

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRECISION CANCER TECHNOLOGIES INC.

Petitioner

v.

ONCOUSTICS INC.

Patent Owner

Patent No. 11,602,330

Inter Partes Review No. IPR2025-00242

PATENT OWNER'S PRELIMINARY RESPONSE

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LISTING OF EXHIBITS

Exhibit No.	Description
2001	Sanabria et al., “Comparative Study of Raw Ultrasound Data Representations in Deep Learning to Classify Hepatic Steatosis” (Ultrasound Med Biol., Oct 2022; 48(10):2060-2078, https://doi.org/10.1016/j.ultrasmedbio.2022.05.031)

Oncoustics Inc. (“Oncoustics” or “Patent Owner”) submits this preliminary response under 37 C.F.R. § 42.107 to the Petition for *Inter Partes* Review (“Petition”) of U.S. Patent No. 11,602,330 (“the ‘330 Patent”), filed by Precision Cancer Technologies Inc. (“PCT” or “Petitioner”).

I. INTRODUCTION

Patent Owner respectfully requests that the Board deny institution. Petitioner did not meet its burden for Ground 1 at least because Petitioner failed to show that Hope-Simpson discloses a “single static set of raw ultrasound radio frequency (RF) data forming a single frame of a tissue area” or “processing the single static set of ultrasound RF data as an input to a machine learning model” as recited in independent claims 1 and 11. While Petitioner proposed claim constructions for these limitations, it failed to apply those constructions in its analysis of the Hope-Simpson reference. The Petition is also flawed because it mixes and matches descriptions of different embodiments in Hope-Simpson without linking them together.

Petitioner did not meet its burden for Ground 2 because it failed to show that any limitations not expressly or inherently disclosed in Hope-Simpson are obvious over Hope-Simpson alone. Petitioner’s assertions that the “single frame” limitation would have been obvious are conclusory and unsupported. Tellingly, none of

Petitioner's contentions in Ground 2 are supported by its expert declaration, which is not cited in this section of the Petition.

Petitioner did not meet its burden for Ground 3 because none of the cited references disclose or suggest: (i) processing the single static set of raw ultrasound RF data into a set of windows to determine a power spectrum; or (ii) processing the determined power spectrum as an input into a machine learning model as recited in independent claims 6 and 19. Petitioner acknowledges that its primary reference, Hope-Simpson, does not disclose either limitation. Petitioner's secondary reference, Nair, also does not disclose these claimed features. And even if, *arguendo*, Nair did disclose these features (it does not), Petitioner provides only conclusory assertions regarding the alleged obviousness of combining Hope-Simpson and Nair.

Petitioner did not meet its burden for Ground 4, which only challenges dependent claim 10, because its reliance on Azizi does not cure the deficiencies in the Hope-Simpson and Nair combination from Ground 3. Moreover, Petitioner failed to show that Azizi is prior art because it provided no evidence or argument as to how Azizi, which is non-patent literature, would have been accessible to a skilled artisan exercising reasonable diligence.

II. OVERVIEW OF THE '330 PATENT

The '330 Patent relates to a method for distinguishing abnormal tissue from normal tissue by processing normally discarded information using machine learning.

Ex. 1001 at Abstract, 1:48-49, 4:50-56, 7:45-47, 9:8-10. This normally discarded information from ultrasound radio frequency data recovers and reveals information that is beyond human perception. *Id.* at 4:50-56. This is unexpected and surprising, since state-of-the-art applications of artificial intelligence (“AI”) only enhance recognition and awareness of information within the bounds of human sense, cognizance and comprehension. *Id.* at 4:56-60.

The '330 Patent explains that “using artificial intelligence/machine learning methods (“ML”) to analyze the ultrasound data as is—instead of conventional mathematical models or ‘fits’ that parameterize the signal—provides for vastly increased accuracy and specificity.” Ex. 1001 at 5:4-8. Advantageously, “this allows for more accurate and specific classification and identification of tissue types and biomarkers related to issue—including for disease states.” *Id.* at 5:8-11. The '330 Patent goes on to explain that in particular, “applying the ML models to the raw data or the frequency spectrum data—rather than the images (e.g. B-mode) after processing—provides much more accurate results because the already heavily processed images have much of the important ultrasound data filtered out, including that which is useful for diagnosis and classification.” *Id.* at 5:11-19.

