

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

LIFENET HEALTH,
Patent Owner.

Case No. IPR2025–00248
U.S. Patent No. 10,137,223

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

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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 1–12 of U.S. Patent Number 10,137,223 (“the ’223 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 7.

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*.¹ 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

¹ *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 ’223 patent. Indeed, the Examiner rejected the patent application’s claims over prior art that is substantially the same as the art asserted here.

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. 68. And even though Petitioner foresaw the applicability of § 325(d), Petitioner fails to even *allege* Examiner error in its Petition. *Id.*

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 ’223 PATENT

A. The ’223 Patent

1. A scaffold comprising electrospun fibers

The ’223 patent is directed to a “scaffold comprising an aligned fiber.” Ex. 1001, Abstract, 13:1–7. This scaffold may be used to facilitate growth of, for example, bone, ligament, or tendon tissue, *id.* at 9:45–56, and may be incorporated into biocompatible implants used for, e.g., “tissue augmentation, contouring, restoring physiological function, repairing or restoring tissues damaged by disease

or trauma, and/or delivering therapeutic agents to normal, damaged or diseased organs and tissues.” *Id.* at 15:61–65.

The ’223 patent discloses that scaffolds comprising aligned fibers may be formed by electrospinning. *Id.* at 13:1–3. Through electrospinning techniques, fibers may be formed “as small as one nanometer.” *Id.* at 2:17–19. The ’223 patent discloses embodiments in which the electrospun fibers are aligned in one direction and may be formed into an elongated roll, elongated sheets, a composite of multiple layers of sheets, or a combination thereof. *Id.* at 8:1–5, 8:10–16. The ’223 patent further explains that these scaffolds may comprise collagen. *Id.* at 13:27–46.

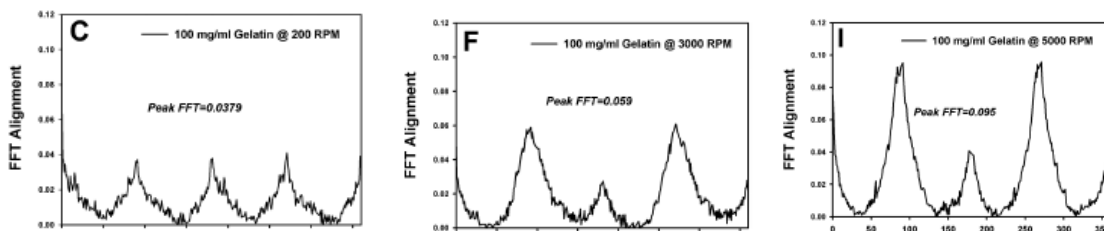
2. Fast Fourier transform analysis

To measure alignment of the scaffold’s fibers, the ’223 patent employs a fast Fourier transform (“FFT”) analysis. *Id.* at 13:16–26. 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 ’223 patent incorporates by reference. *Id.*; Pet. 12; Ex. 1003 ¶ 61.²

² 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. 12, 30. 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. 12; Ex. 1003 ¶ 61. For clarity in recognizing the relationship between Petitioner’s declarant and these papers, Patent Owner refers to them as Dr. Simpson’s papers.

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 608.³

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



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.

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

Similarly, the '223 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, 13:3–7. This is depicted in Figure 8A of the '223 patent, reproduced below alongside Figure 8B.

