id.* at 8. PTAB precedent is clear that if part 1 of this framework is satisfied, and if “the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review.” *Id.* at 9.

Patent Owner urges the Director to exercise discretion to deny here because substantially the same prior art previously was presented to the Office. Specifically, the Examiner rejected the application claims based on Simpson and Patel, which are cumulative to Huang<sup>2</sup> and Lee. *See supra* II.C. Moreover, Petitioner does not even attempt to show material error.

**1. Simpson is substantially the same as Huang<sup>2</sup> and Lee and was presented to the Office previously.**

**a) The Examiner applied Simpson.**

As discussed above, the Examiner rejected application claim 26 as anticipated by Simpson. Ex. 1002–2, 537–538. The Examiner found that Simpson discloses “fibrous scaffolds which [are] anisotropic. The fibers comprise collagen. These are used to repair nerve damage (see e.g. abstract). The fiber anisotropy is measured using Transform analysis.” *Id.* (citing Simpson (Ex. 2001) ¶¶ 11, 35, 49, 100).

In more detail, and as before the Examiner, Simpson discloses that “the invention provides nerve guides which are formed from three dimensional (3D) arrays of highly aligned electrospun fibers.” Ex. 2001 ¶¶ 2, 18 (“The invention provides nerve guides formed from electrospun fibers for use in the directed regeneration of damaged or severed peripheral nerves. The technique of static air-gap electrospinning is used to generate cylindrical, seamless three dimensional (3D) arrays of highly aligned electrospun fibers oriented in parallel with the long axis of the construct.” Simpson discloses that “such fibers can be made from, e.g., collagen or PCL. *Id.* ¶¶ 49, 61–62 (“Natural proteins including collagens ... may also be used in the air gap electrospinning system to produce 3D nerve guides.”).

Simpson also explains that “[t]he relative degree of fiber alignment and the principal angle of fiber orientation were determined for each of the construct formulations using the 2D FFT method.” *Id.* ¶ 100. Simpson’s Figures 9A–9C

depict FFT alignment, where Figure 9A reflects constructs produced from 50–125 mg/ml solutions; Figure 9B reflects alignment of constructs produced from 150–200 mg/ml solutions; and Figure 9C reflects alignment of constructs produced from 225–275 mg/ml solutions. *Id.* ¶ 33.

Simpson explains that unlike with conventional systems, “varying the PCL concentration and/or increasing the average fiber diameter had little effect on fiber alignment in scaffolds produced by the air gap system.” *Id.* ¶ 117; *see also id.* ¶¶ 61–62 (explaining that collagen may be used in the air gap system). However, Simpson noted that “[s]caffolds produced from the 50–100 mg/ml solutions contained structural elements that partially degraded alignment values. These scaffolds each exhibited a characteristic shoulder in the 2D FFT alignment plot (occurring at about 180°).” *Id.* ¶ 117. “[C]onstructs produced from starting concentrations of 125–200 mg/ml lacked th[is] distinct shoulder ... [and] were incrementally more aligned than scaffolds produced from the 50–100 mg/ml solutions (FIG. 9B). A similar trend was observed in scaffolds prepared from the starting solutions of 225–275 mg/ml and these samples displayed the highest degree of fiber alignment (FIG. 9C).” *Id.* ¶ 117; *see also id.* ¶ 33.

Simpson's Figures 9A–9C are reproduced below.