III. SUMMARY OF PETITIONER'S REFERENCES

A. Hope-Simpson (Ex. 1005)

Hope-Simpson relates to an ultrasound imaging system that has a number of potential sources that may be used as inputs to a neural network. Ex. 1005 at Abstract, ¶ [026]. For example, FIG. 1 illustrates an ultrasound system that includes, *inter alia*, ultrasound transducer 113, T/R controller 120, channel memory 110, input data selector 162, neural network 160, and user interface 124. *Id.* at ¶ [028].

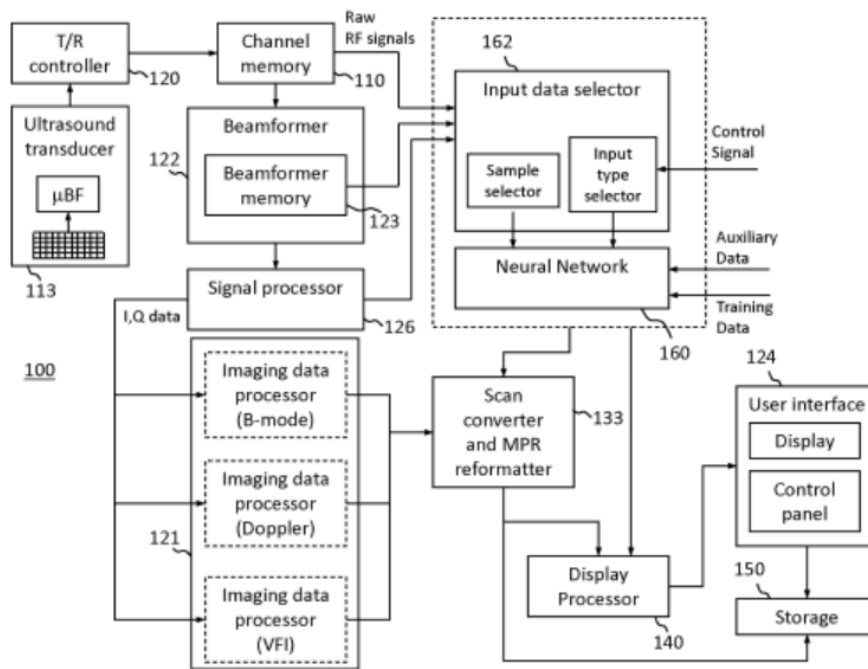


FIG. 1

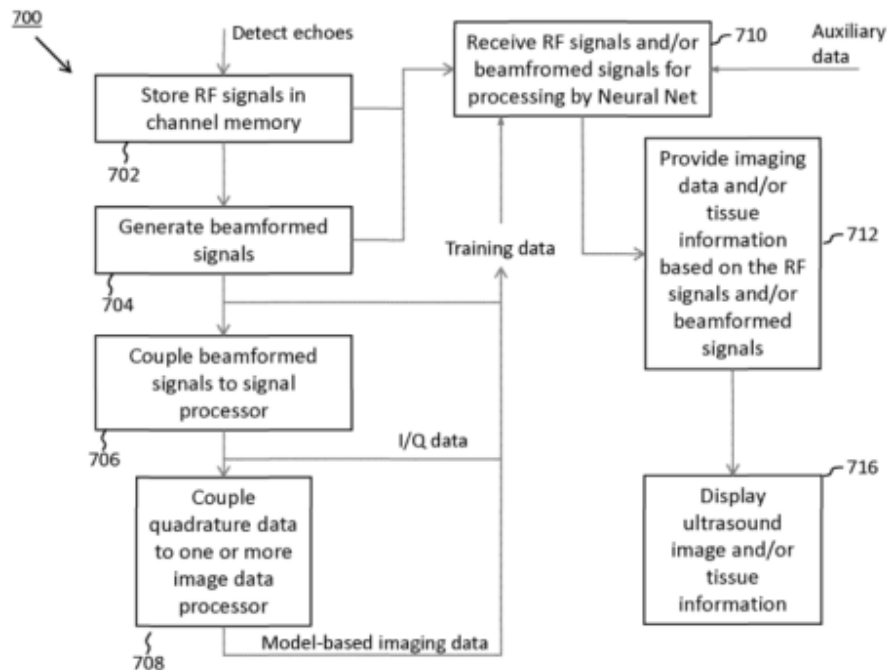
Ex. 1005 at FIG. 1

In FIG. 1, the transmit/receive controller 120 is coupled to transducer 113 and controls the transmission of ultrasound signals by the transducer 113. Ex. 1005 at ¶ [029]. Transducer 113 is also “communicatively coupled to channel memory 110,