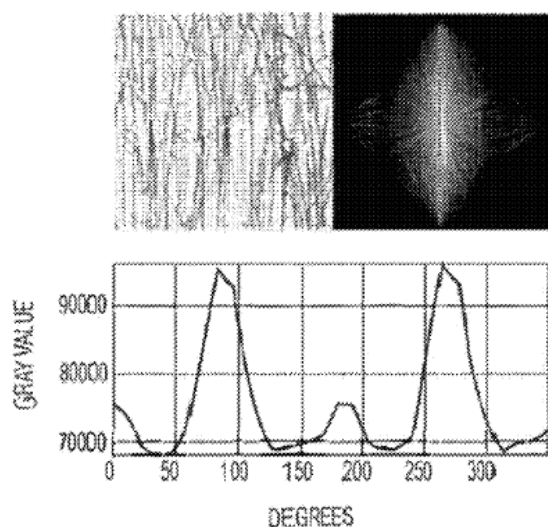


FIG. 8A

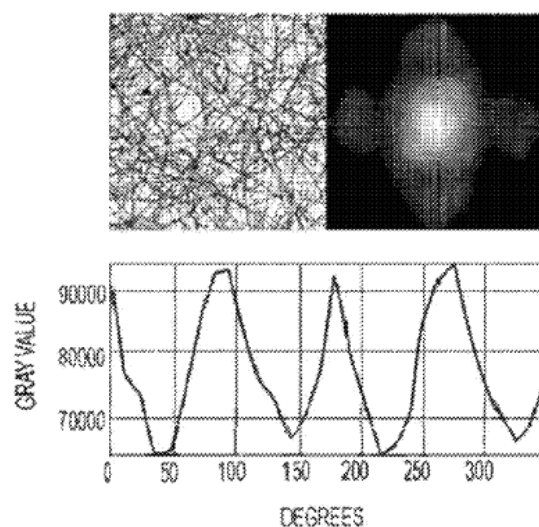


FIG. 8B

Id. at 13:24–26. The '223 patent explains that “FIG. 8 depicts exemplary FFT analysis results (a) of the [aligned] fibers described herein and (b) a control sample.”

Id. at 1:56–57. As shown, the FFT analysis result for aligned fibers in the '223 patent shows “adjacent major peaks with about 180° apart from each other” (Figure 8A), while non-aligned fibers do not (Figure 8B). *Id.* at 13:24–26.

B. The '223 Patent Claims

Of the '223 patent's 15 issued claims, only claims 1–12 are challenged in the Petition. Pet. 1; Ex. 1001, 23:6–24:27. Claim 1, the only independent claim challenged by Petitioner, recites:

1. A scaffold comprising one or more electrospun fibers comprising collagen, wherein a fast Fourier transform (FFT) analysis result of the fibers have adjacent major peaks with about 180° apart from each other.

Ex. 1001, 23:6–9.

C. Prosecution of the '223 Patent

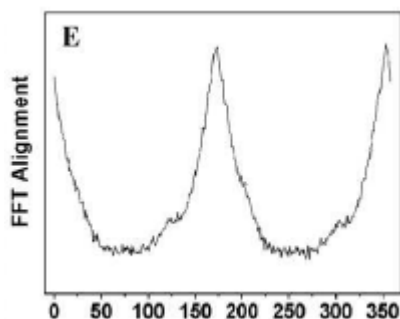
U.S. Patent Application No. 14/776,106 (the "'106 application") was filed on September 14, 2015, and ultimately issued as the '223 patent.⁴ The '106 application is the national stage of PCT Application No. US2014/025636, filed March 13, 2014, and which claims priority to U.S. Provisional Patent Application No. 61/785,031, filed on March 14, 2013. The '106 application was filed with 31 application claims. Ex. 1002–1, 48–51.

⁴ A divisional of the '223 patent, U.S. Patent No. 11,318,227, is challenged by Petitioner in IPR2025-00249.

During prosecution, and as pertinent to Patent Owner's request for discretionary denial under 35 U.S.C. § 325(d), the Examiner issued one office action advancing two prior art rejections. Ex. 1002–1, 208–219.

First, the Examiner rejected application claims 1, 11–12, and 17 under 35 U.S.C. § 102 as anticipated by Huang et al., *Electrospun collagen-chitosan-TPU nanofibrous scaffolds for tissue engineered tubular grafts*, COLLOIDS AND SURFACES B: BIOINTERFACES 82 (2011) 307–315 (“Huang1,” Ex. 1008). Ex. 1002–1, 210–211. The Examiner found that Huang1 discloses “a scaffold comprising one or more electrospun fibers ... wherein a [FFT] analysis result of the fibers have adjacent major peaks with about 180 degrees apart from each other.” *Id.* (citations omitted).

