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 PRELIMINARY RESPONSE
37 C.F.R. § 42.107(a)

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I. INTRODUCTION

Patent Owner LifeNet Health ("LifeNet" or "Patent Owner") submits this Preliminary 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 respectfully requests that the Board deny the Petition because Petitioner fails to meet its statutory burden to demonstrate a reasonable likelihood of prevailing under 35 U.S.C. § 314(a). As detailed below, Petitioner fails to demonstrate that the prior art teaches or suggests "a fast Fourier transform (FFT) analysis result of the fibers hav[ing] adjacent major peaks with about 180° apart from each other," as recited in each challenged claim. Despite presenting anticipation grounds under 35 U.S.C. § 102, Petitioner does not assert that *either* of its primary references disclose the claimed FFT analysis result with adjacent major peaks about 180° apart from each other. Petitioner could not make such an assertion credibly: Petitioner and its expert admit that Huang2[1] discloses a FFT analysis result with only

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[1] Huang et al., *The involvement of integrin β1 signaling in the migration and myofibroblastic differentiation of skin fibroblasts on anisotropic collagen-containing nanofibers*, 33 BIOMATERIALS 1791–1800 (2012) ("Huang2," Ex. 1005).

one single peak, and Lee[2] does not disclose a FFT analysis result at all. Pet. 22; Ex. 1003 ¶ 105; Ex. 1005, 1793–1794;[3] *see generally* Ex. 1011.

Instead, Petitioner impermissibly relies on its expert to fill in this missing limitation. However, in doing so, both Petitioner and its expert studiously avoid the actual language of the challenged claims and instead present inapposite arguments about "aligned" fibers. *See, e.g.*, Pet. 29, 49. But the claims do not recite "aligned" fibers; they recite a specific "fast Fourier transform (FFT) analysis result" that has "adjacent major peaks with about 180° apart from each other." Petitioner fails to demonstrate that "aligned fibers" is the claimed FFT analysis result.

The sole obviousness ground addressing this limitation also fails. Petitioner does not demonstrate a sufficient motivation to modify Lee to incorporate FFT analysis at all, let alone the claimed FFT analysis result. To the contrary, Petitioner recognizes that its purported motivation—to confirm alignment—is already achieved by Lee in *three* distinct ways. Pet. 50–53.

Patent Owner thus respectfully requests that the Board deny institution.

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[2] Lee et al., U.S. Patent Application No. US 2010/0331980 A1, published Dec. 30, 2010 ("Lee," Ex. 1011).

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

II. THE ’223 PATENT

A. The ’223 Patent

1. A scaffold comprising electrospun fibers

The ’223 patent discloses 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 where 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.

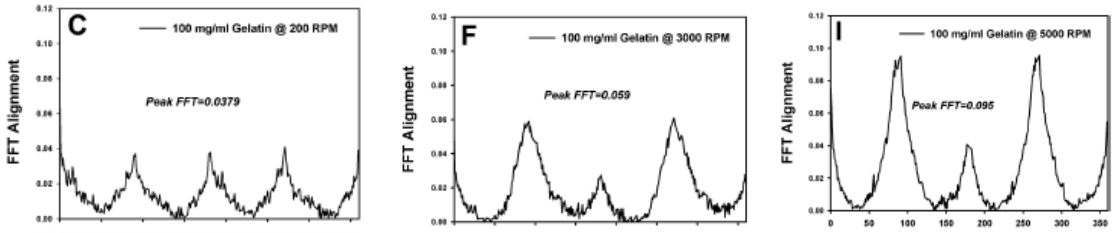
2. Fast Fourier transform analysis

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's declarant Dr. David G. Simpson is the senior author, and which the '223 patent incorporates by reference. *Id.*; Pet. 12; Ex. 1003 ¶ 61.[4]

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.

Dr. Simpson's 2008 paper provides three examples of the results of a FFT analysis, shown below.



Ex. 1010, 608 at Figs. 1C, 1F, 1I. Each figure depicts FFT alignment plotted on a scale from 0 to 360º. *Id*.

[4] 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.

Consistent with these figures, Dr. Simpson's 2008 paper explains that a 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.

Dr. Simpson's 2008 paper explains that a FFT analysis result conveys several pieces of information. For example, "the height and overall shape of the most prominent peaks present in the alignment plot" conveys "[t]he degree of alignment present in the original data image." *Id*. (emphasis added). Additionally, the shape of the peak conveys the uniformity of fiber alignment, where "[a] high and narrow peak indicates a more uniform degree of fiber alignment, [but] a broad peak, or a shoulder on the peak indicates that more than one axis of alignment may be present." *Id.* (emphasis added). Finally, "the principal axis of fiber alignment is determined by the position of the alignment peaks," e.g., in the vertical direction in Figures 1F and 1I above. Ex. 1010, 610 (emphasis added); *see also* Ex. 1003 ¶¶ 41–42 (explaining that a FFT analysis result "reflects the directional orientation of the fibers," "provid[es] a visual summary of the[] orientation," and "illustrates the degree of fiber alignment").

Similarly, the ’223 patent explains that the FFT analysis result of the claimed scaffold with electrospun fibers shows “adjacent major peaks with about 180º 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.

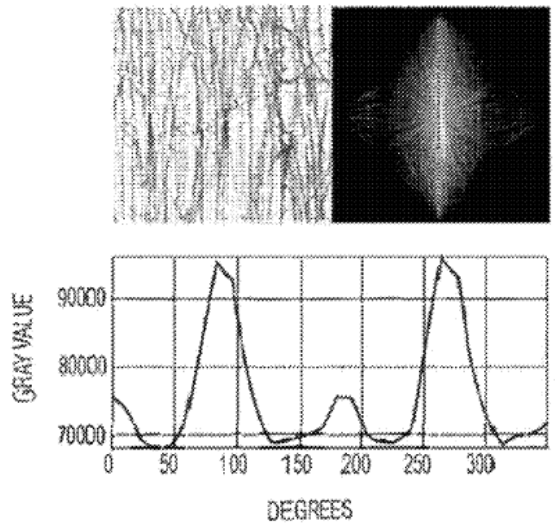


FIG. 8A

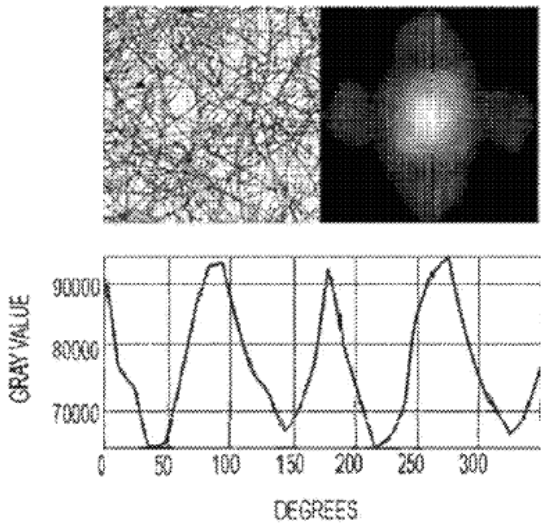


FIG. 8B

Id. at 13:24–26, Figs. 8A–8B. “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 in the ’223 patent is plotted between 0° and 360°, where aligned fibers described in the ’223 patent show “adjacent major peaks with about 180° apart from each other” (Figure 8A), and where 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. Of those, claim 1 is independent and 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

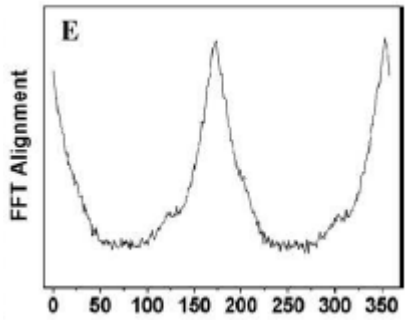
U.S. Patent Application No. 14/776,106 (the “’106 application”) was filed on September 14, 2015, and ultimately issued as the ’223 patent.[5] The ’106 application is the national stage of PCT Application No. US2014/025636, filed March 13, 2014, and which claims priority to U.S. Provisional Patent Application No. 61/785,031, filed on March 14, 2013. The ’106 application was filed with 31 claims. Ex. 1002–1, 48–51.

