

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

LIFENET HEALTH,
Patent Owner.

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

**OPPOSITION TO PATENT OWNER'S REQUEST
FOR DISCRETIONARY DENIAL**

Filed on behalf of Petitioners:

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I. INTRODUCTION

Petitioners herein oppose Patent Owner's request for discretionary denial.¹ Patent Owner's request relies solely on § 325(d). But that provision does not apply where the Petition presents new, noncumulative prior art and arguments. Here, the Petition relies on prior art that was never before the Office, disclosing features Patent Owner previously insisted were *absent* from the art that the Examiner considered.

In particular, during prosecution, Patent Owner argued that the prior art failed to disclose a scaffold containing electrospun fibers *comprising collagen*, where the fibers show peaks 180° apart by what is referred to as a fast Fourier transform ("FFT") analysis. Because of this, the Patent Owner amended all the claims to require that the electrospun fibers contain *collagen* to avoid this prior art. In contrast to Patent Owner's arguments before the Examiner, the Petition at issue relies on not one, but *two* separate references that specifically disclose electrospun fibers comprising *collagen* containing the requisite peaks recited in the claims, and thus completely refute the primary argument advanced by the Patent Owner during prosecution. Indeed, in an attempt to argue that the prior art cited in the Petition is

¹ The Patent Owner's Request for Discretionary Denial, dated April 4, 2025, Paper 8, is referred to as "Req., ____."

cumulative of that previously considered, the Patent Owner now adopts a position that contradicts its earlier prosecution arguments. If the prior art newly cited in the Petition was before the Examiner, the claims of U.S. Patent No. 10,137,233 (“the ’223 patent”) could not have been issued as they are anticipated under 35 U.S.C. § 102. Under well-established precedent, such prior art is the epitome of non-cumulative art—it is directly responsive to what was allegedly missing during prosecution. Accordingly, § 325(d) does not apply, and the Patent Owner’s request for discretionary denial should be denied.

II. FACTUAL BACKGROUND

A. Procedural History

On March 26, 2025, the Patent Trial and Appeal Board (PTAB) issued a memorandum (referred to herein as “Memo”) that announced revised procedures governing discretionary denial in inter partes review (IPR) proceedings.² Because the Petition in this case was accorded a filing date of February 6, 2025 (IPR2025-00248, Paper 5), it falls within the scope of these newly implemented procedures. Consequently, on April 3, 2025, the Patent Office issued an order directing the Patent Owner to file a brief addressing discretionary denial under the new

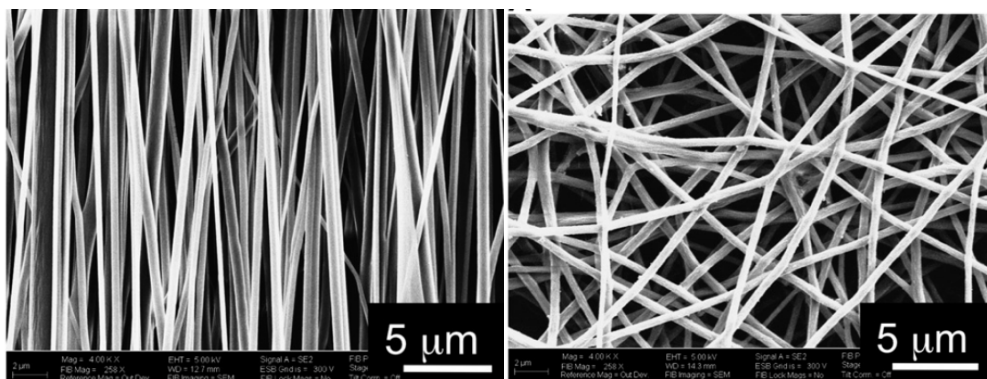
² See <https://www.uspto.gov/sites/default/files/documents/InterimProcessesPTABWorkloadMgmt-20250326.pdf>.

procedures by May 3, 2025. (IPR2025-00248, Paper 6.) Under the updated PTAB guidelines, the Petitioner's response was due a month from this date, or June 3, 2025, regardless if Patent Owner filed its brief early. (*See* FAQ, ¶¶ 3,7.)³ Accordingly, Petitioners submit this response to the Patent Owner's request for discretionary denial on June 3, 2025, in accordance with the PTAB's procedural schedule.

B. Scientific Background

The '223 patent pertains to electrospinning, which is a technique that can be used to create fibers for scaffolds that can repair injuries to tissue. Electrospinning was a well-established method for producing fibers as of March 14, 2013, the earliest priority date alleged for the '223 patent. (*See* EX1003, §§ III.A-B; EX1006, 1-2.) The fibers obtained from electrospinning can either be aligned or randomly oriented, as shown in the following images obtained from a scanning electron microscope:

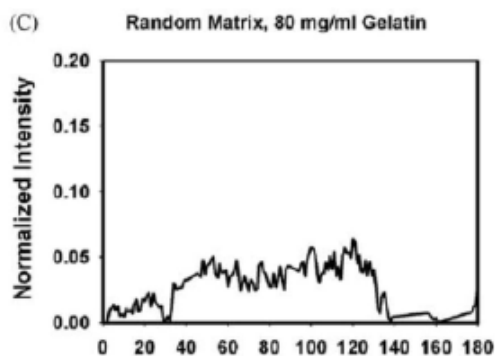
³ The FAQs for Interim Processes for PTAB Workload Management is herein referred to as "FAQ." *See* <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management>.