The Examiner cited Huang1's Figure 4E, reproduced below, as depicting the claimed FFT analysis result.



Id. at 211; Ex. 1008, 311, Fig. 4E. The Examiner found Figure 4E to have “two peaks at 175 degrees and 355 degrees (180 degrees apart).” Ex. 1002–1, 211.

Second, the Examiner rejected claims 1, 5, 6, 11, 12, 17, and 19–22 under 35 U.S.C. § 103 as obvious over U.S. Patent Application Publication 2004/0037813 to

Simpson (“Simpson,” Ex. 1009). *Id.* at 211–213; *see* Pet. 17 n.2 (“This is the also the [*sic*] same Dr. Simpson who has filed a declaration supporting th[e] petition.”). The Examiner found that “Simpson beneficially teaches a scaffold comprising one or more electrospun fibers” where “the secondary structure of collagen is not modified in the process of making the scaffold, as shown by Fourier transform infrared spectroscopy.” Ex. 1002–1, 211 (citations omitted).

The Examiner concluded:

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a scaffold comprising one or more electrospun fibers based upon the beneficial teachings provided by Simpson. If not expressly taught, the adjustment of particular conventional working conditions is deemed merely a matter of judicious selection, design choice and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Id. at 213.

After the Examiner’s rejections in view of the prior art, the applicant cancelled several application claims and amended now-issued claim 1 to recite fibers comprising collagen. *Id.* at 234–236. The applicant argued that “the FFT analysis in Huang’s Fig. 4E relate[s] to pure thermoplastic polyurethane fibers that comprise

no collagen. In contrast, Huang’s electrospun fibers comprising TPU, collagen, and chitosan did not exhibit the degree of alignment as recited in present claim 1; an FFT analysis of these fibers showed major peaks closer than 180° apart from each other.” *Id.* at 238.

The applicant also argued that “both Huang[1] and Simpson disclose an electrodeposition apparatus in which the fiber material is depositing on a rotating cylindrical collector.” *Id.* (citing Ex. 1008 ¶¶ 29, 103, 104). The applicant argued that “Huang[1] further discloses that using an apparatus with a cylindrical collector to prepare electrospun fibers comprising collagen did not produce a scaffold having the claimed fiber alignment. A person of skill, knowing that the device of Huang[1] did not produce the claimed fiber alignment, would not have expected to obtain the claimed fiber alignment using the similar device disclosed in Simpson.” *Id.* at 238–239 (citing Ex. 1008, Fig. 4F).

Following these amendments and arguments, the Office allowed the ’106 application, which issued as the ’223 patent on November 27, 2018. Ex. 1002–2, 572.

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. 18–19.

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. 19.

V. PETITIONER'S ASSERTED GROUNDS AND EVIDENCE

A. The Asserted Grounds of Unpatentability

Petitioner alleges that:

- 1) claims 1–12 are anticipated under 35 U.S.C. § 102 by Huang2;⁵
- 2) claim 4 is obvious under 35 U.S.C. § 103 over Huang2 and Kumbar;⁶
- 3) claims 1–12 are anticipated under 35 U.S.C. § 102 by Lee;⁷ and
- 4) claims 1–12 are obvious under 35 U.S.C. § 103 over Lee.

Pet. 5.

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

⁵ 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).

⁶ Kumbar et al., *Electrospun nanofiber scaffolds: engineering soft tissues*, BIOMED. MATER. 3 (2008) (“Kumbar,” Ex. 1006).