which receives and stores the echo signals acquired by the ultrasound transducer 113.” *Id.* The channel memory 110 also “couple[s] the RF signals to a neural network 160” and more specifically in FIG. 1, “the RF signals from the channel memory 110 are coupled to the neural network 160 via an input data selector 162.” *Id.* at ¶ [030]. Input data selector 162 “may be configured to select, for each point or region of interest (ROI) in an imaging field of view, a corresponding array of m echo signal samples from each or a subset of elements of the transducer array.” *Id.* “After selection of the appropriate input data set [by input data selector 162], imaging and other tissue data extraction would be performed implicitly by the neural network 160 without reliance on conventional beamforming.” *Id.*

FIGS. 4-6 of Hope-Simpson show alternative ultrasound systems according to other embodiments that also include, *inter alia*, a neural network. *See* Ex. 1005 at FIGS. 4-6, ¶¶ [044]-[045], [052], [060]-[061]; Ex. 1002 at ¶ 203 (explaining that “Hope-Simpson describes several embodiments”). In each of these systems, data from the transducer (413, 513, 613) is received first by a channel memory (410, 510, 610) and then by a data selector 462, 562, 662) before reaching the neural network (460, 560, 660). *Id.*

In FIG. 7, Hope-Simpson illustrates a process flow diagram as another embodiment:



Ex. 1005 at FIG. 7

B. Nair (Ex. 1006)

Nair is generally directed to “tissue ablation procedures and imaging with tissue characterization to guide the ablation therapy.” Ex. 1006 at ¶ [0002].

C. Azizi (Ex. 1007)

Azizi is a non-patent document that describes using Temporal Enhanced Ultrasound (TeUS) to grade prostate cancer in a clinical study. Ex. 1007 at Abstract.

IV. LEVEL OF SKILL IN THE ART

Petitioner proposes the following definition for a person of ordinary skill in the art (“POSITA”):

A POSA at the time of the alleged invention would be an individual having a post-undergraduate degree, e.g., Ph.D., in Electrical and Computer Engineering, Computer Science, Biomedical Engineering, Biomedical Physics, or a comparable discipline, and at least 2 years of experience relating to the design, operation, and functioning of imaging systems and detecting tissue abnormalities using quantitative ultrasound.

Petition at 9. For purposes of this Preliminary Response, Patent Owner applies Petitioner's proposed definition. Patent Owner reserves the right to propose a different level of skill should the Board institute an IPR.

V. CLAIM CONSTRUCTION

The Petition proposes three claim constructions. *See* Petition at 10-12. For purposes of this Preliminary Response only, Patent Owner applies Petitioner's proposed claim constructions because Petitioner failed to meet its burden under those constructions. Patent Owner reserves the right to propose different or additional claim constructions should the Board institute an IPR.

A. "Single static set of Raw Ultrasound Radio Frequency (RF) Data Forming a Single Frame" (Claims 1-20)

The phrase "single static set of raw ultrasound radio frequency (RF) data forming a single frame" appears in each independent claim of the '330 Patent. Ex. 1001 at 15:3-5 (claim 1), 15:35-39 (claim 6), 16:2-5 (claim 11), 16:36-38 (claim 19). Petitioner proposes construing this phrase as "a single static set of ultrasound radio frequency (RF) data that is not pre-processed, forming a single frame." Petition at

10-11. The only difference between the express claim language and Petitioner's proposed construction are that the claims use the word "raw," whereas the proposed construction uses the phrase "that is not pre-processed." Thus, Patent Owner understands that Petitioner is proposing to construe the term "raw" as "not pre-processed."

B. "Processing the Single Static Set of Ultrasound RF Data as an Input to a Machine Learning Model" (Claims 1-5, 11-18)

The phrase "process[ing] the single static set of raw RF ultrasound data with a machine learning model" appears in independent claims 1 and 11 of the '330 Patent. Ex. 1001 at 15:14-15 (claim 1) 16:6-7 (claim 11). Petitioner proposes construing this limitation as "processing the single static set of ultrasound RF data using a machine learning model." Petition at 11. Putting Petitioner's claim construction proposals together, independent claims 1 and 11 require processing the single static set of ultrasound RF data that is not pre-processed using a machine learning model. *Supra*, § VI.A.