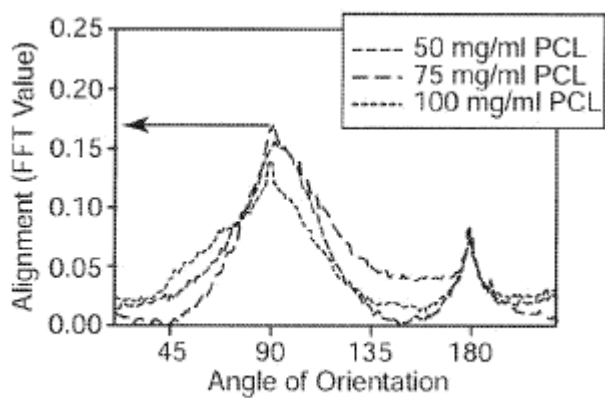


*Figure 9A*

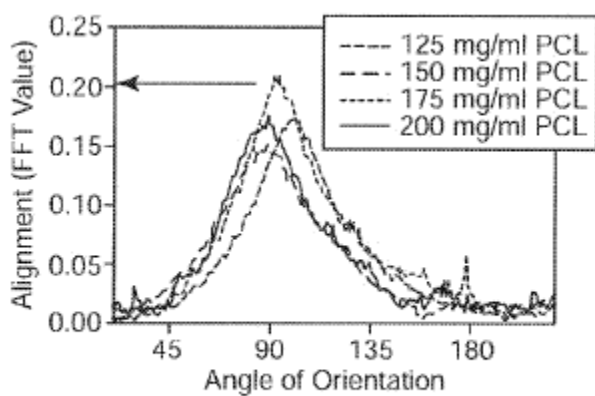


*Figure 9B*

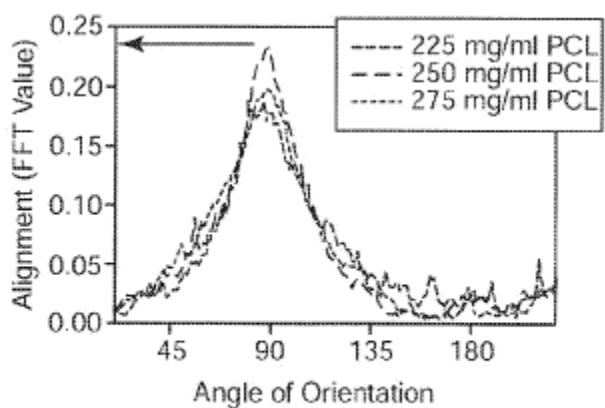


*Figure 9C*

Figures 9A–9C depict FFT an “[a]nalysis of fiber alignment by 2D FFT,” with Figure 9C depicting the most highly aligned fibers. *Id.* ¶¶ 33, 117.

Finally, Simpson also discloses that cells may be cultured on the fibers to facilitate the regeneration of damaged or severed peripheral nerves. *Id.* ¶¶ 18–19. “Because the air gap electrospinning process is very rapid it is possible to place substances of interest, e.g. cells ... within the scaffold as the fibers are depositing into the fiber arrays. The supplementation of the guides with growth factors and/or cells, etc. can be used to further regulate the regenerative environment afforded by the scaffolds.” *Id.* ¶ 19.

**b) Simpson is cumulative.**

Petitioner alleges that the Petition’s prior art is new and noncumulative but provides no discussion or analysis to support that conclusory statement. Pet. 64–65 (simply noting that these references were not before the Examiner, but not addressing whether they are substantially the same).<sup>15</sup> And Petitioner’s conclusion

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<sup>15</sup> Although Petitioner purports to reserve a “right” to respond to Patent Owner’s § 325(d) arguments, Petitioner has no such right by statute or regulation. *See infra* Section VI.A.3. Although the March 26, 2025, Memorandum authorizes Petitioner to respond to this brief, the Petition’s failure to address a required element of the § 325(d) analysis should not be overlooked. Indeed, because Petitioner failed to present any allegation of error, Patent Owner is deprived of an opportunity to respond effectively. To the extent the Director is not inclined to deny the Petition after Petitioner’s responsive brief, Patent Owner respectfully requests an opportunity to respond to Petitioner’s brief to address any arguments regarding 35 U.S.C. § 325(d).

is wrong: Simpson is cumulative to Huang2 and Lee. Therefore, the Director should defer to the previous Office evaluation and deny with respect to each challenged claim. *Advanced Bionics*, IPR2019-01469, Paper 6 at 9.