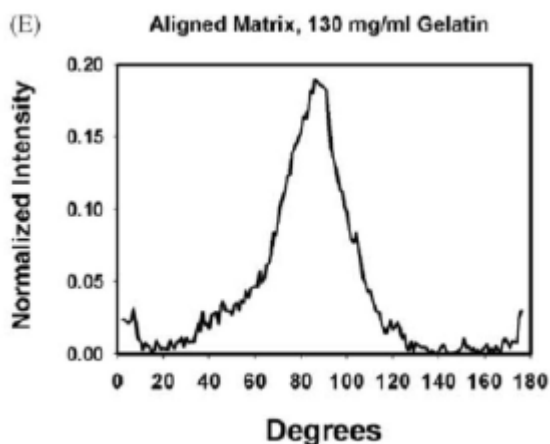
(EX1005, 1793; EX1003, ¶¶ 38-45.) The image on the left shows fibers that are aligned, while the image on the right shows fibers that are randomly oriented. (*Id.*) Increased fiber alignment was well-known in the prior art to enhance the mechanical and biological properties of scaffolds. (EX1003, ¶¶ 36-38; EX1006, 6; EX1010, 604; EX1018, [0112].)

To quantify fiber alignment, Dr. Simpson, Petitioners' declarant, pioneered a method, which is incorporated into the specification of the '223 patent and is recited in its claims. The details of this method are discussed more fully in Dr. Simpson's declaration. (EX1003, § III.D.)

The method uses a mathematical tool called fast Fourier transform (2D FFT) in order to generate a 2D FFT alignment plot. (EX1013, 4; EX1010, 609; EX1003, ¶¶ 38-39.) The plot illustrates the degree of fiber alignment. (EX1003, ¶ 42; EX1010, 610; EX1013, 4.) Randomly aligned fibers can produce many short peaks (*see figure below*), while aligned fibers show a single peak between 0° and 180° (*see figure below*). (EX1013, 12; EX1010, 608, 614; EX1003, ¶ 44.)



(EX1013, 15 (Unaligned 2D FFT alignment plot).)



(EX1013, 15 (Aligned 2D FFT alignment plot).)

Typical practice was (and is) to report 2D FFT alignment plots from 0° to 180° , because the FFT, through its inherent mathematical properties, produces a symmetrical plot. Thus, according to Dr. Simpson's seminal papers on the method, reporting beyond 180° is unnecessary. (EX1003, ¶ 46; EX1010, 609; EX1013, 4.)

"Typically, the [FFT] 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." (EX1010, 609; EX1003, ¶ 62.) Therefore, 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. (EX1003, § III.D., ¶ 46.)

C. The '223 Patent

The '223 patent issued on November 27, 2018. It issued from U.S. Application No. 14/776,106 filed September 14, 2015. The face of the patent also lists a provisional application, Provisional App. No. 61/785,031, which was filed on March 14, 2013.

1. The Subject Matter of the '223 Patent

The '223 patent “relates to a scaffold comprising one or more electrospun fibers.” (EX1001, Abstract; EX1003, §IV.) The specification discloses that “electrospray/electrospinning techniques can be used to form particles and fibers as small as one nanometer in principal direction.” (EX1001, 2:17–19.) The specification further notes that collagen is a material that can be used in creating fibers from electrospinning. (*Id.*, 14:52–57.)

The specification states that for some embodiments, the fibers of the scaffold are aligned such that “a fast Fourier transform (FFT) analysis result of the fibers [in the scaffold] have adjacent major peaks with about 180° apart from each another.” (*Id.*, 13:2-6.) According to the specification, “the ‘major peaks’ . . . refer to peaks higher than the average peaks in the result.” (*Id.*, 13:6-7.)

The specification states that “the FFT analysis may be performed by the methods described in *Measuring fiber alignment in electrospun scaffolds; a user’s guide to the 2D fast Fourier transform approach*, Ayres C.E., Jha B.S., Meredith

H., Bowman J.R., Bowlin G.L., Henderson S.C., and Simpson D.G, Biomater Sci Polym Ed. 2008; 19(5): 603-21, which is incorporated by reference in its entirety herein.” (*Id.*, 13:16–24.) As mentioned above, Dr. Simpson, whose declaration was included with the Petition, is the senior author of the Ayres paper. (EX1003, §§I.A–C, ¶ 61.)

FIG. 8 of the '223 patent, reproduced below, discloses the results of an FFT analysis of prepared fibers: “FIG. 8 depicts exemplary FFT analysis results (a) of the fibers described herein and (b) a control sample.” (EX1001, 1:55–56.) The specification further states that “[i]n some embodiments, FFT result of fibers described herein may have adjacent major peaks with about 180° apart from each other as shown in FIG. 8.” (*Id.*, 13:24–26.)