During prosecution, the Examiner issued one office action advancing two prior art rejections. Ex. 1002–1, 208–219. 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

[5] A divisional of the ’223 patent, U.S. Patent No. 11,318,227 is challenged by Petitioner in IPR2025-00249.

("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 having 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. Figure 4E of Huang1 depicts a graph plotted between 0° and 360°, which the Examiner found to have "two peaks at 175 degrees and 355 degrees (180 degrees apart)." Ex. 1002–1, 211.

Thus, the Examiner found the claimed "fast Fourier (FFT) analysis result" to be satisfied by a graph plotted between 0° and 360° that depicts two peaks with about 180° apart from each other. Ex. 1008, 309.

The Examiner also 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). Ex. 1002–1, 211–213; *see* Pet. 17 n.2 ("This is the also the 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, 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.* (citations omitted). The applicant argued

> 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. *See* Huang, Fig. 4F. A person of skill, knowing that the device of Huang 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 (citations omitted).

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 FAILS TO PRESENT A REASONABLE LIKELIHOOD OF UNPATENTABILITY FOR ANY CHALLENGED CLAIM

A. Petitioner's Assertions of Unpatentability

1. The Asserted Grounds

Petitioner asserts that claims 1–12 are anticipated under 35 U.S.C. § 102 based on Huang2 (Ground 1) or Lee (Ground 3). Pet. 5. Petitioner, however, fails to demonstrate that either reference discloses—either expressly or inherently—the claimed FFT analysis result having adjacent major peaks with about 180º apart from each other. Accordingly, neither reference anticipates.

Petitioner also asserts that claims 1–12 are obvious under 35 U.S.C. § 103 based on Lee (Ground 4). Pet. 5. But Petitioner fails to demonstrate that a POSITA would have been motivated to modify Lee to *further* confirm alignment with FFT analysis when Lee already confirms alignment with *three alternate* mechanisms. Petitioner fails to demonstrate that a fourth confirmation mechanism would have been employed; instead, Petitioner asserts only that it "could" be done. Pet. 65.

Finally, Petitioner asserts that claim 4 is obvious under 35 U.S.C. § 103 based on the combination of Huang2 and Kumbar[6] (Ground 2). Petitioner fails to demonstrate that a POSITA would have applied Kumbar's porosity to Huang2's

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

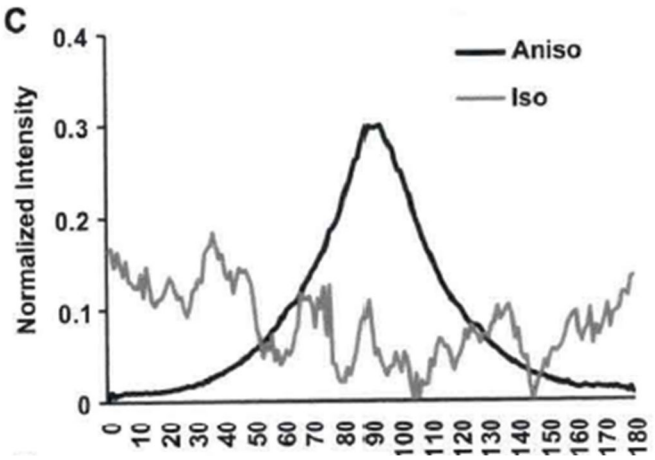
fibers, given that Huang2 and Kumbar disclose scaffolds made of fundamentally different materials with different properties. This ground, addressing only a dependent claim, also suffers from the same fatal deficiencies as Ground 1.

2. The Asserted Prior Art

a) 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.



Huang2's Figure 1C depicts "[n]ormalized intensity plots against the angle of acquisition for isotropic and anisotropic nanofibrous matrices," plotted from 0°–180° degrees, where the anisotropic fibers have a single peak.[7] *Id.* at 1793. Huang2 explains that "[t]he narrow peak ... 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.

b) Lee

Lee discloses scaffolds for muscle tissue repair. 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

[7] Huang2 defines "isotropic" as "fibers collected randomly with no alignment" and "anisotropic" as "fibers collected with alignment." Ex. 1005, Abstract.

"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. The scaffold may be formed by electrospinning collagen, optionally with other synthetic polymers like PCL. *Id.* ¶ 6.

Lee does not disclose FFT analysis. Lee examines the scaffolds with, e.g., scanning electron microscopy, "ImageTool 3.0" freeware, and tensile testing. *Id.* ¶¶ 65–67.

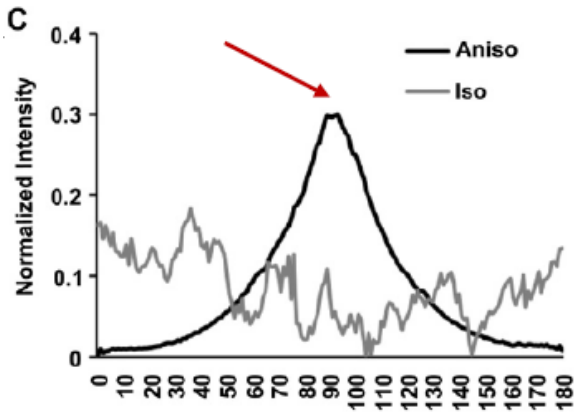
B. Ground 1: Petitioner Fails To Show Anticipation of Claims 1–12 by Huang2

"A claim is anticipated" under 35 U.S.C. § 102 "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Petitioner's allegations of anticipation by Huang2 clearly fail this requirement. Huang2 does not disclose a FFT "analysis result of the fibers hav[ing] adjacent major peaks with about 180° apart from each other."

1. Claims 1–12 are not expressly anticipated.

Petitioner alleges that "Huang2 discloses this element." Pet. 29. However, Petitioner points to no disclosure of "adjacent major peaks with about 180° apart from each other" in Huang2. *Id.* at 29–33. Petitioner could not do so because, by its own admission, Huang2 discloses only a *single* peak. *Id.* at 30–31 ("with a 'major

peak'"). As emphasized by Petitioner's annotation of Huang2's Figure 1C, shown below, Huang2's FFT result of anisotropic fibers depicts only one peak.



Pet. 30 (red annotation). Dr. Simpson agrees: "the dark line shows the FFT result … has *a single 'major peak'* around about 90°." Ex. 1003 ¶ 105 (emphasis added). A FFT analysis result with <u>one</u> peak does not expressly anticipate "adjacent major peaks with about 180° apart from each other."[8]

[8] This is not a case to apply *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) even had Petitioner suggested to do so (it did not). *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 851 F.3d 1270, 1274–1275 (Fed. Cir. 2017) ("*Kennametal* does not stand for the proposition that a reference missing a limitation can anticipate a claim if a skilled artisan viewing the reference would 'at once envisage' the missing limitation. Rather, *Kennametal* addresses whether the disclosure of a limited number of combination possibilities discloses one of the possible combinations.… *Kennametal* does not permit the Board to fill in missing limitations simply because a skilled artisan would immediately envision them.").