When considering whether newly cited prior art is substantially the same as that previously presented to the Office, the Office considers whether the new prior art (Huang2 and Lee) presents a different structure that serves a different purpose from that disclosed in the previously presented prior art (Simpson). *See Oticon Med. AB v. Cochlear Ltd.*, IPR2019-00975, Paper 15 at 15–16 (PTAB Oct. 15, 2019) (precedential). The Office also considers whether Petitioner relies upon the newly cited prior art (Huang2 and Lee) in substantially the same manner as the Examiner relied upon the previously presented prior art (Simpson). *Advanced Bionics*, IPR2019-01469, Paper 6 at 15–19.

### **(1) Substantially the same structure**

Simpson, considered by the Examiner, discloses substantially the same structure as Huang2 and Lee. *See Oticon*, IPR2019-00975, Paper 15 at 15. Specifically, each reference teaches:

- An aligned electrospun fiber scaffold.
  - o *Compare* Ex. 2001 (Simpson) ¶¶ 2 (“highly aligned electrospun fibers”), 35 (“scaffolds”),

- *with* Ex. 1005 (Huang2), Abstract (“anisotropic (*i.e.*, fibers collected with alignment)”), 1791 (“scaffolds”; “electrospun nanofibrous matrices”)
- *and* Ex. 1011 (Lee) ¶¶ 52 (“aligned electrospun mesh”), 54 (“scaffolds are formed by the electrospinning technique”).
- The fiber scaffold is formed of materials including collagen.
  - *Compare* Ex. 2001 (Simpson) ¶¶ 61–62 (disclosing PCL and collagen),
  - *with* Ex. 1005 (Huang2), 1792 (disclosing PCL/collagen blends)
  - *and* Ex. 1011 (Lee) ¶ 63 (disclosing collagen optionally blended with PCL).
- The alignment of the fiber scaffold is evaluated, including by FFT in Simpson and Huang2 (Lee does not disclose FFT).
  - *Compare* Ex. 2001 (Simpson) ¶ 100 (“the relative degree of fiber alignment was measured ... [with the] 2D fast Fourier transform (2D FFT) function” and citing Dr. Simpson’s 2008 paper),
  - *with* Ex. 1005 (Huang2), 1792 (determining “[t]he orientation of electrospun nanofibers ... with a fast Fourier transform (FFT)” and also citing Dr. Simpson’s 2008 paper)

- *and* Ex. 1011 (Lee) ¶¶ 65–67 (characterizing “electrospun PCL/collagen nanofiber meshes” with “scanning electron microscopy,” UTHSCSA ImageTool 3.0, and “tensile properties”).
- The scaffold is seeded with cells to facilitate repair of specific types of tissue.
  - *Compare* Ex. 2001 (Simpson) ¶¶ 18 (“for use in the directed regeneration of damaged or severed peripheral nerves”), 19 (“it is possible to place substances of interest, e.g. cells ... within the scaffold as the fibers are depositing into the fiber arrays”),
  - *with* Ex. 1005 (Huang2), Abstract (“skin wound repair”), 1792 (“fibroblasts were seeded on the nanofibrous matrices”)
  - *and* Ex. 1011 (Lee) ¶¶ 2 (“engineering of muscle tissues”), 72 (“hSkMCs were seeded onto the electrospun meshes”).

Thus, the Petition’s newly applied prior art does not present a substantially different structure than that of Simpson. Rather, Huang2 and Lee disclose substantially the same structure, i.e., aligned fiber scaffolds comprising collagen that are seeded with specific cell types.

## (2) Substantially the same purpose

Additionally, Simpson, previously considered by the Examiner, discloses the same purpose as Huang2 and Lee. *See Oticon*, IPR2019-00975, Paper 15 at 15–16. Specifically, each reference fabricates the scaffold described above for use in

repairing specific types of tissues. *Compare* Ex. 2001 (Simpson) ¶ 2 (“for use in nerve regeneration”), *with* Ex. 1005 (Huang2), Abstract (“for skin wound repair”) *and* Ex. 1011 (Lee) ¶ 52 (“for skeletal muscle regeneration”). Among the three pieces of prior art, only Simpson repairs nerve tissue as claimed.