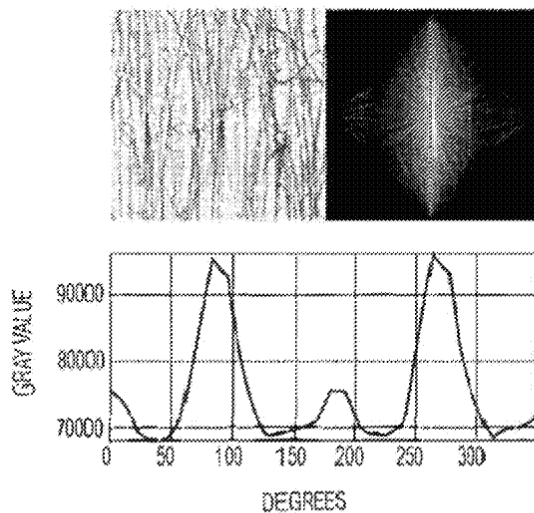


FIG. 8A

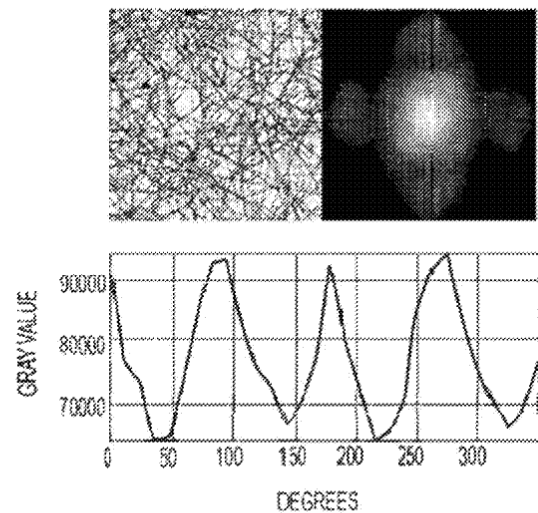


FIG. 8B

2. Claims

Claim 1 of the '223 patent recites a scaffold of electrospun fibers that *include collagen* wherein a FFT analysis shows that the fibers are aligned such that they have adjacent major peaks about 180° apart from each other. As discussed in detail below, this claim was amended during prosecution to require that the fibers contain collagen. Independent claim 1 is reproduced below.

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.

(EX1001, 23:5-9.) The '223 patent's dependent claims depend either directly or indirectly from claim 1. These dependent claims also require aligned fibers as recited by claim 1 that comprise collagen and further cover scaffolds that have additional constituents and/or properties, as well as conventional methods for culturing cells on scaffolds.

3. Relevant Prosecution History

The '223 application received one office action rejection before allowance. The Examiner rejected claims 1 (corresponding to claim 1), 11 (corresponding to allowed claim 4), 12 (corresponding to allowed claim 5), and 17 (corresponding to allowed claim 6), as invalid as anticipated under 35 U.S.C. § 102(b) by Huang et al., *Electrospun collagen-chitosan-TPU nanofibrous scaffolds for tissue engineered tubular grafts*, 82 Colloids and Surfaces B: Biointerfaces 307-315

(2011) (hereinafter referred to as “Huang1,” attached as EX1008 to the Petition).

The Examiner stated that “Huang discloses a scaffold comprising one or more electrospun fibers” where the “aligned nanofibrous scaffolds” were “based on collagen, chitosan, thermoplastic polyurethane (TPU) blends[.]” (EX1002, 210.)

The Examiner further stated that “a fast Fourier transform (FFT) analysis result of the fibers have adjacent major peaks with about 180° apart from each other (Fig. 4E: pg. 309, Col. 2, two peaks at 175° and 355° (180° apart)).” (*Id.*, 211.)

The Patent Owner responded to the rejection, arguing that the prior art fibers disclosed in Huang1 satisfied the claimed alignment but *only* for “pure thermoplastic polyurethane fibers that comprise *no collagen*.” (*Id.*, 238 (emphasis added).) In contrast, for the fibers that *did contain collagen*, the Patent Owner argued that those fibers were *not* aligned. (*Id.*) “[Huang1’s] electrospun fibers comprising TPU, *collagen*, and chitosan *did not* exhibit the degree of alignment as recited in present claim 1.” (*Id.* (emphasis added).) Indeed, Huang1 itself states that for the collagen blended fibers: “[a]lthough two main peaks could also be found at 5° and 185°, *the existence of other peaks indicates that some nanofibers are not well aligned*.” (EX1008, 309 (emphasis added).) Patent Owner even quotes this passage in its current request. (Req., 16.)

The Patent Owner thus amended independent claim 1 to *require* the inclusion of collagen to overcome Huang1. Because the pending dependent claims

depended from claim 1, the amendment to include collagen applied to those claims as well. Thus, the Patent Owner stated that based on this amendment, “[pending] claims 1, 11, 12, and 17 should not be rejected again as anticipated by Huang.” (EX1002, 238.)

The Examiner had further rejected pending claims 1, 5, 6, 11-12, 17, 19, 20-22 (corresponding to issued claims 1-10) as obvious under 35 U.S.C. § 103(a) by U.S. Patent App. Pub. No. 2004/0037813 (“Simpson”). (EX1002, 211–13.)⁴ While Simpson discloses the concept of aligned collagen fibers (EX1009, [0102]), it does *not* provide any examples or data of actually obtaining aligned collagen fibers. (*See id.*)

The Examiner explained that “Simpson beneficially teaches a scaffold comprising one or more electrospun fibers” and that “Simpson teaches that the secondary structure of collagen is not modified in the process of making the scaffold, as shown by Fourier transform infrared spectroscopy[.]” (EX1002, 211.) The Examiner thus rejected these pending claims because “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to make a scaffold comprising one or more electrospun fibers based upon the

⁴ This Simpson reference was attached as EX1009 to the Petition. This is the same Dr. Simpson who has filed a declaration supporting the Petition.

beneficial teachings provided by Simpson,” and that “[f]rom 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.” (*Id.*, 213 (emphasis added).)

The Patent Owner overcame the obviousness rejection based on Simpson by arguing that the scaffold in Simpson and Huang1 was prepared using a rotating cylindrical collector, while the apparatus in the claimed invention uses a rotating, rod-shaped electrode to arrive at the claimed fiber alignment with collagen fibers. (*Id.*, 238–39.) Since, according to the Patent Owner, Huang1 demonstrated that using a cylindrical collector to prepare electrospun fibers did not result in the claimed fiber alignment for blended collagen fibers, a skilled artisan would *not* look to Simpson to arrive at the claimed fiber alignment, as Simpson also uses the same rotating cylindrical collector. (*Id.*) Thus, a Person of Ordinary Skill in the Art (“POSA”) “would not have expected to obtain the claimed fiber alignment” following the Simpson reference. (*Id.*) Accordingly, based on the Patent Owner’s amendment requiring collagen, the claims of the ’223 patent were allowed. (*Id.*, 243–45.)