Petitioner also alleges that Huang2 discloses "nanofibers that are visually highly aligned" and "aligned in the same direction." Pet. 29–30. This is inapposite; claims 1–12 do not recite "aligned" fibers. Nor do they recite a subjective interpretation of the fibers as "visually highly aligned." Instead, the claims recite a specific FFT analysis result having "adjacent major peaks with about 180° apart from each other." Had the applicant intended to claim "visually highly aligned" fibers, it would have. It did not.

Accordingly, Huang2 does not disclose this limitation.

2. Claims 1–12 are not inherently anticipated.

This leaves the possibility of inherent anticipation. Inherent anticipation is a strict doctrine that "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *PAR Pharm., Inc. v. TWI Pharms., Inc*., 773 F.3d 1186, 1195 (Fed. Cir. 2014) (quotation omitted). Rather, "[a]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that *must necessarily include* the unstated limitation." *Transclean Corp. v. Bridgewood Servs., Inc*., 290 F.3d 1364, 1373 (Fed. Cir. 2002) (emphasis added). "The keystone of the inherency doctrine is inevitability…. Absent inevitability, inherency does not follow even from a very high likelihood that a prior art method will result in the claimed invention." *In re Montgomery*, 677 F.3d 1375, 1384 (Fed. Cir. 2012)

As an initial matter, neither the Petition nor Petitioner's expert clearly allege (much less clearly show) that this limitation is inherent. In fact, the word "inherent" never appears in the Petition's discussion of Huang2 or this Ground (*see* Pet. 19–23, 28–44) nor in its expert's discussion (*see* Ex. 1003 ¶¶ 69–80, 94–114). The Petition makes a single reference to inherency, arguing that, "through its inherent mathematical properties," a FFT analysis "produces a symmetrical plot" such that "a single peak in a 2D FFT alignment plot from 0° to 180° indicates that the plot from 0° to 360° has adjacent major peaks that are 180° apart from each other." Pet. 9–10. The Petition also alleges that a second major peak "would necessarily" exist in certain FFT analysis results due to this alleged symmetry. Pet. 14 (discussing the '223 patent), 23 (discussing Huang2), 31 (same).

Apparently recognizing that Huang2 discloses only one single peak, Petitioner further contends that, "if the scale [of Huang2's FFT plot] were extended to 0°–360°," then "Huang2's FFT analysis would necessarily show a second major peak at around 270°." Pet. 31. Petitioner relies on testimony of its expert Dr. Simpson to contend that a POSITA "would know from the alignment of the fibers depicted in [Huang2's] image of Figure 1B and the major peak at around 90° in Figure 1C that the fibers are aligned, such that there would be a second peak about 180° apart at 270°." *Id.* Petitioner contends that Dr. Simpson's own testing of Huang2's images confirmed as much. Pet. 31–33.

To the extent these vague and imprecise statements are an attempt to argue that Huang2 inherently discloses a "FFT analysis result … hav[ing] adjacent major peaks with about 180° apart from each other," they fall short of Petitioner's high burden to show, through competent evidence and technical reasoning, that such a limitation is "necessarily present" in Huang2, not just possibly or probably present.[9] Petitioner's allegations fail.

a) Expert testimony cannot fill in the gaps to supply missing claim limitations.

Petitioner and Dr. Simpson acknowledge that Huang2 discloses only a single peak. Pet. 30–31; Ex. 1003 ¶ 105. To cure this defect, Petitioner turns to its expert to supply the missing limitation of "adjacent major peaks with about 180° apart from each other."

But Petitioner cannot rely on expert testimony to fill gaps in Huang2. *Inter partes* review is limited to review based upon "patents and printed publications," which Dr. Simpson's testimony plainly is not. 35 U.S.C. § 311(b); *Qualcomm Inc. v. Apple Inc.*, No. 23-1208, slip op. at 17 (Fed. Cir. Apr. 23, 2025) ("Section 311(b) states that a petitioner 'may request to cancel as unpatentable' claims 'only on the basis of prior art consisting of patents or printed publications.' This means that 'the

[9] "Ultimately, it is the petitioner's burden to present a clear argument." *See Netflix, Inc. v. DivX, LLC*, 84 F.4th 1371, 1377 (Fed. Cir. 2023). Petitioner fails to do so.

basis' of an IPR ground asserting unpatentability can 'only' include 'prior art consisting of patents or printed publications.'").

Furthermore, case law and guidance confirm that expert testimony cannot be used to fill gaps in Petitioner's references. *See, e.g.*, *Scripps Clinic & Rsch. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991) (overruled on other grounds, *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009)) ("The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill …, not to fill gaps in the reference."); *Nidec Motor Corp.*, 851 F.3d at 1274–75 (holding that the Board is not permitted "to fill in missing limitations simply because a skilled artisan would immediately envision them"); PTAB Consolidated Trial Practice Guide (Nov. 2019) ("CTPG") 36 ("[A] petitioner asserting anticipation cannot rely on its expert to supply disclosure of a claim element that is not expressly or inherently present in the reference…. [E]xpert testimony may explain 'patents and printed publications,' but is not a substitute for disclosure in a prior art reference itself.").

b) Obviousness arguments do not demonstrate inherency.

Moreover, Petitioner's contentions amount to an argument that a POSITA would have known (1) how to modify Huang2's single-peak FFT analysis result to double the length of its x-axis and plot the graph to 360° instead of 180° and (2) if they made such a modification, the POSITA would have expected to see "adjacent

major peaks with about 180° apart from each other." Pet. 31.

But this argument is directed to obviousness, not anticipation, and necessarily fails. *See Scripps*, 927 F.2d at 1577 ("If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground is not § 102 anticipation, but § 103 obviousness."); *Developmental Techs., LLC v. E. M. P. Enters., Inc.*, IPR2021-01560, Paper 16 at 8–9 (PTAB June 1, 2022) ("Because Petitioner relies solely on Durkheim … as part of its anticipation challenge, and does not argue that the limitation would have been obvious as part of any other challenge in the Petition, Petitioner's failure to establish that Durkheim necessarily discloses the limitation requires denial of *inter partes* review."); *see also In re Certain Laser Bar Code Scanners & Scan Engines, Components Thereof & Prods. Containing Same*, 2008 ITC LEXIS 950, *156–157 (USITC May 1, 2008) ("[The expert] relies on the knowledge of one of ordinary skill in the art to satisfy those limitations that he admits are missing…. However, in so doing, [the expert] seemingly confuses obviousness under 35 U.S.C. § 103 with anticipation under 35 U.S.C. § 102. The Federal Circuit has made absolutely clear that to prove inherency, the missing limitations must necessarily be present in the allegedly anticipating prior art reference.").

Petitioner is the master of the Petition. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) ("[I]n an *inter partes* review the petitioner is master of its complaint.").

The Petition contends that Huang2 *anticipates* the challenged claims under 35 U.S.C. § 102; Petitioner did not allege that claim 1 is obvious under § 103 based on Huang2. Accordingly, even if a POSITA might have known how to modify Huang2's FFT analysis result, that is irrelevant to the ground presented in the Petition; it has no bearing on whether Huang2 *inherently discloses* a FFT analysis result having adjacent major peaks with about 180º apart from each other.