Simpson also discloses the same additional purpose of cell culture as Huang2 and Lee with respect to independent claim 7. *Compare* Ex. 2001 (Simpson) ¶¶ 120–128 (disclosing “Cell Culture Experiments ... DRGs [dorsal root ganglia] were implanted directly into the cylindrical scaffolds”), *with* Ex. 1005 (Huang2), 1792 (disclosing “Cell seeding and culture onto nanofibrous matrix ... fibroblasts were seeded on the nanofibrous matrices”) *and* Ex. 1011 (Lee) ¶ 72 (disclosing “Cell adhesion and proliferation ... hSkMCs were seeded onto the electrospun meshes”).

### **(3) Substantially the same manner**

Finally, Petitioner relies upon Huang2 and Lee in substantially the same manner as the Examiner relied upon Simpson. Specifically, like the Examiner who found Simpson to be anticipatory, Petitioner asserts that Huang2 and Lee teach nearly every limitation of challenged claims 1–6 and relies on Kuo only with respect to the specific type of tissue to be repaired; Petitioner also asserts that Huang2 anticipates each limitation of challenged claims 7–8. *Compare* Ex. 1002–2, 538 (anticipation by Simpson), *with* Pet. 28–45, 59–63 (analysis of Huang2’s teachings) *and* 45–59 (analysis of Lee’s teachings).

The additional testimony of Petitioner’s declarant, Dr. Simpson, does not substantially alter the manner of reliance. As noted above, the Examiner already considered much of Dr. Simpson’s work. And the declaration offered here, to support Petitioner’s allegations regarding the understanding and applicability of FFT, adds nothing more than what the Examiner would have already considered in Dr. Simpson’s 2008 paper, which is referenced in Simpson and the ’227 patent. Ex. 2001 ¶ 167; Ex. 1001, 13:39–46.

#### **(4) Conclusion**

Because the newly cited prior art to Huang2 and Lee presents substantially the same structure and purpose as Simpson, and where Petitioner presents the references in substantially the same manner as the Examiner applied Simpson, this prior art is “substantially the same prior art” as that presented during prosecution. Accordingly, *Advanced Bionics* instructs that the Director consider whether Petitioner has shown Examiner error. It has not. *See infra* Section VI.A.3.

### **2. Patel is substantially the same as Huang2 and Lee and was presented to the Office previously.**

#### **a) The Examiner applied Patel.**

As discussed above, the Examiner rejected application claim 26 as anticipated by Patel. Ex. 1002–2, 537–538. The Examiner found that Patel taught “construction of fibrous scaffolds with collagen which is anisotropic. These are used to repair tendon, ligament or nerve damage. As evidenced above, the fiber anisotropy is

measured using Fourier Transform analysis.” *Id.* at 538 (citing Ex. 2002 (Patel) ¶¶ 168, 189, 323.

In more detail, and as before the Examiner, Patel discloses “fibrous scaffolds with at least one layer of diametrically patterned polymer fibers,” used “for the repair of wounds.” Ex. 2002 ¶ 2. Patel explains that electrospun collagen fibers may be used. *Id.* ¶ 114. Patel discloses that, depending on the tissue to be repaired, aligned fibers may be utilized. For example, “[i]n several aspects, diametrically aligned layers of polymer fibers comprise biodegradable polymers. These layers can be used to guide the morphogenesis of tissue types having anisotropic structure, *e.g.*, biological tissues such as nerve, skin, blood vessel, skeletal muscle, cardiac muscle, tendon and ligament. These diametrically aligned layers can also be used in the development of three-dimensional tissue constructs. Using the scaffolds described herein, three-dimensional constructs of nerve tissue, spinal cord tissue, skin tissue, vascular tissue, muscle tissue, and many other tissues can be created.” *Id.* ¶ 168.