⁷ Lee et al., U.S. Patent Application No. US 2010/0331980 A1, published Dec. 30, 2010 (“Lee,” Ex. 1011).

primary references asserted by Petitioner – Huang2 and Lee – are substantially the same as, and cumulative to, Huang1 and Simpson, over which Examiner rejected the pending application claims. *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. 7–8. However, during prosecution the Examiner already considered *four* of Dr. Simpson’s publications and nonetheless determined to allow the claims. *See, e.g.*, Ex. 1001, code (56) (listing U.S. Patent Application Publication Numbers 2002/0090725, 2004/0037813, 2012/0221025, and Simpson’s 2008 paper); *see supra* II.A.2 n.2.

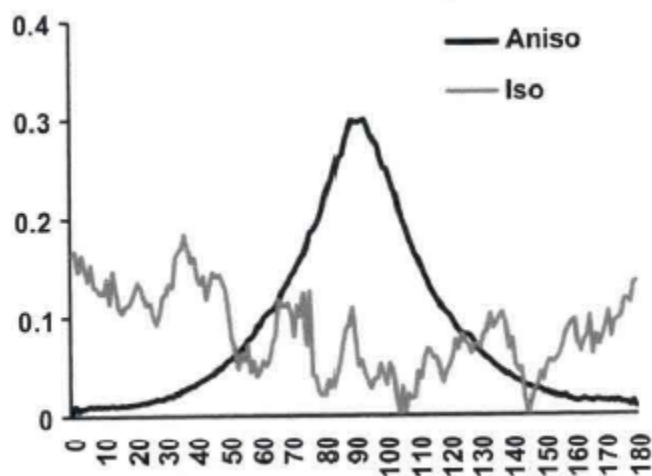
The Director need not revisit the Examiner’s conclusions in view of these cumulative materials. Institution should be denied given (1) the substantial similarity between the prior art applied by the Examiner and that asserted in the Petition, (2) Petitioner’s failure to identify Examiner error, and (3) 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.”⁸ *Id.* at 1793, Fig. 1C.



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

⁸ Huang2 defines “isotropic” as “fibers collected randomly with no alignment” and “anisotropic” as “fibers collected with alignment.” Ex. 1005, Abstract.

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.

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.

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 Huang1 and Simpson, which are cumulative to Huang2 and Lee. *See supra* II.C. Moreover, Petitioner does not even attempt to show material error.

1. Huang1 is substantially the same as Huang2 and Lee and was presented to the Office previously.

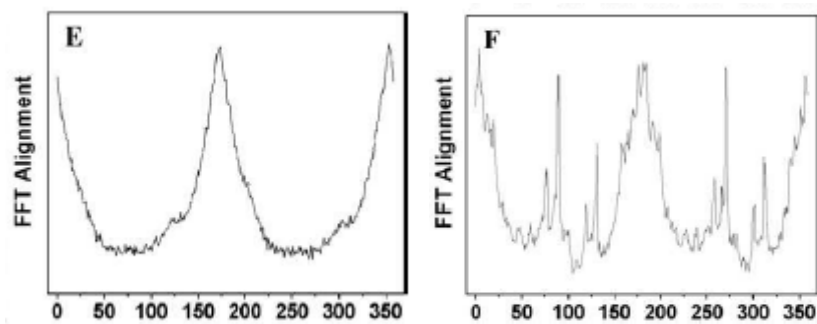
a) The Examiner applied Huang1.

As discussed above, the Examiner rejected application claims 1, 11–12, and 17 as anticipated by Huang1. Ex. 1002–1, 210–211. The Examiner found that

Huang1 discloses “a scaffold comprising one or more electrospun fibers ... wherein a [FFT] analysis result of the fibers have adjacent major peaks with about 180 degrees apart from each other.” *Id.* (citing Huang (Ex. 1008), Abstract, 308, 309, Fig. 4E).

In more detail, and as before the Examiner, Huang1 discloses that “[r]andom and aligned nanofibrous scaffolds based on collagen-chitosan-thermoplastic polyurethane (TPU) blends were electrospun to mimic the componential and structural aspects of the native extracellular matrix.” Ex. 1008, Abstract. Huang1 discloses that two sets of fibrous scaffolds were created: (1) those with collagen, TPU, and chitosan blended nanofibers, and (2) those with pure TPU nanofibers. *Id.* at 308.