Indeed, by arguing that Huang2 allegedly would show a second peak "*if* the scale were extended," Petitioner demonstrates that a second peak is not necessarily present in Huang2's FFT analysis result—the FFT analysis result would have to be modified to allegedly depict such a peak. Pet. 31 (emphasis added); *see also* Ex. 1003 ¶ 113.

c) Petitioner's evidence is insufficient to meet its burden.

Even if we accept *arguendo* that Petitioner's contention—that a POSITA would have known to modify Huang2's FFT analysis result to report the graph to 360° instead of 180°—has any bearing on anticipation, Petitioner fails to show that, even if so extended, Huang2's modified FFT analysis result would necessarily have an adjacent major peak with about 180º apart from the peak depicted in Figure 1C. The evidence Petitioner relies upon is simply insufficient to meet its burden.

(1) Dr. Simpson's Testimony

Petitioner relies on Dr. Simpson to support this conclusion. Pet. 9–10, 12, 14,

22–23 (citing Ex. 1003 ¶¶ 42, 44, 46, 62, 64, 77). However, the cited testimony is conclusory and entitled to little or no weight. 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.").

The cited paragraphs of Dr. Simpson's declaration do not disclose sufficient underlying facts, data, or technical reasoning to support the conclusion that "the 2D FFT output image is symmetric about the horizontal axis, so a pixel summation to 360° is unnecessary." *See* Ex. 1003 ¶ 46; *see also id.* ¶¶ 42, 44, 62, 64, 77. Dr. Simpson simply repeats this conclusion without explaining how or why it is reached.

For example, at paragraph 46, Dr. Simpson's testimony simply circles around itself: "[T]he 2D FFT output image is symmetric about the horizontal axis, so a pixel summation to 360° is unnecessary. As a way of further explanation, the fact that the 2D FFT output image is symmetric about the horizontal axis, ensures that the peaks in the 2D FFT alignment plot repeat between 0°–180° and 180°–360°." This statement does not provide "further explanation" of how or why the "2D FFT output image is symmetric"; it is simply a circular conclusion that improperly relies on itself for support. *See, e.g.*, *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential) ("[Petitioner's expert] does not cite to any additional supporting evidence or provide any technical reasoning to support his

statement…. [The] testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight."); *Honeywell Int'l Inc. v. 3G Licensing, S.A.*, 124 F.4th 1345, 1356 n.6 (Fed. Cir. 2025) ("[O]ur cases have consistently held that conclusory expert testimony does not qualify as substantial evidence.").

Accordingly, Dr. Simpson's testimony should be given little or no weight. The only additional evidence cited to support the conclusion of symmetry—Dr. Simpson's own past papers—are similarly insufficient, as detailed below.

(2) Dr. Simpson's Identified Evidence

To the extent Dr. Simpson cites evidence, but does not sufficiently discuss or explain it, that evidence is also insufficient. Indeed, to support his symmetry conclusion, Dr. Simpson cites only to his own past papers, which do not provide independent corroboration. *See, e.g.*, Ex. 1003 ¶ 46 (citing Ex. 1010, 609; Ex. 1013, 4).[10]

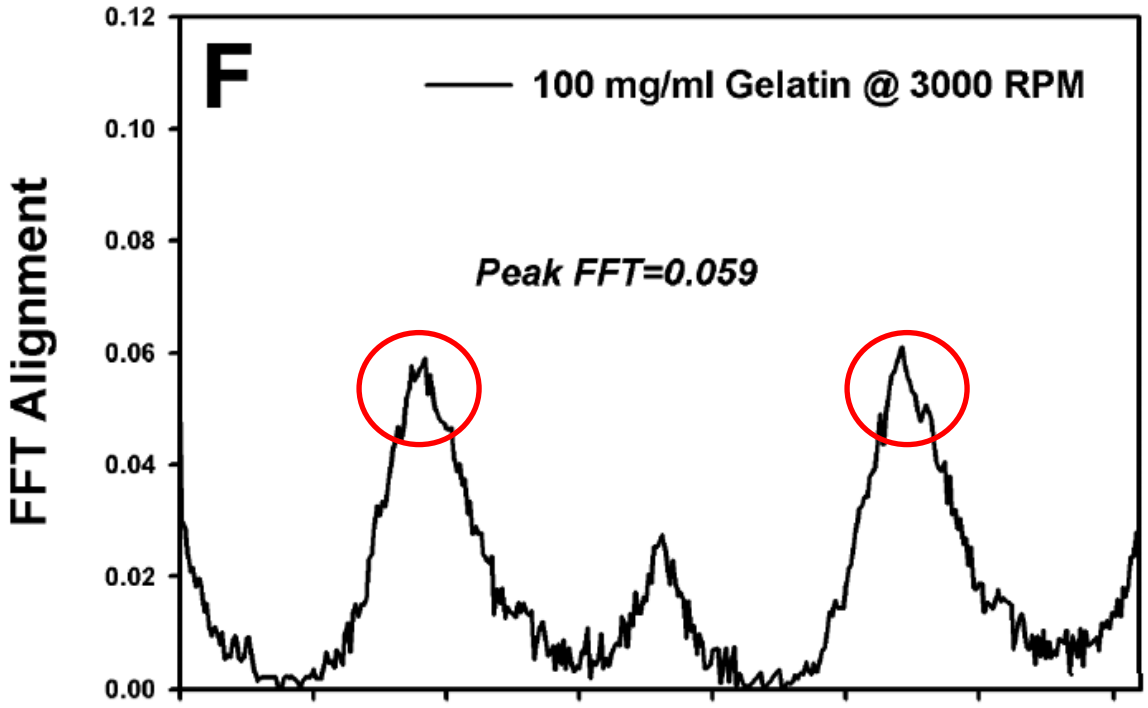
Like his declaration, these papers fail to provide sufficient underlying facts, data, or technical reasoning to support the conclusion that FFT analyses are

[10] Other named authors, junior to Dr. Simpson, appear on these papers. Ex. 1003 ¶ 61 ("I am senior author …."). However, as detailed below, these papers suffer from the same lack of underlying data and technical reasoning as Dr. Simpson's declaration testimony and are equally conclusory.

necessarily and always symmetric about the horizontal axis. Dr. Simpson's 2008 paper, for example, states: "Typically, the data from this analysis is reported for 0 to 180°; the frequency plot is symmetric so a complete summation from 0 to 360° is not technically necessary." Ex. 1010, 609. But the discussion ends there. The paper provides no support for this statement, despite identifying independent footnote support for other statements in the same section. *See id.*

Moreover, the 2008 paper itself undermines Dr. Simpson's testimony. First, Dr. Simpson does not explain the pertinence of the term "Typically," in the sentence above. Inherent anticipation requires that a FFT analysis result *necessarily*—not typically—have adjacent major peaks with about 180º apart from each other, due to the alleged symmetry. But the use of "Typically" here casts doubt on whether adjacent major peaks are *necessarily* present. Furthermore, Dr. Simpson's paper itself presents FFT analysis results plotted to 360°, not 180°, undermining Dr. Simpson's testimony that plots to 180° are the "typical[]" practice. Ex. 1010, 608 (Figures 1C/F/I all plotted to 360°); *see also* Ex. 1008, 311 (Huang1's Figures 4E–4F plotted to 360°).