C. "Output Classification" (Claims 1-5 and 19-20) and "Outputting a Classification" (Claims 6-18)

The Petition proposes construing the phrases "output classification" (claims 1-5 and 19-20) and "outputting a classification" to mean "output/outputting information indicating the class or classes of tissue type for the tissue area in the frame." Petition at 11.

**VI. PETITIONER HAS NOT ESTABLISHED A REASONABLE
LIKELIHOOD ANY CLAIM IS UNPATENTABLE**

The Board should deny institution because Petitioner has not met its burden of showing a reasonable likelihood that any claim of the '330 Patent is unpatentable. In particular, while Petitioner proposes certain claim constructions, it fails to apply or analyze those constructions when comparing the challenged claims and the alleged prior art.

A. Ground 1: Purported Anticipation by Hope-Simpson (Claims 1, 2, 4, 5, 11, 14, and 16)

In Ground 1, Petitioner alleges that Hope-Simpson anticipates claims 1, 2, 4, 5, 11, 14, and 16. Petition, 20-38. Petitioner has not met its burden for any of these challenged claims.

1. Independent Claim 1

**a. The Petition Relies on Different Embodiments of
Hope-Simpson**

As discussed above, and acknowledged by Petitioner's expert, Dr. Papanicolau, Hope-Simpson describes several different embodiments. *Supra*, § III.A; Ex. 1002 at ¶¶ 111, 203 (admitting that Hope-Simpson "describes several embodiments"). The Petition relies on descriptions from multiple embodiments in Hope-Simpson. For example, Petitioner relies on the system shown in FIG. 1 and its

corresponding description for certain limitations. Petition at 21-22 (limitation 1.1)¹, 24-26 (limitation 1.4). For other limitations, Petitioner relies on the process flow diagram in FIG. 7. *Id.* at 26 (limitation 1.4), 27 (limitation 1.5), 28 (limitation 1.6). Petitioner also relies on Hope-Simpson's claims for certain limitations. *Id.* at 23 (limitation 1.2), 24 (limitation 1.3). Indeed, for some limitations, Petitioner relies on a combination of FIG. 1, FIG. 7, and/or the claims. *Id.* at 29 (limitation 1.6).

“A reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination.” *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (internal quotation marks omitted). Accordingly, when a petitioner relies on different embodiments in a single reference for anticipation, it must “identify guidance in the disclosure to link them together.” *Otonomy, Inc. v. Auris Med., AG*, 743 F. App'x 430, 439 (Fed. Cir. 2018). As discussed above, the Petition mixes and matches different disclosures from different embodiments of Hope-Simpson throughout its discussion of claim 1. However, neither Petitioner nor Dr. Papanicolau explain if or how a POSITA would “at once envisage” a combination

¹ This Preliminary Response uses the same limitation identifiers as the Petition for ease of reference. *See* Petition at ix-x.

of, for example, the FIG. 1 system and FIG. 7 process in Hope-Simpson that are relied upon throughout the Petition or otherwise link Hope-Simpson's different embodiments together.

The Board has denied institution in similar cases where a petitioner relied on multiple embodiments without sufficiently linking those embodiments together. *See, e.g., Intelligent Wellhead Sys., Inc. v. Downing Wellhead Equip., LLC*, IPR2024-00583, Paper 9 at 17-18 (PTAB Sept. 12, 2024) (denying institution because “[n]either Petitioner nor Petitioner's Declarant discuss the combinability of the embodiment described on pages 11 and 12 of Ciezobka and the embodiment described on page 4 of Ciezobka”); *Ontel Prods. Corp. v. Guy A. Shaked Invs. Ltd.*, IPR2020-01703, Paper 12 at 13-14 (PTAB Apr. 13, 2021) (denying institution because “Petitioner's analysis of claim 1 relies on features found in different embodiments of Choi without ever explaining how the reference discloses the combinability of those features or why an ordinarily skilled artisan would immediately envisage combining those features in the claimed manner”).