Finally, Patel also discloses that cells may be cultured on the fibers. “Cells were seeded onto membranes having different types of nanofiber alignment (8A: random, 8B: uniaxial, 8C: diametrical) and were allowed to migrate into an induced gap defect.” Ex. 2002 ¶ 41; *see also id.* ¶¶ 318–320 (details of cell culture experimentation). Patel explains that, “[o]n randomly oriented nanofibers, the MSC [mesenchymal stem cells] population showed a correspondingly random orientation

and the wound coverage after 7 days was distinctly incomplete with very few cells reaching the center of the wound.” *Id.* ¶ 320. “The uniaxially aligned fibers induced corresponding uniaxial alignment of the cells and the wound coverage was much greater.... [but] cell migration was much faster along the axis of fiber alignment than perpendicular to that axis.”. *Id.* Finally, with respect to “diametrically patterned fibers, the cells oriented toward the center of the wound at all points around the periphery, and migration was subsequently enhanced toward the center from all directions. Wound coverage on the diametrical fibers was nearly complete after 7 days with only a few small areas remaining uncovered.” *Id.*

**b) Patel is cumulative.**

Petitioner alleges that the Petition’s prior art is new and noncumulative but provides no discussion or analysis to support that conclusory statement. Pet. 64–65 (simply noting that these references were not before the Examiner, but not addressing whether they are substantially the same). And Petitioner’s conclusion is wrong: Patel is cumulative to Huang2 and Lee.

As discussed above, when considering whether newly cited prior art is substantially the same as that previously presented to the Office, the Office considers whether the new prior art (Huang2 and Lee) presents a different structure that serves a different purpose from that disclosed in the previously presented prior art (Patel). *Oticon*, IPR2019-00975, Paper 15 at 15–16. The Office also considers whether

Petitioner relies upon the newly cited prior art (Huang2 and Lee) in substantially the same manner as the Examiner relied upon the previously presented prior art (Patel). *Advanced Bionics*, IPR2019-01469, Paper 6 at 15–19.

**(1) Substantially the same structure**

Patel, considered by the Examiner, discloses substantially the same structure as Huang2 and Lee. *See Oticon*, IPR2019-00975, Paper 15 at 15. Specifically, each reference teaches:

- An aligned electrospun fiber scaffold.
  - *Compare* Ex. 2002 (Patel) ¶¶ 2 (“fibrous scaffolds”), 74 (“individual fibers within the membrane can be diametrically aligned during electrospinning”),
  - *with* Ex. 1005 (Huang2), Abstract (“anisotropic (*i.e.*, fibers collected with alignment)”), 1791 (“scaffolds”; “electrospun nanofibrous matrices”)
  - *and* Ex. 1011 (Lee) ¶¶ 52 (“aligned electrospun mesh”), 54 (“scaffolds are formed by the electrospinning technique”).
- The fiber scaffold is formed of materials including collagen.
  - *Compare* Ex. 2002 (Patel) ¶ 17 (disclosing PCL and collagen, including blends),
  - *with* Ex. 1005 (Huang2), 1792 (disclosing PCL/collagen blends)