D. The Art Cited in the Petition Was Not Before The Examiner and Renders the Claims of the ’223 Patent Invalid

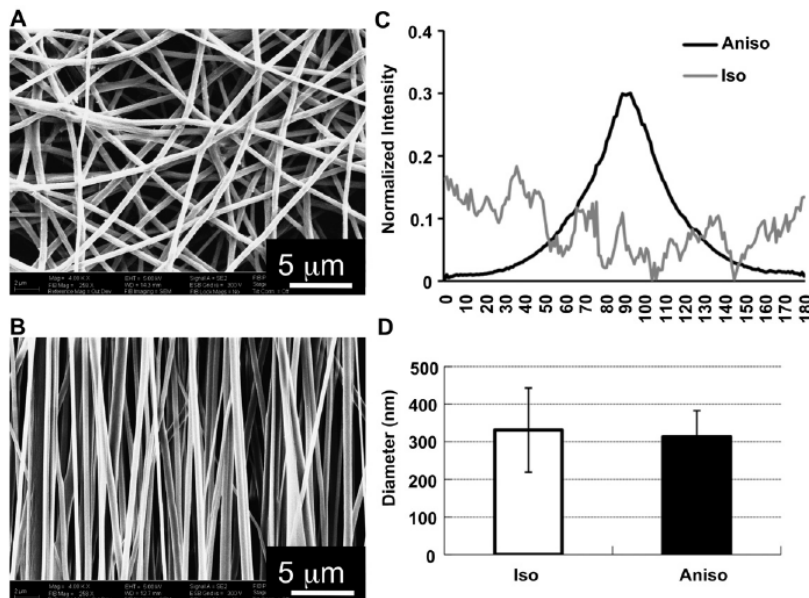
In direct contrast to the arguments raised by the Patent Owner during prosecution, the two references cited in the Petition, Huang2 and Lee, specifically

describe the preparation of actual blended collagen fibers with the requisite FFT peaks recited in the claims of the '223 patent.

1. Huang2

Huang2 (attached as EX1005 to the Petition) is a different prior art reference from a different research group than the Huang1 reference that was cited during prosecution of the '223 patent. Huang2 was not cited during prosecution of the '223 patent.

Huang2 studied fibers comprising collagen and sought to examine the effect of aligned fibers compared to non-aligned fibers on the attachment and growths of normal human dermal fibroblasts ("NHDFs"), including fibroblast-to-myofibroblast differentiation. (EX1005, 1797; EX1003, §V.A.) To do this, Huang2 created scaffolds of "stable" *collagen blended fibers* for engineering skin grafts. (EX1005, 1791–92.) Images of the fibers comprising collagen oriented in Huang2's scaffolds, and an FFT analysis of such images, are shown in Figure 1:



These images show the aligned fiber sample (EX1005, 1793 (Figure 1B)) and the non-aligned sample (EX1005, 1793 (Figure 1A)).

To determine and show the alignment of the fibers used in the scaffolds, Huang2 performed an FFT analyses using Dr. Simpson's technique. The FFT analysis graph is reported at Figure 1C. (*Id.*) The aligned sample has one major peak at about 90° with no other major peaks present. (*Id.*) Based on this readout, and as discussed in detail in the Petition, because of the symmetry in an FFT readout between 0° to 180° and 180° to 360°, a POSA would know that if the scale were extended to 360°, a second peak for the aligned sample would necessarily be at the symmetrical position of about 270°. (EX1003, ¶ 77.) No other major peaks would be present between 180° and 360° degrees for the aligned sample. (*Id.*) Therefore, and in direct contrast to how the Patent Owner specifically

characterized the prior art before the Examiner, Figure 1C in Huang2 for the aligned sample shows aligned fibers *containing collagen* that have major peaks 180° apart from each other, and thus squarely fall within the scope of the claims of the '223 patent. (*Id.*)

Dr. Simpson conducted his own analysis of Figure 1B using the FFT analysis published in his papers, and described in Huang2 and the '223 patent, and reported data from 0° to 360°. (*Id.*, ¶¶ 110–11.) The graph generated from the FFT analysis performed by Dr. Simpson further confirmed that the aligned fibers comprising collagen in Huang2 have a major peak at about 90° and, because Dr. Simpson reported all the peaks through 360°, a second major peak at about 270°, which shows that the peaks are 180° apart as recited in claim 1. (*Id.*) None of this data was before the Examiner during prosecution.