Huang1 explains that “[a] two-dimensional fast Fourier transform (2D FFT) approach was adapted to measure fiber alignment in electrospun matrix.” *Id.* (citing Dr. Simpson’s 2008 paper, Ex. 1010); *see also id.* at 309 (same). The FFT alignment plots, which the Examiner found to be the claimed “FFT analysis result” (Ex. 1002–1, 211), are reproduced below.



Ex. 1008, 311. Figure 4E (left) and 4F (right) depict the FFT analysis results of pure TPU nanofibers and collagen blended fibers, respectively. *Id.* at Fig. 4.

Huang¹ explains that “[t]he two peaks at 175° and 355° in Fig. 4E show that ... pure TPU nanofibers were highly arrayed along one direction, however, in the three-material based system [with collagen, TPU, and chitosan] (Fig. 4F), fiber orientation could not be regulated with such a high uniformity. Although two main peaks could also be found at 5° and 185°, the existence of other peaks indicates that some nanofibers are not well aligned.” *Id.* at 309.

b) Huang¹ 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. 67–68 (simply noting that these references were not before the Examiner, but not addressing whether they are substantially the same).⁹ And Petitioner’s conclusion

⁹ 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*

is wrong: Huang1 is cumulative to Huang2 and Lee. Therefore, the Director should defer to the previous Office evaluation of the evidence of record. *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 (Huang1). *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 (Huang1). *Advanced Bionics*, IPR2019-01469, Paper 6 at 15–19.

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).

(1) Substantially the same structure

Huang1, 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. 1008 (Huang1), 307 (“aligned nanofibrous scaffolds ... were electrospun”),
 - *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. 1008 (Huang1), 308 (disclosing both collagen-chitosan-TPU blends and pure TPU),
 - *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 Huang1 and Huang2 (Lee does not disclose FFT).

- *Compare* Ex. 1008 (Huang1), 308 (disclosing a “two-dimensional fast Fourier transform (2D FFT) approach ... to measure fiber alignment in electrospun matrix” 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”).

Additionally, Lee employs a “rotating drum system” for electrospinning, like the apparatus used in Huang1. *Compare* Ex. 1011 (Lee) ¶ 91 (“In this study the rotating drum system was used.”), *with* Ex. 1008 (Huang1), 308 (“Aligned nanofibers were formed on a rotating drum.”).

Thus, the Petition’s newly applied prior art does not present a substantially different structure than that of Huang1. Rather, Huang2 and Lee disclose substantially the same structure, i.e., aligned fiber scaffolds comprising collagen.

(2) Substantially the same purpose

Huang1, considered by the Examiner, discloses substantially the same purpose as Huang2 and Lee. *See Oticon*, IPR2019-00975, Paper 15 at 15–16. Specifically, each reference fabricates a scaffold to mimic native tissue for use in

repairing specific types of tissue. *Compare* Ex. 1008 (Huang1), Abstract (“The objective of this study is to design a novel kind of scaffolds for blood vessel and nerve repairs ... [that] mimic[s] the componential and structural aspects of the native extracellular matrix.”), *with* Ex. 1005 (Huang2), Abstract (“Utilization of nanofibrous matrices for skin wound repair holds great promise due to their morphological and dimensional similarity to native extracellular matrix (ECM).”) *and* Ex. 1011 (Lee) ¶¶ 52 (“[C]ollagen and fibrin biomaterials have been used as a scaffolding system for skeletal muscle regeneration.”), 90 (“To closely mimic the skeletal muscle architecture, this study was designed to fabricate nanofiber meshes that are aligned in a unidirectional manner ...”).