- *and* Ex. 1011 (Lee) ¶ 63 (disclosing collagen optionally blended with PCL).
- The alignment of the fiber scaffold is controlled (neither Patel nor Lee disclose FFT).
  - *Compare* Ex. 2002 (Patel), Abstract (“[T]he extent and direction of alignment of each layer can be controlled.”), ¶ 235 (“The alignment of the fibers depositing on the collector is directly influenced by the arrangement, geometries, and electrical charges of the various elements within the electrospinning area.”),
  - *with* Ex. 1005 (Huang2), 1792 (determining “[t]he orientation of electrospun nanofibers ... with a fast Fourier transform (FFT)” and citing Dr. Simpson’s 2008 paper), 1794 (“A majority of the fibers (~90%) collected on the rotating mandrel aligned in the same direction as the rotation.”)
  - *and* Ex. 1011 (Lee) ¶¶ 65–67 (characterizing “electrospun PCL/collagen nanofiber meshes” with “scanning electron microscopy,” UTHSCSA ImageTool 3.0, and “tensile properties”), 90 (“[T]his study was designed to fabricate nanofiber meshes that are aligned in a unidirectional manner.”).
- The scaffold is seeded with cells to facilitate repair of specific types of tissue.

- *Compare* Ex. 2002 (Patel) ¶¶ 78 (“to patch and/or regrow tissue in a subject, particularly ... surgical wounds, non-surgical wounds, biopsy defects, and areas of tissue damage or trauma”), 318 (“human mesenchymal stem cells (MSCs) were then seeded at confluency on the membranes around the periphery of each disk”),
- *with* Ex. 1005 (Huang2), Abstract (“skin wound repair”), 1792 (“fibroblasts were seeded on the nanofibrous matrices”)
- *and* Ex. 1011 (Lee) ¶¶ 2 (“engineering of muscle tissues”), 72 (“hSkMCs were seeded onto the electrospun meshes”).

Thus, the Petition’s newly applied prior art does not present a substantially different structure than that of Patel. Rather, Huang2 and Lee disclose substantially the same structure, i.e., aligned fiber scaffolds comprising collagen that are seeded with specific cell types.

## (2) Substantially the same purpose

Additionally, Patel, considered by the Examiner, discloses the same purpose as Huang2 and Lee. *See Oticon*, IPR2019-00975, Paper 15 at 15–16. Specifically, each reference fabricates the scaffold described above for use in repairing specific types of tissues. *Compare* Ex. 2002 (Patel), ¶ 2 (“for the repair of wounds”), *with* Ex. 1005 (Huang2), Abstract (“for skin wound repair”) *and* Ex. 1011 (Lee) ¶ 52 (“for skeletal muscle regeneration”). Among the three pieces of prior art, only Patel

is used to repair tendon, ligament, or nerve tissue as claimed. Ex. 2002 (Patel) ¶ 2. (“for the repair of wounds ... ligaments, ... nerves, ... tendons”).

Patel also discloses the same additional purpose of cell culture as Huang2 and Lee, with respect to independent claim 7. *Compare* Ex. 2002 (Patel) ¶ 41 (“Cells were seeded onto membranes having different types of nanofiber ... and were allowed to migrate into an induced gap defect”), *with* Ex. 1005 (Huang2), 1792 (disclosing “Cell seeding and culture onto nanofibrous matrix ... fibroblasts were seeded on the nanofibrous matrices”) *and* Ex. 1011 (Lee) ¶ 72 (disclosing “Cell adhesion and proliferation ... hSkMCs were seeded onto the electrospun meshes”).

### **(3) Substantially the same manner**

Finally, Petitioner relies upon Huang2 and Lee in substantially the same manner as the Examiner relied upon Patel. Specifically, like the Examiner who found Patel to be anticipatory, Petitioner asserts that Huang2 and Lee teach each limitation of challenged claims 1–6 and relies on Kuo with respect to the specific type of tissue to be repaired; Petitioner also asserts that Huang2 anticipates each limitation of challenged claims 7–8. *Compare* Ex. 1002–2, 538 (anticipation by Patel), *with* Pet. 28–45, 59–63 (analysis of Huang2’s teachings) *and* 45–59 (analysis of Lee’s teachings).

Petitioner’s added testimony of its declarant, Dr. Simpson, does not substantially alter the manner of reliance. As noted above, the Examiner already considered much of Dr. Simpson’s work. And the declaration offered here, to

support Petitioner’s allegations regarding the understanding and applicability of FFT, adds nothing more than what the Examiner would have already considered in Dr. Simpson’s 2008 paper, which is referenced in the ’227 patent. Ex. 1001, 13:39–46.