Additionally, the FFT plots in Simpson's 2008 paper appear inconsistent with Dr. Simpson's statement that peaks between 0°–180° necessarily repeat between 180°–360°, further discrediting Dr. Simpson's unsupported statements. Ex. 1003 ¶ 46. Figure 1F of the 2008 paper is annotated and reproduced below.



Ex. 1010, 608 (annotated circles). In Figure 1F, for example, the FFT analysis result depicts two peaks, wherein the first large peak that appears near 90° varies in its shape, including its rise and fall, as compared to the second large peak appearing near 270°. For example, the top of the peak near 90° includes three ridges, while the top of the peak near 270° presents a smoother peak. *See also id.* at Figs. 1C, 1I (also depicting variations across peaks).

These peaks do *not* necessarily appear to be "repeats" of each other. *Contra* Pet. 12 ("[T]he peaks from 180° to 360° are repeats of the peaks from 0° to 180°."); Ex. 1003 ¶ 46. Dr. Simpson declined to provide any support or explanation for his testimony regarding the extent of repetition that he contends is necessarily present. Accordingly, Dr. Simpson's unsupported conclusion conflicts with the record and

warrants little to no weight. *See Homeland Housewares, LLC v. Whirlpool Corp*., 865 F.3d 1372, 1378 (Fed. Cir. 2017) ("[W]e must disregard the testimony of an expert that is plainly inconsistent with the record.").

Dr. Simpson's second cited paper fares no better. This paper also states that "the FFT is symmetric about the horizontal axis so a pixel summation to 360° is unnecessary," but again, with no identified support. Ex. 1013, 4.

(3) Dr. Simpson's Testing

Finally, Petitioner relies on Dr. Simpson's own post-hoc testing to bolster its assertion that Huang2's FFT analysis result necessarily has adjacent major peaks with about 180º apart from each other. Pet. 31–33 (citing Ex. 1003 ¶¶ 110–111). But this testing offends the Board's rules, which require that Dr. Simpson provide testimony to explain "[h]ow the test was performed and the data was generated." 37 C.F.R. § 42.65(b). Accordingly, it is entitled to little to no weight.

Rather than explain how his post-hoc testing was performed, Dr. Simpson simply states: "I conducted my own analysis of Figure 1B [of Huang2] using the FFT analysis described in Huang2 and the '223 patent. I report the data from 0° to 360° and normalized the y-axis." Ex. 1003 ¶ 110. This is the extent of explanation and is insufficient to satisfy § 42.65(b). *See Abbott Vascular, Inc. v. Flexstent,* IPR2019-00882, Paper 48 at 35 (PTAB Oct. 2, 2020) (excluding a declaration for failure to satisfy § 42.65(b) where it "lacks adequate details" and "does not describe

the test used[,] … whether the test used was one known and accepted in the art," or "how the data [the expert] collected was used to determine the values reported in his Declaration"); *Luitpold Pharms., Inc. v. Kovi et al.*, IPR2018-01640, Paper 19 at 23–24 (PTAB Mar. 6, 2019) (finding that an expert declaration that "fails to provide any specificity as to the steps taken" and "provides no independent testing data" to be insufficient evidence).

In addition to Dr. Simpson's failure to explain his testing protocol, the record raises independent concerns. First, Huang2 and the '223 patent employ FFT analyses described in different papers, so it is unclear which analysis Dr. Simpson employed when he states that he "conducted my own analysis … using the FFT analysis described in Huang2 *and* the '223 patent." Ex. 1003 ¶ 110 (emphasis added). Namely, the FFT analysis employed by Huang2 relies upon Dr. Simpson's 2006 paper (Ex. 1013), *see* Ex. 1005, 1792 at 2.2, while the '223 patent relies upon the FFT analysis discussed in Dr. Simpson's 2008 paper (Ex. 1010), *see* Ex. 1001, 13:16–26. Petitioner does not establish that these analyses are the same.[11]

[11] Despite baldly claiming that these FFT analyses are the same, Petitioner fails to establish as much. Pet. 30. Petitioner provides insufficient bases to determine that these papers disclose the same FFT process or that the same version of software was used. *Id.*; *compare* Ex. 1010, 607–609, 611–612, 615 (discussing aspects of image type, calibration, software version, illumination, variations in light intensity, optical and electronic noise, and masks that are important to FFT analysis), *with* Ex. 1013 (providing no discussion of these aspects).

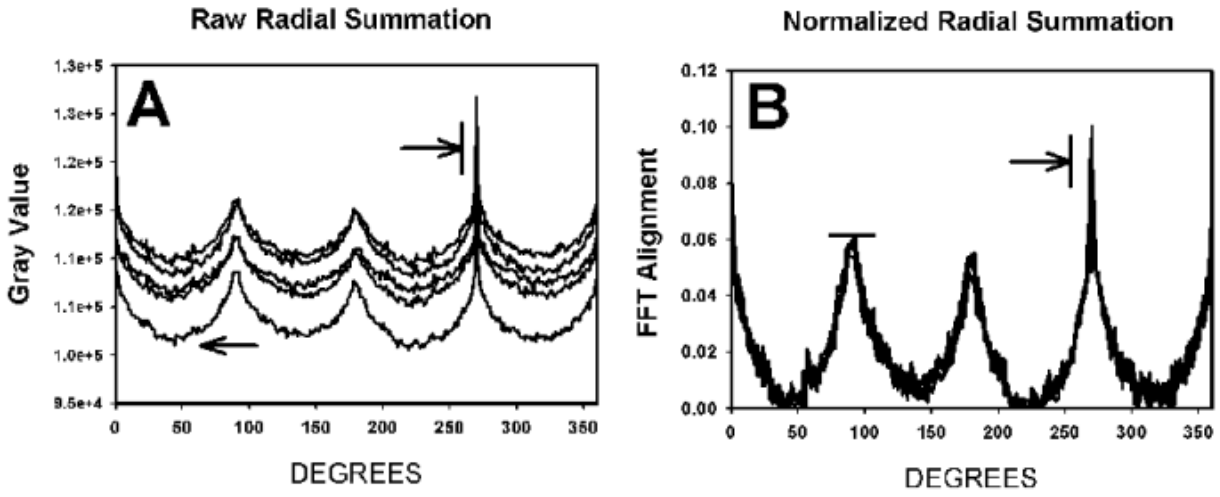
Second, the 2008 paper, incorporated by reference into the '223 patent, describes various aspects of FFT analysis that are essential to accurate testing but are not acknowledged in Dr. Simpson's post-hoc testing of Huang2's images. For example, the 2008 paper explains that images should be "stored and analyzed as uncompressed .TIF files to preserve image integrity; the image compression used in .JPG format will degrade image integrity." Ex. 1010, 607. Dr. Simpson does not explain how he obtained the image utilized in his testing; therefore, it is unknown to what extent image integrity degraded. Ex. 1003 ¶¶ 110–111.

The 2008 paper also explains that "[a]ngle information concerning the principle direction of fiber alignment must be calibrated to the specific version of the NIH ImageJ software and oval profile plugin used for analysis" because "[s]ome versions of ImageJ (1.36b) altered [standard] convention…. Minor corrections were incorporated into our analysis to correct for this condition, but may not be necessary for all 2D FFT programs." Ex. 1010, 607. Again, Dr. Simpson does not explain which version of the software or plugin he used, whether or how calibration was completed, and to what extent error may have been introduced. Ex. 1003 ¶¶ 110–111.