b. Hope-Simpson Does Not Disclose Limitation 1.1

Independent claim 1 of the '330 Patent recites “a transducer configured to output a single static set of raw ultrasound radio frequency (RF) data forming a single frame of a tissue area” (hereinafter, “Limitation 1.1”). Ex. 1001 at 15:3-5. As discussed above, the Petition proposes construing Limitation 1.1 so that the term

“raw” means “not pre-processed.” *Supra* § VI.A. While the Petition alleges that Hope-Simpson discloses “raw” ultrasound RF data, Petitioner’s analysis of Limitation 1.1 does not even mention its claim construction, let alone explain how the “raw” data in Hope-Simpson “is not pre-processed” under its claim construction. Petition at 21-23. Petitioner’s expert, Dr. Papanicolau, fares no better than the Petition as he also fails to apply Petitioner’s proposed claim constructions when comparing Hope-Simpson to the claims.² Ex. 1002 at ¶¶ 84-86.

Even if Hope-Simpson discloses a transducer that generates a single static set of ultrasound RF data “that is not pre-processed” under Petitioner’s claim construction, Hope-Simpson does not disclose that this RF data forms “a single frame of a tissue area” as required in claim 1. Ex. 1001 at 15:3-5. Petitioner argues that Hope-Simpson discloses the “single frame” limitation because Limitation 1.1 “is analogous to how a standard video camera captures video at a given frame-rate, i.e., one frame at a time.” Petition at 22 (citing Ex. 1002 at ¶ 84). But other than citing to its expert, Petitioner provides no evidence (e.g., from the ‘330 Patent) suggesting that the claimed “single frame” is analogous to a standard video camera. *Id.* Indeed, unlike a camera that captures image data, Limitation 1.1 recites a single

² Dr. Papanicolau’s claim construction “opinions” are verbatim restatements of Petitioner’s arguments. *Compare* Ex. 1002 at ¶¶ 24-26 *with* Petition at 10-12.

static set of ultrasound RF data. Ex. 1001 at 15:3-5; Ex. 2001 at 3 (providing an example of an “ultrasound frame” that includes “[a] total of 250 RF lines”). Moreover, Petitioner fails to explain how Limitation 1.1 being allegedly analogous to a video camera means that Hope-Simpson expressly or inherently discloses Limitation 1.1. Petition at 21-22.

Dr. Papanicolau similarly attempts to analogize the claimed transducer to a “standard video” camera but provides no technical reasoning nor cites any support for his opinion. Ex. 1002 at ¶ 84. Under the Board’s precedent, such conclusory expert testimony is entitled to little or no weight. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15-17 (PTAB Aug. 24, 2022) (precedential) (denying institution because “declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little 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”); *see also TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (holding that conclusory expert testimony is insufficient).

Petitioner also argues that Hope-Simpson discloses Limitation 1.1 because the neural network analyzes “localized data sets” or “a subset of echo signals.” Petition at 22. There are two problems with this. First, Petitioner does not explain how Hope-Simpson’s “localized data sets” or “a subset of echo signals” constitute a single *static*

set of ultrasound RF data *forming a single frame*. *Id.*; *see also* Ex. 1002 at ¶¶ 85-86 (repeating Petitioner's arguments without additional technical reasoning). Second, even if Hope-Simpson's "localized data sets" or "a subset of echo signals" that are analyzed by the neural net were a single static set of RF data forming a single frame, that does not mean that Hope-Simpson's transducer is configured to generate a single static set of ultrasound RF data that forms a single frame. Indeed, Hope-Simpson indicates that subsets of echo signals are generated by the input data selector 162 – not the transducer 113. Ex. 1005 at ¶ [030].

Additionally, Dr. Papanicolau states that "[i]t is clear *to me* . . . that the transducer of Hope-Simpson is configured to output a single static set of raw ultrasound RF data forming a single frame of a tissue area." Ex. 1002 at ¶ 86. However, the fact that this is allegedly "clear" to Dr. Papanicolau personally does not mean that it would be "clear" to a POSITA, especially because Dr. Papanicolau appears to have more qualifications than one of ordinary skill in the art. *Compare* Ex. 1002 at ¶¶ 5-6 (indicating that Dr. Papanicolau has a Ph.D. in computer science and "a decade of experience") *with* Petition at 9 (defining POSITA as someone with "a post-undergraduate degree" and "at least 2 years of experience"). While "a person of extraordinary skill may opine on the knowledge of [the] . . . hypothetical" POSITA, Dr. Papanicolau failed to offer such an opinion. *Duramed Pharms., Inc. v. Watson Lab'ys, Inc.*, 413 F. App'x 289, 296 (Fed. Cir. 2011). In any event, the Board

should not afford Dr. Papnicolau's *ipse dixit* testimony any weight. 37 C.F.R. § 42.65(a).