#### **(4) Conclusion**

Because the newly cited prior art to Huang<sup>2</sup> and Lee presents substantially the same structure and purpose as Patel, and where Petitioner presents the references in substantially the same manner as the Examiner applied Patel, this prior art is “substantially the same prior art” as that presented during prosecution. Accordingly, *Advanced Bionics* instructs that the Director consider whether Petitioner has shown Examiner error. It has not.

#### **3. Material error is not shown.**

It is Petitioner’s burden to show material error. *Advanced Bionics*, IPR2019-01469, Paper 6 at 9 (“If ... the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review.”). Material error is not shown where reasonable minds can differ about the Office’s prior treatment of the art or arguments. *Id.* at 9.

As discussed above, the Examiner applied Patel and Simpson to the application claims and provided supporting citations that linked the Examiner’s analysis to the prior art disclosures. *See supra* Section II.C. The Examiner did not maintain the rejections after the applicant cancelled application claim 26. *Id.*

The Petition fails to even *acknowledge* the Office’s prior consideration of Patel or Simpson, much less demonstrate material error in the Examiner’s consideration of the art. Pet. 18–20, 64–65. Instead, Petitioner purports to “reserve the right to respond” to “show[] ... that the Examiner erred.” *Id.* at 65. When the Petition was filed, Petitioner had no such right. Indeed, neither statute nor regulation permits a reply as of “right”; rather, the Board’s regulations authorize a reply only upon “a showing of good cause.” 37 C.F.R. § 42.108(c). The Board generally finds good cause to be lacking where an issue was reasonably foreseeable and could have been addressed in a party’s principal brief. *See, e.g., Seko S.P.A. v. CM2W JSC*, IPR2020–01636, Paper 8 at 5 (PTAB Dec. 2, 2020) (denying reply).

Although the March 26, 2025, Memorandum authorizes Petitioner to file a response to Patent Owner’s instant briefing, Petitioner’s failure to address material error in its Petition should not be overlooked. Indeed, Petitioner devoted five pages of the Petition to the prosecution history but failed to even mention the Examiner’s application of Simpson or Patel to the application claims. Pet. 16–20. Nowhere in this discussion did Petitioner allege Examiner error. Petitioner has the burden to show Examiner error and should have presented its arguments in the Petition. Petitioner’s attempt to reserve a right to respond demonstrates that it foresaw the applicability of § 325(d) but declined to address it in its Petition. Pet. 65.

Because the Petition did not address material error, Patent Owner is deprived of the opportunity to meaningfully respond, apart from noting the Examiner's diligent application of the prior art to the claims, in which the Examiner identified support for their findings of fact and conclusions of law. To the extent the Director is not inclined to deny the Petition after Petitioner's responsive brief, Patent Owner respectfully requests an opportunity to reply to address Petitioner's arguments regarding 35 U.S.C. § 325(d).

## **VII. CONCLUSION**

Because the prior art asserted in the Petition is substantially the same as that previously considered by the Office, and because "[P]etitioner fails to make a showing of material error," Patent Owner requests that the Director "exercise discretion not to institute *inter partes* review." *Advanced Bionics*, IPR2019-01469, Paper 6 at 9.

Dated: April 4, 2025

Respectfully submitted,

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**Certification under 37 C.F.R. § 42.24(d)**

I hereby certify that this preliminary response, excluding its table of contents, table of authorities, certification under 37 C.F.R. § 42.24(d), and certificate of service has 6763 words as counted by Microsoft Word, the word-processing system used to prepare this preliminary response.

Dated: April 4, 2025

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**Certification of Service**

Pursuant to 37 C.F.R. § 42.6, the undersigned certifies that on April 4, 2025, a copy of the foregoing document and attached exhibits were served by electronic mail upon the following counsel of record for Petitioner:

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