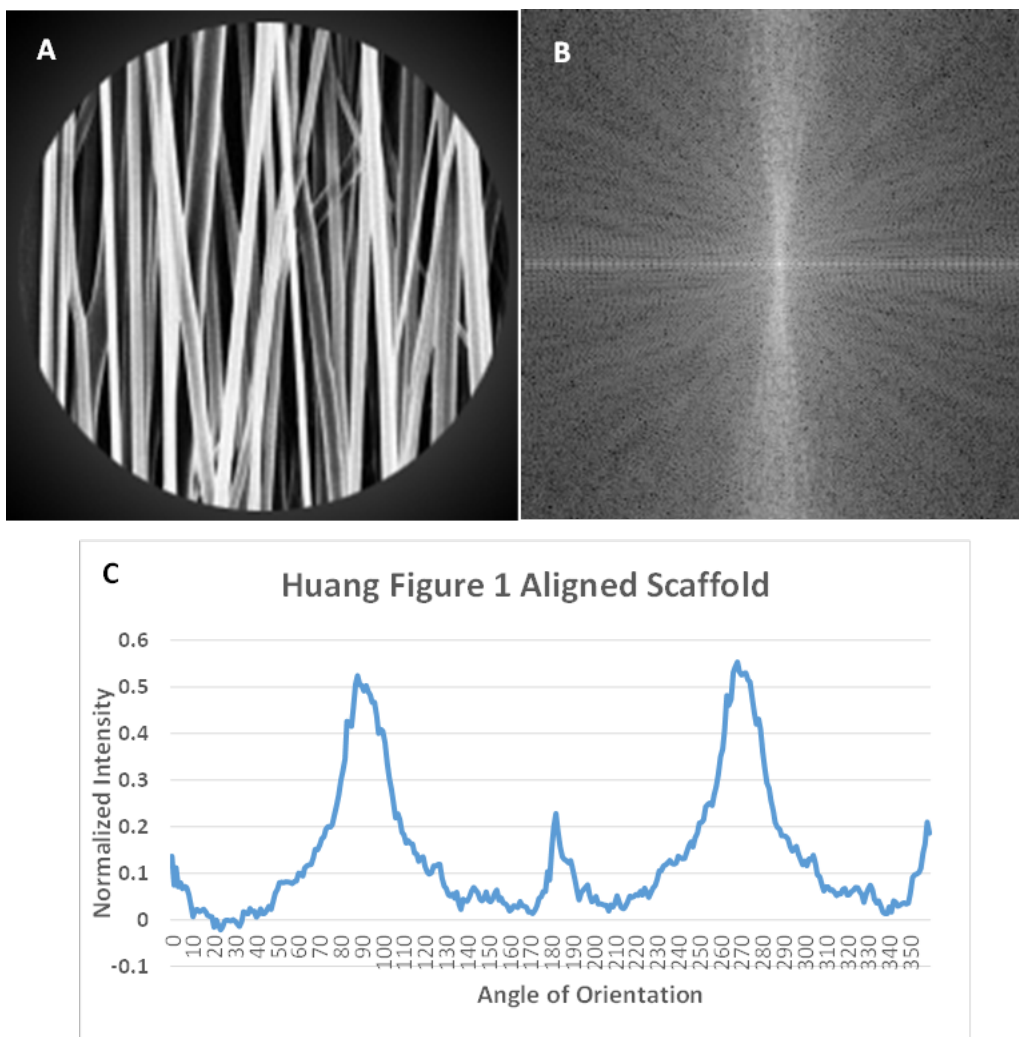


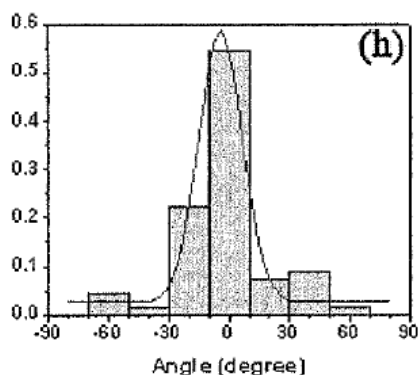
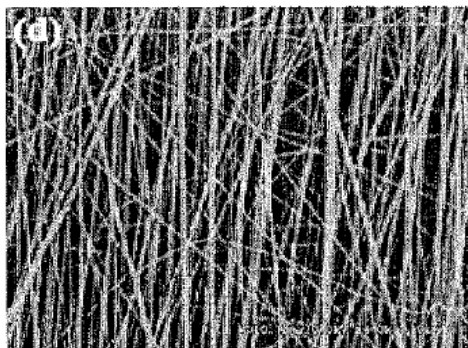
Figure 2. (A) Figure 1 from Huang aligned scaffold cropped and masked for 2DFFT. (B) 2DFFT spectrum of aligned scaffold, the image has been rotated to correct for the rotation intrinsic to the FFT analysis. (c) Normalized intensity values for aligned scaffold 0-360 degrees.

(Id.)

2. Lee

Lee (attached as EX1011 to the Petition) was also not cited as prior art during the prosecution of the '223 patent. Lee is directed at the reconstruction of skeletal muscle tissue due to a traumatic injury. (EX1011, [0003]; EX1003, §V.C.)

Lee obtained Type 1 *collagen* and electrospun nanofiber meshes “using a blend of PCL and collagen[.]” (EX1011, [0062]-[0063].) Lee’s most aligned fibers comprising collagen are shown in Figure 1D and corresponding histogram Figure 1H.⁵

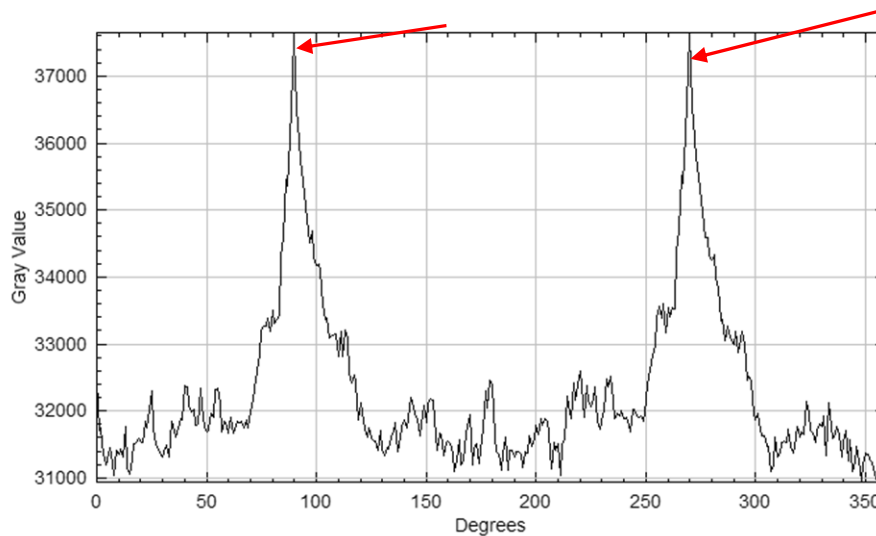


(EX1021, Figs. 1D, 1H.)