The Petition also argues that “[t]he localized data sets described by Hope-Simpson *are equivalent to* the claimed ‘single static set of raw ultrasound [RF] data forming [a – sic] single frame of a tissue area.’” Petition at 22 (emphasis added). But the Federal Circuit has made clear that “anticipation by equivalents” is not a cognizable legal theory. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (“The jury had erroneously been instructed that anticipation may be shown by equivalents, a legal theory that is pertinent to obviousness under Section 103, not to anticipation under Section 102”).

c. Hope-Simpson Does Not Disclose Limitation 1.5

As discussed above, Petitioner's proposed claim constructions require that the machine learning model processes a single static set of ultrasound radio RF data that is not pre-processed, forming a single frame. *Supra*, § VI.B. Similar to Limitation 1.1, Petitioner never mentions its proposed claim construction in its analysis of Limitation 1.5, let alone explains how Hope-Simpson meets that construction. Petition at 27-28.

**(i) Hope-Simpson Does Not Disclose Processing
Ultrasound RF Data “That is Not Pre-**

Processed”

For the FIG. 1 system embodiment, Hope-Simpson states that “the RF signals from the channel memory 110 are coupled to the neural network 160 via an input data selector 162,” as shown below. Ex. 1005 at ¶ [030].

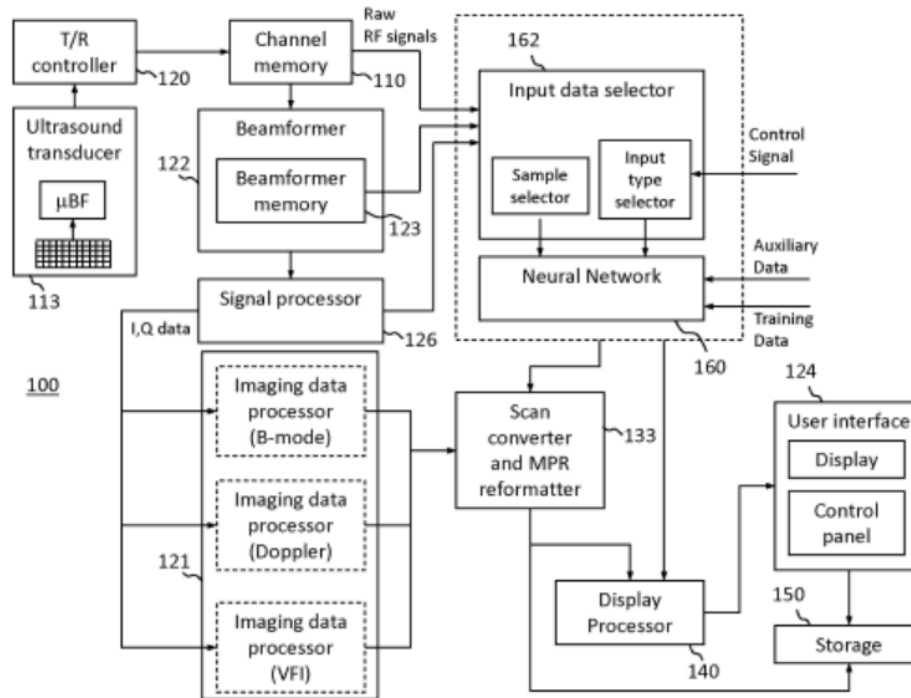


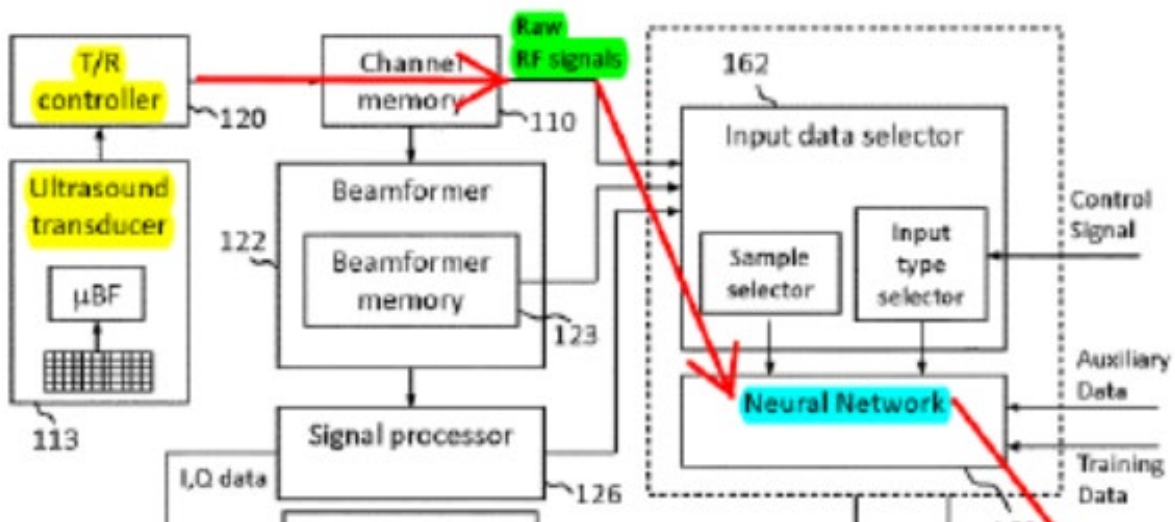
FIG. 1

Ex. 1005 at FIG. 1