Additionally, the 2008 paper highlights risks associated with uneven illumination: "Care should be taken at the time of image capture to optimize sample illumination; uneven illumination can complicate and introduce error into the

alignment analysis." Ex. 1010, 609. Again, Dr. Simpson does not establish whether the image presented in Huang2—a reproduction of a scanning electron microscope image obtained from a dated library publication (Pet. 19 n.3)—provides sufficient illumination for testing and to what extent error may have been introduced. Ex. 1003 ¶¶ 110–111; Ex. 1005, 1 (cover page with library sticker).

Unrecognized in Dr. Simpson's analysis, the 2008 paper also states that "[n]ormalization … is necessary to account for differences in sample thickness, camera performance, operator preference for contrast/brightness, and other variables that impact sample illumination at the time of image capture." Ex. 1010, 610. For example, in Figures 2A and 2B, reproduced below, the 2008 paper shows the extreme variation that arises when identical fibers are captured at five different light intensities (Fig. 2A) as compared to when those images are normalized (Fig. 2B).



Id. at 610–611. Dr. Simpson does not state whether he normalized images when he performed his testing, the extent or mechanism by which he might have done so, and

to what extent error may have been introduced. Ex. 1003 ¶¶ 110–111.

The 2008 paper also explains that "as light intensity increases, the relative amount of optical noise present in a brightfield microscopic image also will increase. Detector noise functions in an inverse fashion. As light intensity is decreased and detector gain is increased to generate an image, electronic noise begins to be incorporated into the data set. Noise from either source (optical and/or electronic) can introduce artifacts into a data image and adversely impact the 2D FFT process." Ex. 1010, 612. Once again, Dr. Simpson does not address whether noise impacted his testing, which type of noise might have been introduced by the applied light intensity, or how he might have accounted for that. Ex. 1003 ¶¶ 110–111.

Finally, the 2008 paper also discusses notable artifacts in the FFT analysis that may be caused by the array of fibers in the image, as shown in Figure 3N. Ex. 1010, 614–615. "Th[e] noise effect is quite pronounced in a model scaffold containing aligned fibers that are arrayed approximately 45° with respect to the edges of the image…. The unmasked image produces a 2D FFT alignment plot with artifacts in the guise of small peaks on either side of the alignment peaks (Fig. 3N, arrows). Processing the image with a window mask removes this spurious information without altering the height of the alignment peaks (i.e., 2D FFT alignment value, Fig. 3N). Although this type of mask can be useful in many applications, it reduces the total surface area available for analysis." Dr. Simpson's testing depicts a mask.

See Ex. 1003 ¶ 110, Fig. 2A (Figure caption, "cropped and masked"). But Dr. Simpson does not discuss the impact of the mask's "reduc[tion of] the total surface area available for analysis," and to what extent that may have affected his testing.

In sum, Dr. Simpson's testing protocol is essentially unknown. Dr. Simpson's own 2008 paper lays bare the holes in his post-hoc testing. Lacking the required explanation, Patent Owner and the Board cannot fairly understand "[h]ow the test was performed and the data was generated." For at least these reasons, Dr. Simpson's post-hoc testing of Huang2's images is entitled to little or no weight.

d) Conclusion

Ultimately, it is Petitioner's burden to show—in the Petition itself—why the claims it challenges are unpatentable under the legal theories Petitioner chose to present. *See Harmonic Inc. v. Avid Tech., Inc*., 815 F.3d 1356, 1363 (Fed. Cir. 2016) ("In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable."); *see also Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) ("[T]hat burden never shifts to the patentee."). Petitioner fails to do so.

Petitioner chose to assert anticipation but failed to establish that Huang2 discloses—either expressly or inherently—a FFT analysis result having adjacent major peaks with about 180° apart from each other. The FFT analysis result

disclosed in Huang2 plainly has only a single peak. And Petitioner's argument that a POSITA would have known that Huang2's FFT plot could be expanded is directed to obviousness, not anticipation, and necessarily fails. Moreover, Petitioner fails to demonstrate that this FFT analysis result would necessarily include adjacent major peaks with about 180° apart from each other, even if Huang2's FFT analysis result were extended to 360°. Dr. Simpson's unsupported testimony and unexplained testing protocol cannot fill in these gaps in the reference upon which Petitioner chose to rely.

It is the Petition alone that defines the grounds of unpatentability that the Board must evaluate in determining whether Petitioner met its institution burden. Petitioner's failure to satisfy its *prima facie* unpatentability case in the Petition cannot be cured through further briefing. CTPG (Nov. 2019) 73 ("Petitioner may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability."); *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc*., 853 F.3d 1272, 1286 (Fed. Cir. 2017) ("It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify with particularity the evidence that supports the grounds for the challenge to each claim.").

Each challenged claim includes this limitation of sole independent claim 1. For these reasons, Petitioner's asserted Ground 1 fails on the merits, as does Ground 2, which depends therefrom.

C. Ground 2: Petitioner Fails to Show Obviousness of Claim 4 over Huang2 and Kumbar

Dependent claim 4 further recites that "the scaffold has an average porosity from about 60% to about 90%." Ex. 1001, 23:14–15.

Petitioner alleges that Huang2 describes scaffolds characterized by "high porosity"[12] and cites Kumbar (Ex. 1006) in support of its alternate contention that a POSITA "who desired to make aligned collagen blended fibers (as taught by Huang2) with 'high porosity' (as also taught by Huang2) would have been motivated to look at the reference cited by Huang2 in support of the 'high porosity,'" and that this combination would have been obvious. Pet. 44–46; Ex. 1006, 7. However, Petitioner fails to demonstrate that a POSITA would have been motivated, with a reasonable expectation of success, to employ Kumbar's porosity with Huang2's fibers.

Huang2's scaffolds are made from a blend of collagen and polycaprolactone

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[12] This broad disclosure is plainly insufficient to anticipate the specific porosity range recited in claim 4, as Petitioner alleges in Ground 1. Pet. 35 ("A POSA would understand that 'high porosity' would include percentages of porosity that are within the range of 60% to 90% ….").

(PCL). Ex. 1005, 1792 (Section 2.2 describing the matrix preparation). Specifically, Huang2 employs a 3:1 blend of PCL and collagen. *Id.* ("Nanofibrous matrices of PCL and Collagen at a weight ratio of 3:1 were fabricated using electrospinning as previously described."). Huang2 selects this blended composition intentionally, explaining that, due to the "rapid degradation and poor mechanical properties" of electrospun collagen fibers, "either crosslinking *or* combination with other materials is necessary to obtain a stable scaffold." *Id.* at 1791 (emphasis added). Accordingly, Huang2 elects to blend collagen and PCL to achieve stability and does not use pure collagen or cross-linked pure collagen. *Id.* at 1792.

Contrary to Huang's blended material, which is selected to ensure adequate stability, Petitioner relies on Kumbar's embodiments disclosing either pure collagen (with 89% porosity) or cross-linked pure collagen (with 71% porosity). Pet. 45. Petitioner does not identify any portion of Kumbar that discloses the porosity of a 3:1 PCL/collagen blend such as Huang2's. *Id.* at 44–47. Indeed, Kumbar recognizes that scaffolds made from pure collagen, cross-linked pure collagen, or a blend of PCL/collagen each present different properties. Ex. 1006, 8 (explaining that "[c]ross linking collagen nanofibers resulted in decrease of porosity from 89% [for collagen] to 71% [for cross-linked collagen].... Blended nanofibers of collagen and polycaprolactone (PCL) supported growth, proliferation and migration of fibroblasts inside the matrices").