Petitioners’ expert, Dr. Simpson, ran an FFT analysis on Figure 1D. The resulting graph and analysis shows clear adjacent major peaks at around 90° and

⁵ The image analysis was done using Lee’s provisional, U.S. Provisional Patent App. No. 61/025,350, which discloses the same data, but with a clearer image.

270°. (EX1003, ¶¶ 188–190.) These peaks are thus about 180° apart from each other (annotated in **red**):



(*Id.*) Again, neither Lee, nor the FFT data analyzing Lee, was before the Examiner during the prosecution of the '223 patent.

E. The Petition

Because Huang2 and Lee disclose scaffolds comprising *collagen* fibers with the claimed FFT peaks, the very subject matter the Patent Owner argues was *missing* from the prior art, those references not before the Examiner during prosecution anticipate claims 1-12 of the '223 patent. Accordingly, on December 4, 2024, Petitioners filed their Petition seeking *inter partes* review seeking to cancel them. (Paper 2 (referred to herein as “Pet.”).)⁶

⁶ In the alternative, Petitioners also included two obviousness grounds, which also primarily rely on Huang2 and Lee. (Pet., §§ XI (Ground 2), XIII (Ground 4).)

III. ARGUMENT

A. The Art Relied on in the Petition Is Not Cumulative of the Art Considered During Prosecution

The Patent Owner argues that the prior art raised in the Petition is cumulative to that before the Examiner based on a comparison of the alleged “structures” of the fibers in the art before the Examiner and the structure of the fibers actually prepared and described in the new references (Huang2 and Lee) relied on in the Petition. (Req., 14-27.) The Patent Owner then argues the Petition should be discretionarily denied because Petitioners failed to point to “material error” made by the Examiner in considering the references raised during prosecution. (Req., 28-29.)

Patent Owner’s argument, however, misstates the controlling framework and is based on an incorrect premise. The proper inquiry—set forth in *Advanced Bionics* and guided by *Becton, Dickinson*—requires a threshold determination of whether the art is cumulative, i.e., whether the same or substantially the same art was previously presented to the Office. *Only* if that threshold is met does the Board consider whether any material error occurred. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6, at 8–9 (P.T.A.B. Feb. 13, 2020) (precedential) (“*Advanced Bionics*”). This is precisely what happened in *Oticon Medical AB v. Cochlear Ltd.*, IPR2019-00975, Paper 15 (Oct. 16, 2019) (“*Oticon*”). In *Oticon*, a precedential opinion, the Board declined to

exercise its discretion under § 325(d) based on the petition's reliance on new, noncumulative prior art. *Oticon*, at 19–20. The Board identified no other factor as relevant to that determination and specifically rejected the Patent Owner's assertions that Petitioners failed to point out “error” by the Examiner based on the fact that the reference was non-cumulative. *Id.* Thus, in that case, the presence of non-cumulative art alone was sufficient to warrant institution.

As in *Oticon*, the threshold inquiry of whether a reference is cumulative is simply not met here. Huang2 and Lee were never before the Office and are not cumulative of the art considered during prosecution. As detailed above, they disclose collagen fiber scaffolds with FFT peaks approximately 180° apart—features Patent Owner argued were *absent* from Huang1 and Simpson. (EX1002, 238-39; *see* Pet. at § VI.C; *supra*, § II.C(3).) Thus, the art that the Examiner considered is meaningfully different, and the Examiner never considered substantially the same arguments presented by the Petition. Patent Owner's argument rests on circular reasoning. It *assumes* that the prior art is cumulative, and then faults Petitioners for failing to show material error—an inquiry that only arises if the art is cumulative in the first place. Because Huang2 and Lee are not cumulative, no further showing is necessary.

Indeed, in assessing the threshold question, the Board considers the *Becton*, *Dickinson* factors, including: the similarities and material differences between the

asserted prior art and the art considered during prosecution; whether the asserted art is cumulative of previously considered art; and the extent of overlap between arguments made during examination and those advanced in the petition. *Advanced Bionics* at 9–10.

Here, as mentioned above, Huang2 and Lee, were never before the Office, and both were able to achieve the very features—*collagen* fibers with FFT peaks 180° apart—that the Patent Owner previously argued were *absent* from the art. This directly contradicts Patent Owner’s assertions that Huang2 and Lee have “substantially the same structure” as the art before the Examiner. (Req., 18-19, 24-25.) Indeed, as set forth above, Patent Owner’s contention that Huang2 and Lee are cumulative of Huang1 and Simpson cannot be squared with arguments made by the Patent Owner during the ’223 patent’s prosecution history.

To the contrary, during prosecution, Patent Owner emphasized that neither Huang1 nor Simpson disclosed *collagen* fibers exhibiting the FFT peak alignment required by the claims—an argument that directly led to allowance when the Patent Owner then amended *all* the claims to specifically require collagen. (See § II.C(3), *supra*.) As set forth above, Huang1 itself states that the fibers containing blended collagen fibers were not sufficiently aligned. (EX1008, 309; Req., 16.)