“The input data selector 162 may be configured to select, for each point or region of interest (ROI) in an imaging field of view, a corresponding array of m echo signal samples from each or a subset of elements of the transducer array.” *Id.* Hope-Simpson goes on to explain that “[a]fter selection of the appropriate input data set [by input data selector 162], imaging and other tissue data extraction would be performed implicitly by the neural network 160 without reliance on conventional

beamforming.” *Id.* Petitioner admits that in FIG. 1, the RF data is an “input to data selector 162 which is configured to select a discrete set of echo samples from the input raw RF signals.” Petition at 24.

Even if Petitioner were correct that the input data selector 162 receives a single static set of RF signals “that are not pre-processed” from the transducer 113, Petitioner does not explain how the neural network 160 (alleged machine learning model) processes RF signals “that are not pre-processed” given that they are processed by input data selector 162 prior to reaching the neural network 160. Ex. 1005 at ¶ [030]. Petitioner appears to tacitly acknowledge this problem by drawing an arrow directly between the “raw RF signals” and neural network 160, as shown below:



Petition at 29 (annotating Ex. 1005, FIG. 1)

However, Petitioner does not identify any teaching or suggesting in Hope-Simpson that the “raw RF signals” can go directly from the channel memory 110 to the neural

network 160 for processing. Petition at 24-30. That is because Hope-Simpson does not disclose any way for the “raw RF signals” in FIG. 1 to reach the neural network 160 without first passing through the input data selector 162.

With respect to the FIG. 7 embodiment, the Petition highlights box 710, but does not explain how the referenced “RF signals” are a single static set of data forming a single frame that is not preprocessed prior to processing by the neural net. Petition at 26.