(3) Substantially the same manner

Finally, Petitioner relies upon Huang2 and Lee in substantially the same manner as the Examiner relied upon Huang1. Specifically, like the Examiner, Petitioner asserts anticipation and alleges that Huang2 and Lee disclose each limitation of the challenged claims. *Compare* Ex. 1002–1, 210–211 (anticipation by Huang1), *with* Pet. 28–44 (anticipation by Huang2) *and* 47–64 (anticipation by Lee).

Petitioner’s addition of an obviousness ground based on Lee, supplemented only with the 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 the allegation that

a POSITA would have recognized the applicability of FFT to Lee, adds nothing more than what the Examiner would have already considered in Dr. Simpson’s 2008 paper, which is referenced in Huang1 and the ’223 patent. *See, e.g.*, Pet. 65 (“It was, however, well within the ordinary knowledge of a POSA at the applicable time that ‘FFT analysis’ and ImageJ software could be run on Lee’s SEM images to confirm the degree of alignment.”); Ex. 1003 ¶ 243; Ex. 1008, 308; Ex. 1001, 13:16–26.

(4) Conclusion

Because the newly cited prior art to Huang2 and Lee presents substantially the same structure and purpose as Huang1, and where Petitioner presents the references in substantially the same manner as the Examiner applied Huang1, 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. Simpson is substantially the same as Huang2 and Lee and was presented to the Office previously.

a) The Examiner applied Simpson.

As discussed above, the Examiner rejected application claims 1, 5, 6, 11, 12, 17, and 19–22 as obvious over Simpson. Ex. 1002–1, 211–213. The Examiner found that “Simpson beneficially teaches a scaffold comprising one or more electrospun fibers” where “the secondary structure of collagen is not modified in the

process of making the scaffold, as shown by Fourier transform infrared spectroscopy.” *Id.* at 211

In more detail, and as before the Examiner, Simpson discloses “combining electroprocessed collagen and cells to form engineered tissue,” and discloses electrospinning as an example of electroprocessing. Ex. 1009 ¶¶ 2, 10. According to Simpson, “there exists a need in the art for collagen materials that may be used to form biocompatible implants that possess structural integrity and retain such integrity after implantation. Preferably, such materials should be able to mimic the chemistry and structure of extracellular matrices and promote infiltration of cells.” *Id.* ¶ 6.

Simpson discloses aligned fibers but does not disclose using fast Fourier transform to measure alignment. For example, Simpson discloses that “electroprocessed materials are used to form seamless and complex, three-dimensional shapes by depositing fibrils of electrospun collagen along a defined axis to control the alignment and distribution of cells within a bioengineered organ.” *Id.* ¶ 102; *see also id.* ¶¶ 176 (“Rotating targets or mandrels during electroprocessing to cause the electroprocessed materials to have a specific polarity or alignment.”); 221 (“By aligning the fibrils of the electrospun sheet of material in parallel with the long axis of the outer cylinder a scaffolding for the production of a muscle-like, electroprocessed composition is produced.”); 300 (“In this example a cardiac patch

is prepared. A sheet of electroprocessed material is prepared with aligned filaments of collagen.”).

Simpson also examined “how the local fiber direction modulates the material properties of the electrospun matrix. Materials testing of scaffolds in parallel with the principal axis fibril alignment indicated [data regarding average load and average modulus]. These data indicate the local orientation of the fibers that compose an electrospun scaffolding directly modulate the material properties of the engineered matrix.” *Id.* ¶ 315.

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. 67–68 (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: Simpson 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 (Simpson). *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 (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. 1009 (Simpson) ¶¶ 102 (“fibrils of electrospun collagen [deposited] along a defined axis to control the alignment”), 221 (“aligning the fibrils of the electrospun sheet of material”),
 - o *with* Ex. 1005 (Huang2), Abstract (“anisotropic (*i.e.*, fibers collected with alignment)”), 1791 (“scaffolds”; “electrospun nanofibrous matrices”)
 - o *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.
 - o *Compare* Ex. 1009 (Simpson) ¶¶ 137 (“Type I collagen electrospun fiber scaffold”), 96–99 (disclosing blends with collagen, including PCL),
 - o *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 (neither Simpson nor Lee disclose FFT).
 - *Compare* Ex. 1009 (Simpson) ¶ 315 (“examination of how the local fiber direction modulates the material properties of the electrospun matrix”),
 - *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)
 - *and* Ex. 1011 (Lee) ¶¶ 65–67 (characterizing “electrospun PCL/collagen nanofiber meshes” with “scanning electron microscopy,” UTHSCSA ImageTool 3.0, and “tensile properties”).