Further, while the Patent Owner *now* argues that Simpson was considered during prosecution and discloses the concept of obtaining aligned collagen fibers

(Req., 24-26), during prosecution, the Patent Owner specifically argued that a POSA following Simpson “would not have expected” (EX1002, 238–39) to obtain aligned collagen fibers in light of the failure of Huang1 to obtain such fibers. Indeed, as also discussed above, Simpson does not contain *any* data showing FFT analysis of collagen blended fibers. (§ II.C(3), *supra*; see EX1009.) In contrast, both Huang2 and Lee relied on in the Petition achieved success, showing the preparation of aligned fibers containing collagen that have the requisite FFT peaks recited in the claims, as confirmed by Dr. Simpson. (See §§ II.D 1–2, *supra*.)

Accordingly, not only was the art cited in the Petition substantially different than what was before the Examiner, but so were the arguments that the Examiner considered. As such, and contrary to Patent Owner’s assertions, the references relied on in the Petition are also not being used in “substantially the same manner” (Req., 20, 26–27) for “substantially the same purpose” (Req., 19-20, 26) as the art during prosecution. Indeed, that substantially different arguments are raised in the Petition than that advanced during prosecution is yet another reason why Patent Owner’s cumulative assertions fail. See *Advanced Bionics* at 7-8.

In light of those arguments made during prosecution, it is not tenable for Patent Owner to now argue that Huang2 and Lee are cumulative of Huang1 and Simpson. According to Patent Owner’s own prosecution arguments, Huang1 and Simpson do *not* disclose collagen fibers with the claimed FFT peaks or a means of

“reasonably” obtaining them. But, as discussed in the Background Section, the Petition, and Dr. Simpson’s Declaration, Huang² and Lee *do disclose* such fibers. (See §II.D, *supra*; Pet. at §§ IX.A, IX.C, X.A, XII.A; EX1003 §§ V.A, V.C, V.A.1, VI.C.1.)

Thus, the references *cannot* be cumulative—references that disclose the very features Patent Owner previously argued were absent cannot be dismissed as cumulative under well-established precedent. See *e.g.*, *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1352–53 (Fed. Cir. 2021) (rejecting “argument that the withheld art . . . is ‘cumulative’” because the patent owner’s current “argument is directly at odds with its argument during prosecution that the claimed range was ‘critical.’”); *Plr Worldwide Sales Ltd. v. Flip Phone Games, Inc.*, No. IPR2024-00209, 2024 WL 2106683, at *7 (P.T.A.B. May 10, 2024) (faulting the patent owner for relying on a “high-level comparison of the references” and explaining that newly cited art in the petition was not “substantially the same” as the art cited during prosecution where the new art disclosed a claim element that was specifically added to the claims during prosecution to avoid the cited prior art); *Tide Int’l (USA), Inc. v. UPL NA, Inc.*, No. IPR2020-01113, 2021 WL 225942, at *9–11 (P.T.A.B. Jan. 22, 2021) (finding art not cumulative where the new art cited in the petition contradicted the reasons stated by the examiner in allowing the claims to issue). Here, the Examiner believed the Patent Owner’s representations

that the prior art did not, and could not, obtain collagen fibers with the claimed FFT peaks. Such representations could not have been made if Huang² and Lee were before the Examiner.

Indeed, that the Patent Owner is now forced to take the opposite position that it argued during prosecution demonstrates the weakness of its position. In its current brief, Patent Owner *now* argues that the prior art discloses “aligned fiber scaffolds comprising collagen.” (Req., 19, 25-26.) But before the Examiner, it argued the *opposite*—that the prior art did *not* disclose aligned collagen fibers with the requisite peaks recited in the claims. (EX1002, 238-39.) In this regard, if aligned collagen fibers with the requisite peaks were disclosed in the art, the Patent Owner has effectively conceded that its claims should never have issued and are unpatentable. Patent Owner fails to explain how it is possibly entitled to a patent if the prior art plainly disclosed aligned collagen fibers with peaks 180° apart in the FFT. In contrast, if such features were not present in the prior art, which is what the Patent Owner explicitly argued during prosecution, then Huang² and Lee bridge that gap and cannot possibly be cumulative. Either way, § 325(d) offers no basis for denying institution.

The Patent Owner also attempts to discount Dr. Simpson’s declaration as duplicative. (Req., 11, 20–21, 27.) This is incorrect. Dr. Simpson provides a detailed FFT analysis using the very method that underlies the ’223 patent claims.

(See EX1001, Claim 1, 13:15–26; EX1003, ¶¶ 110–111, 188–190; *see also* §§II.B, II.D *supra*.) His declaration applies this methodology to the images in Huang2 and Lee and demonstrates that the collagen-blended fibers disclosed there exhibit FFT peaks consistent with the claims. (EX1003, ¶¶ 110–111, 188–190.)

Dr. Simpson also confirmed that the FFT results shown in Huang2 disclose collagen-blended fibers with the same FFT alignment peaks claimed in the '223 patent. (EX1003, ¶¶ 101-109.) Neither this data nor Dr. Simpson's analysis was before the Examiner. The Patent Owner itself emphasizes Dr. Simpson's expertise, acknowledging that some of his work was considered during prosecution. (Req., 11, 20-21, 27.) That only enhances the credibility of his declaration. Far from being cumulative, Dr. Simpson's sworn analysis offers new, relevant insight into prior art not previously evaluated by the Office and directly addresses key claim limitations.

B. Patent Owner's Arguments Concerning "Material Error" Are Misplaced

As set forth above, because the prior art relied in the Petition is not cumulative to what was before the Examiner, the threshold inquiry is not met, and Patent Owner's arguments about "material error" are misplaced. (See Req., 28–29.) In any event, it should be noted that the March 26, 2025 Memorandum expressly authorizes petitioners to respond to § 325(d) arguments. (Memo, 2-3.) And the recently issued FAQ makes that even more clear. (FAQ at ¶ 24 ("The petition

should not address discretionary issues. A petitioner should raise any discretionary issues in its opposition to a patent owner’s discretionary denial brief”).)