Given the different materials and properties disclosed by Huang2 and Kumbar, Petitioner fails to demonstrate that a POSITA would have applied the porosity disclosed by Kumbar, which is only associated with pure collagen or cross-linked pure collagen scaffolds, to Huang2's PCL/collagen blended fibers, or that a POSITA would have expected success in such a modification. Petitioner fails its burden.

D. Ground 3: Petitioner Fails To Show Anticipation of Claims 1–12 by Lee

Petitioner's anticipation allegations based on Lee suffer the same deficiencies detailed above regarding Ground 1, only amplified, because Lee does not utilize FFT *at all*, much less disclose a FFT analysis result having adjacent major peaks with about 180° apart from each other as claimed.

1. Claims 1–12 are not expressly anticipated.

All challenged claims require a "FFT analysis result … hav[ing] adjacent major peaks with about 180° apart from each other." Ex. 1001, 23:7–9. Petitioner contends that Lee discloses this element. Pet. 49. However, Lee does not disclose FFT *at all*, much less the claimed FFT analysis result. *See generally* Ex. 1011.

Petitioner alleges that Lee "investigated the impact of alignment and the orientation" of the scaffold's fibers without FFT, including by (1) scanning electron microscopy (SEM) examination, (2) ImageTool 3.0 freeware analysis, and (3) tensile testing, all of which demonstrated the presence of "highly aligned fibers."

Pet. 49–52 (SEM and ImageTool), 53 (tensile testing). But "investigat[ing] the impact of alignment and the [fiber] orientation" is not the claimed result of a FFT analysis. And, as discussed above, the claims do not recite "aligned fibers" or a subjective interpretation of the fibers as "highly aligned." Instead, the claims recite a specific FFT analysis result having "major adjacent peaks that are about 180° apart from each other."

Lee's silence regarding FFT is dispositive. Lee cannot expressly anticipate the claimed FFT analysis result when FFT is not employed.

2. Claims 1–12 are not inherently anticipated.

Recognizing Lee's silence with respect to FFT, Petitioner additionally contends that a POSITA "would know that the degree of alignment could also be determined using ImageJ software to run an 'FFT analysis,'" which "was well known at the time" and "could be performed to further confirm alignment." Pet. 52. Petitioner contends that such an analysis "would show the fibers were oriented on the scaffold in Lee in an aligned manner," which is confirmed by Dr. Simpson's own FFT analysis of Lee's images. *Id.* at 52–53.

But neither Petitioner nor its expert clearly allege (much less clearly show) that this limitation is inherently disclosed and necessarily present in Lee. *See* Pet. 47–64 (failing to mention inherency at all); Ex. 1003 ¶¶ 85–93, 173–240 (same). In fact, the opposite is true: the claimed FFT analysis result is necessarily *not* present

in Lee, because Lee does not employ FFT at all. To the extent this Ground could be construed as an attempt to argue inherent anticipation, it falls short.

a) Expert testimony cannot fill in the gaps to supply missing claim limitations.

Lee does not disclose a FFT analysis result at all. To cure this defect, but in contravention of the statutory requirement that asserted grounds be premised on "patents and printed publications," Petitioner impermissibly relies on the testimony of Dr. Simpson to supply this missing claim limitation. As above, however, it is plainly improper for Petitioner to rely on Dr. Simpson's testimony to bridge that gap in the reference. *See Scripps*, 927 F.2d at 1576; CTPG 36; 35 U.S.C. § 311; *see supra* V.B.2.a.

b) Obviousness arguments do not demonstrate inherency.

Petitioner's contentions amount to an argument that a POSITA would have known how to modify Lee to employ FFT and, if they did so, the FFT analysis result would have adjacent major peaks with about 180° apart from each other. Pet. 31.

But this obviousness-based argument fails. The Petition contends that Lee *anticipates* the challenged claims under 35 U.S.C. § 102; this Ground does not allege obviousness under § 103. Accordingly, even if a POSITA might have known how to employ a FFT analysis on Lee's fibers, that is irrelevant to this ground; it has no bearing on whether Lee *inherently discloses* a FFT analysis result having adjacent major peaks with about 180° apart from each other. *See Scripps,* 927 F.2d at 1577

("If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground is not § 102 anticipation, but § 103 obviousness."); *Developmental Techs., LLC*, IPR2021-01560, Paper 16 at 8–9.

c) Petitioner's evidence is insufficient to meet its burden.

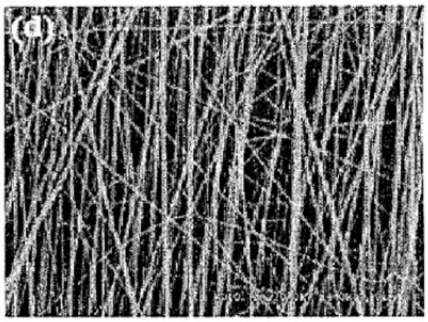
Even if the Board were to accept *arguendo* that Petitioner's contention—that a POSITA would have known how to perform a FFT analysis on Lee's images—has any bearing on anticipation, Petitioner fails to show that, even if so performed, that analysis would necessarily produce a FFT result having adjacent major peaks with about 180° apart from each other. The evidence Petitioner relies upon is simply insufficient to meet this burden. Pet. 52–53.

Petitioner relies primarily on post-hoc testing performed by its expert, Dr. Simpson, to bolster its assertion that a FFT analysis of Lee's Figure 1D, if it were performed, would necessarily include adjacent major peaks with about 180° apart from each other. *Id.* (citing Ex. 1003 ¶¶ 186, 188–191). But this testing is entitled to little or no weight because Dr. Simpson again provides insufficient explanation of how the testing was performed. 37 C.F.R. § 42.65(b).

Dr. Simpson states that he "conducted [his] own analysis on Lee's Figure 1D using the FFT analysis described in the '223 patent." Ex. 1003 ¶ 188. This is the only cited portion of Dr. Simpson's declaration explaining "[h]ow the test was

performed and the data was generated."[13] 37 C.F.R. § 42.65(b). This is insufficient. *See Luitpold Pharms.*, IPR2018-01640, Paper 19 at 23 (PTAB Mar. 6, 2019); *see also Abbott,* IPR2019-00882, Paper 48 at 35 (PTAB Oct. 2, 2020).

Dr. Simpson purports to have analyzed Figure 1D from Lee's provisional application, which is reproduced below. Ex. 1003 ¶ 184.



Immediately apparent from visual inspection of this image is its poor image quality. The record establishes the importance of image quality in the FFT analysis, casting doubt on the veracity of Dr. Simpson's testing or its purported results. *See, e.g.*, Ex. 1010, 605 ("If an objective with inadequate resolving power is used to capture data sets, individual fibers are not detected and the resulting image is composed largely of optical noise. In general, this type of optical image/data set is unsuitable

[13] Paragraph 187 of the declaration generally discusses how FFT analysis works. Ex. 1003 ¶ 187. This paragraph is not cited in the Petition. Moreover, it does not explain how Dr. Simpson's own testing of Lee's image was performed.

for analysis."). Dr. Simpson does not reckon with this image quality or the extent of "optical noise" it depicts. *Id.*

Additionally, Dr. Simpson purports to have performed the FFT analysis described in the '223 patent, which incorporates Dr. Simpson's 2008 paper by reference. As discussed above, *see supra* V.B.2.c.3 and incorporated herein by reference, the 2008 paper describes various aspects of the FFT analysis that are essential for accuracy but are not acknowledged by Dr. Simpson in his post-hoc testing of Lee's image. Specifically, Dr. Simpson does not establish that he appropriately accounted for issues such as:

- image compression and storage type (*see* Ex. 1010, 607 (discussing the importance of using uncompressed .TIF files, as opposed to compressed .JPG files, "to preserve image integrity"));
- necessary calibration for certain versions of the ImageJ software and oval profile plugin (*see id.* (explaining that "[s]ome versions of ImageJ (1.36b) altered [standard] convention," necessitating "[m]inor corrections … to correct for this condition, [which] may not be necessary for all 2D FFT programs"));
- uneven illumination (*see id.* at 609 (explaining that "[c]are should be taken at the time of image capture to optimize sample illumination; uneven

illumination can complicate and introduce error into the alignment analysis”));

- variations in light intensity (*see id.* at 610–612 (explaining that “[n]ormalization … is necessary to account for differences in sample thickness, camera performance, operator preference for contrast/brightness, and other variables that impact sample illumination at the time of image capture”));
- optical and electronic noise (*see id.* at 612 (explaining that “[n]oise from either source (optical and/or electronic) can introduce artifacts into a data image and adversely impact the 2D FFT process”)); or
- fiber array and any applied mask (*see id.* at 615 (explaining that noise may be introduced with “fibers that are arrayed approximately 45^{o} with respect to the edges of the image” such that “[t]he unmasked image produces a 2D FFT alignment plot with artifacts in the guise of small peaks on either side of the alignment peaks,” but also recognizing that application of a mask “reduces the total surface area available for analysis”).

Dr. Simpson does not explain how any aspect of his testing was performed, violating 37 C.F.R. § 42.65(b), and certainly does not establish that his testing conditions were sufficient to ensure reliable results.

For at least these reasons, Dr. Simpson's post-hoc testing of Lee's image is entitled to little or no weight.

d) Conclusion

Petitioner chose to assert anticipation based on Lee even though Lee does not employ FFT at all. Accordingly, Petitioner necessarily fails to establish that Lee discloses the claimed FFT analysis result with adjacent major peaks with about 180° apart from each other. Dr. Simpson's unsupported conclusions and unexplained post-hoc testing cannot fill in these gaps in the prior art that Petitioner itself chose to assert. CTPG 36 ("[A] petitioner asserting anticipation cannot rely on its expert to supply disclosure of a claim element that is not expressly or inherently present in the reference.").

E. Ground 4: Petitioner Fails to Show Obviousness of Claims 1–12 over Lee

As an alternative to its anticipation ground, Petitioner also alleges that claims 1–12 would have been obvious over Lee. Pet. 65–66 (citing Ex. 1003 ¶¶ 241–245). Petitioner contends that it was "well within the ordinary knowledge of a [POSITA] at the applicable time that 'FFT analysis' and ImageJ software could be run on Lee's SEM images to confirm the degree of alignment," and that a POSITA would have been motivated to do so. *Id.* (citing Ex. 1003 ¶¶ 242–243). Petitioner also contends that the POSITA would have expected success, as demonstrated by Dr. Simpson's testing. *Id.* at 65–66 (citing to Ground 3's analysis of the FFT

limitation, Pet. 49–53).

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic*, 815 F.3d at 1363. This burden never shifts to Patent Owner. *See Dynamic Drinkware*, 800 F.3d at 1378.

Here, Petitioner fails to satisfy its burden to demonstrate a motivation to modify Lee. Petitioner acknowledges that Lee already confirms fiber alignment through three different mechanisms: (1) scanning electron microscopy (SEM) examination, (2) ImageTool 3.0 freeware analysis, and (3) tensile testing. Pet. 49–52 (SEM and ImageTool), 53 (tensile testing); *see also id.* at 65. Given that alignment has already been confirmed in three different ways, Petitioner fails to explain why a POSITA would have been motivated to confirm alignment yet again, by a fourth mechanism. *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) ("To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.").

For example, Petitioner does not show that a fourth confirmation mechanism based on FFT would have been needed, expected, or typical in the art. Nor does Petitioner identify any deficiency in the first (SEM examination), second

(ImageTool 3.0 analysis), or third mechanisms (tensile testing) by which Lee already confirmed alignment. Petitioner also does not contend that FFT analysis would have imparted some additional or unique benefit over the three mechanisms that Lee already employed. And while Petitioner alleges that FFT was an "established tool," the fact that Lee already employed three other confirmation mechanisms suggests that they were "established" as well. *See, e.g.*, *Edwards Lifesciences Corp. v. Aortic Innovations LLC*, IPR2023-01232, Paper 10 at 36–37 (PTAB Feb. 7, 2024) (finding the purported motivation to be "inchoate" and "unpersuasive" because the "benefits" of the combination "are already conferred"); *see also UiPath, Inc. v. Rule 14 LLC*, IPR2024-01304, Paper 8 at 26–27 (PTAB Mar. 14, 2025) (finding no motivation to combine where the primary reference "already includes the option for the user to manually select a data source from a plurality of data sources" and petitioner and its expert offered only conclusory argument in support of its proposed combination).

The Petition was the place for Petitioner to identify any such motivating reason to modify Lee; this failure in its *prima facie* case cannot be cured post-institution. "Because of the expedited nature of IPR proceedings, it is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify with particularity the evidence that supports the grounds for the challenge to each claim." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330 (Fed. Cir. 2019). Accordingly, "the Board must base its decision on arguments

that were advanced by a party, and to which the opposing party was given a chance to respond." *In re Magnum,* 829 F.3d at 1381; *see also AMP Plus, Inc. v. DMF, Inc.*, 2025 U.S. App. LEXIS 6374 (Fed. Cir. 2025) ("[T]he law of obviousness does not require the court, or the Board, to develop arguments for a limitation that the petition simply did not make.").

Petitioner also argues that a POSITA knew that a FFT analysis "could be run on Lee's SEM images to confirm the degree of alignment." Pet. 65. But this is irrelevant. "Could have" is not the test for obviousness; a credible reason to modify must be shown. *See Belden, Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("Obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention."); *Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 888 (Fed. Cir. 2024) ("It does not suffice to simply be known. A reason for combining must exist."). Here, Petitioner fails to provide a sufficiently articulated reasoning with rational underpinning to support its conclusion of obviousness.

Finally, Petitioner relies upon Dr. Simpson's post-hoc testing to support its contention that a POSITA would have expected success in applying a FFT analysis to Lee. Pet. 65–66; Ex. 1003 ¶ 243 ("[A] POSA would have more than a reasonable expectation of success of successfully running an FFT on Lee's SEM images.

Indeed, I was able to run such an analysis."). However, the obviousness inquiry concerns the time of invention, not the time an expert declaration is prepared. Even if Dr. Simpson's post-hoc testing was not deficient for the reasons discussed above (it is, *see supra* V.D.2.c), this testing is insufficient to show that a POSITA *at the time* of invention would have expected success. *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc*., 752 F.3d 967, 974 (Fed. Cir. 2014) ("Obviousness, and expectation of success, are evaluated from the perspective of a person having ordinary skill in the art *at the time of invention*.") (emphasis added)).

As such, Petitioner plainly fails to demonstrate that a POSITA would have been motivated to modify Lee as alleged. Petitioner's obviousness ground fails.

VI. CONCLUSION

For the reasons discussed above, Petitioner has failed to meet its burden under 35 U.S.C. § 314(a). Patent Owner respectfully requests that the Board deny institution of *inter partes* review.

Dated: May 6, 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 9,649 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 May 6, 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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