Additionally, Lee employs a “rotating drum system” for electrospinning, like the apparatus used in Simpson. *Compare* Ex. 1011 (Lee) ¶ 91 (“In this study the rotating drum system was used.”), *with* Ex. 1009 (Simpson) ¶ 182 (describing electrospinning embodiments where “[a] mandrel is placed 7 inches from the syringe tip and rotated at a selected speed”).

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 structures as Simpson, i.e., aligned fiber scaffolds comprising collagen.

(2) Substantially the same purpose

Additionally, Simpson, considered by the Examiner, discloses substantially the same purpose as Huang2 and Lee. *See Oticon*, IPR2019-00975, Paper 15 at 15–16. Specifically, each reference fabricates a scaffold to mimic native tissue for use in repairing specific types of tissue. *Compare* Ex. 1009 (Simpson), Abstract (“The invention is directed to formation and use of electroprocessed collagen, including use as an extracellular matrix and, together with cells, its use in forming engineered tissue.”), *with* Ex. 1005 (Huang2), Abstract (“Utilization of nanofibrous matrices for skin wound repair holds great promise due to their morphological and dimensional similarity to native extracellular matrix (ECM).”), *and* Ex. 1011 (Lee) ¶¶ 52 (“[C]ollagen and fibrin biomaterials have been used as a scaffolding system for skeletal muscle regeneration.”), 90 (“To closely mimic the skeletal muscle architecture, this study was designed to fabricate nanofiber meshes that are aligned in a unidirectional manner”).

(3) Substantially the same manner

Finally, Petitioner relies upon Huang2 and Lee in substantially the same manner as the Examiner relied upon Simpson. Specifically, Petitioner alleges that Huang2 and Lee disclose each limitation of the challenged claims and, alternatively,

alleges that Lee renders obvious the challenged claims when considered in light of the knowledge of a POSITA. *See* Pet. 28–44 (anticipation by Huang2), 47–64 (anticipation by Lee), and 64–66 (obviousness over Lee). Likewise, the Examiner rejected the pending claims as obvious over Simpson when considered in light of the knowledge of a POSITA; the Examiner did not rely upon teachings of a secondary reference to satisfy any claim limitation. *See* Ex. 1002–1, 211–213 (obviousness over Simpson).

Additionally, as noted above, the Examiner already considered much of Dr. Simpson’s work. And the declaration offered here, to support the allegation that a POSITA would have recognized the applicability of FFT to Lee, adds nothing more than what the Examiner would have already considered in Dr. Simpson’s 2008 paper, which is referenced in the ’223 patent. *See, e.g.*, Pet. 65 (“It was, however, well within the ordinary knowledge of a POSA at the applicable time that ‘FFT analysis’ and ImageJ software could be run on Lee’s SEM images to confirm the degree of alignment.”); Ex. 1003 ¶ 243; Ex. 1001, 13:16–26.

(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.

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 Huang1 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 amended the claims and submitted responsive argument. *Id.*

Petitioner fails—in fact, does not even attempt—to demonstrate material error in the Office's previous consideration of Huang1 and Simpson. Instead, Petitioner purports to "reserve the right to respond" to "show[] ... that the Examiner erred." Pet. 68. 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 was aware of the Examiner's consideration of Huang¹ and Simpson and devoted four pages of the Petition to reviewing the Examiner's rejections and the applicant's responses. Pet. 15–18. 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. 68.

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 5979 words as counted by Microsoft Word, the word-processing system used to prepare this preliminary response.

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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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