C. The Merits Overwhelmingly Support Institution

The March 26, 2025 Memorandum expressly invites the parties to address the strength of the unpatentability grounds. (Memo, 2.) Here, the merits are extremely strong and warrant institution.

The claims hinge on aligned collagen comprising fibers with specified FFT peaks. Huang² specifically disclosed blended collagen fibers that contain the requisite FFT peaks recited in the claims. (Pet., 29–33; EX1003, ¶¶ 101–14.) Lee also prepared collagen comprising fibers and confirmed they were aligned using three different methods, as *admitted* by the Patent Owner in its Patent Owner Preliminary Response (“POPR”). (POPR, 11, 43–44 (“Lee already confirms alignment with three alternate mechanisms”).) Further, Dr. Simpson—the very pioneer of the FFT technique recited in the claims—applied that method to the images of the collagen comprising fibers in both Huang² and Lee and confirmed that both references disclosed collagen fibers with the claimed FFT peaks. (Pet., §§X.A(3), XII.A(3); EX1003, ¶¶ 110–111, 188–190; *see* §§II.B, II.D, *supra*.) It is hard to conceive of a more straightforward showing of unpatentability: the prior art was analyzed using the claimed technique by its original developer and shown to meet the claim limitations. *Sage Prods., LLC v. Stewart*, 133 F.4th 1376, 1385

(Fed. Cir. 2025) (“Our precedents establish that expert opinion ‘may be used to interpret [an] allegedly anticipating reference and to shed light on what it would have meant to’” a POSA.)

Patent Owner, however, contends in its POPR that neither Huang² nor Lee actually disclose collagen fibers having FFT peaks 180° apart. (POPR, 14–33, 35–42.) Yet, this is purely a technical question as to how a POSA would view the references, and the Patent Owner offers *solely* attorney argument, which can be discounted. *Elbit Sys. of Am., LLC v. Thales Visionx, Inc.*, 881 F.3d 1354, 1359 (Fed. Cir. 2018) (rejecting attorney argument about how a POSA would view the prior art in the face of contradictory expert evidence because “[a]ttorney argument is not evidence’ and cannot rebut other admitted evidence”); *KEYnetik, Inc. v. Samsung Elecs. Co., Ltd.*, No. 2022-1127, 2023 WL 2003932, at *2 (Fed. Cir. Feb. 15, 2023) (rejecting Patent Owner’s attorney argument that Petitioner’s expert’s testimony was “inadequate” because “attorney argument is no substitute for evidence”).

As set forth above, Huang² discloses a single peak in a 180° field, which a POSA would understand would show a second peak at the symmetrical position if the field were extended to 360°. Both Ayres 2008, which is expressly incorporated into the ’223 patent, and Dr. Simpson, in his testimony supporting the Petition, expressly state this. (EX1003, ¶¶ 101–09; EX1010, 609; EX1013, 4.) Indeed,

Huang2 itself specifically states it captured data for the full 360 degree field—“360 points such that the degree interval was 1°.” (EX1005, 1792.) Huang2 only needed to show data through 180°, however, because that is how the data is “typically” reported, as set forth by Ayres 2008 (EX1010, 8),⁷ and because there was only one peak in the 180° field. A POSA, as testified by Dr. Simpson, would clearly understand that there would be a second peak at the symmetrical position if the full data was reported. (EX1003, ¶¶ 101–09.) Patent Owner’s contradictory attorney argument should be discounted.

Moreover, Patent Owner’s attacks on Dr. Simpson’s testing in its POPR are without merit. (See POPR, 26-31, 38-42.) As before, Patent Owner’s assertions are based solely on attorney argument without any supporting expert testimony. Dr. Simpson performed the testing from the perspective of a skilled artisan, and Patent Owner’s attorney’s assertions that Dr. Simpson, the inventor of the technique,

⁷ In contrast to Patent Owner’s assertions (POPR, 24), Ayres explains that this is the way data is typically reported, not that the plot is typically symmetrical. Ayres 2006 and 2008 makes clear that the positions of the peaks are in fact symmetrical in a 360 field. (EX1013, 4 (“the FFT is symmetric about the horizontal axis so a pixel summation to 360° is unnecessary”); EX1010, 609 (“the frequency plot is symmetric so a complete summation from 0 to 360° is not technically necessary”).)

performed his own method incorrectly should be completely discounted. Notably, the '223 patent itself does not report a single parameter that the Patent Owner now alleges is essential in performing the method. (*See* EX1001, 13:15-26 (only citing Ayres 2008 for FFT methodology).) Patent Owner also does not put forward any evidence showing that an alleged “correct” application of the FFT technique would provide different results. The Patent Owner could not do so, as both Huang² and Lee do, in fact, disclose aligned collagen fibers exhibiting the necessary peaks in the FFT—a tool that is simply used to assess fiber alignment.

IV. CONCLUSION

The Petition presents new, noncumulative prior art that discloses precisely the features Patent Owner previously identified as missing from the references considered during prosecution. Further, the merits of the Petition are extremely strong. Thus, Patent Owner’s request for discretionary denial under § 325(d) fails and institution is warranted.

Respectfully submitted,

Dated: June 3, 2026

By: /Howard Levine/
Howard Levine (Reg. No. 41,453)

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing **Opposition to Patent Owner's Request for Discretionary Denial** contains 5355 words, as measured by the word-processing system used to prepare this paper.

Dated: June 3, 2026

By: /Howard Levine/
Howard Levine (Reg. No. 41,453)

CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2025, I caused a true and correct copy of the forgoing Opposition to Patent Owner's Request for Discretionary Denial to be served via electronic upon to the Patent Owner's counsel of record at the following addresses:

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