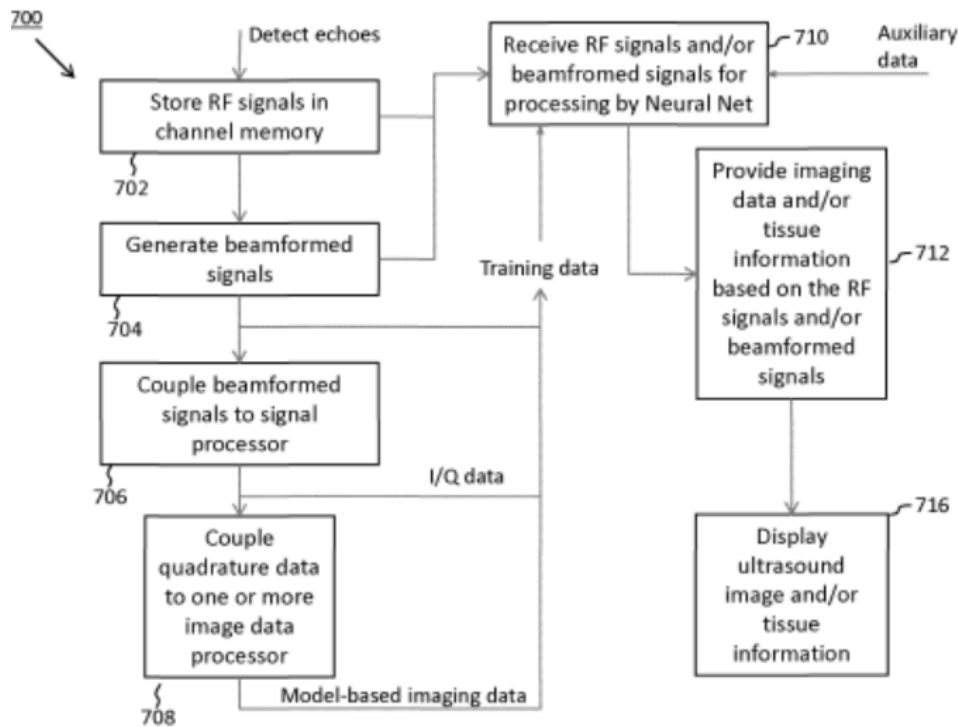


FIG. 7

Ex. 1005 at FIG. 7

As discussed above, Petitioner failed to tie the FIG. 7 embodiment to any of the other embodiments it relies on, including FIG. 1. *Supra*, § VII.A.a. To the extent FIG. 7 is

a process flow diagram that corresponds to the FIG. 1 embodiment, then it fails to disclose Limitation 1.1 under Petitioner's construction for the same reasons discussed above.

**(ii) Hope-Simpson Does Not Disclose Processing a
Single Static Set of Ultrasound RF Data
Forming a Single Frame**

Even if the neural network in Hope-Simpson processes ultrasound RF data “that is not pre-processed” under Petitioner's claim construction (which it does not), Hope-Simpson does not disclose processing a *single static set* of raw ultrasound RF data *forming a single frame* as claimed for at least two reasons. Ex. 1001 at 15:3-5.

First, as discussed above, while Hope-Simpson states that the transducer 113 generates ultrasound RF data, Hope-Simpson does not expressly disclose that the transducer is configured to generate a single static set of raw ultrasound RF data forming a single frame. *Supra*, § VII.A.1.b.

Second, regardless of the format of the output of the transducer 113, Hope-Simpson does not disclose that the neural network processes a *single static set* of raw ultrasound RF data *forming a single frame*. For the FIG. 7 embodiment, Hope-Simpson does not disclose the format of the “RF signals” that are processed by the neural network, let alone whether that the “RF signals” are a single static set that forms a single frame. *See* Ex. 1005 at ¶ [066]. In fact, Petitioner does not address the

requirements of a “single static set” and “forming a single frame” at all in its discussion of Limitation 1.5. Petition at 27-28.

d. Hope-Simpson Does Not Disclose Limitation 1.6

Because Hope-Simpson does not disclose Limitation 1.5, it necessarily does not disclose Limitation 1.6, which recites “output classification of the raw RF ultrasound data from an output of the machine learning model,” for at least the reasons discussed above. Ex. 1001 at 15:16-17; *supra*, §§ VII.A.1.b-c. In other words, because Hope-Simpson does not process a single static set of raw ultrasound RF data forming a single frame using a machine learning model, it does not output classification of the raw RF ultrasound data from an output of the machine learning model. *Id.*

In its discussion of Limitation 1.6, Petitioner argues that its anticipation theory is supported by a comparison between FIG. 3 of the ‘330 Patent and FIGS. 1 and 7 of Hope-Simpson, which allegedly show that “Hope-Simpson’s system and the system of the 330 Patent are structurally and operationally analogous.” Petition at 29-30. However, an anticipation analysis requires comparing the ‘330 Patent’s claims to Hope-Simpson, not merely the example in FIG. 3. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1053 (Fed. Cir. 1988) (holding that court “erred in comparing these specification figures with the prior art to determine the patentability of the invention”).

2. Independent Claim 11

Petitioner failed to meet its burden for independent claim 11 for at least the same reasons as independent claim 1. For example, similar to claim 1, Petitioner improperly mixes different embodiments from Hope-Simpson and fails to apply its proposed claim constructions. *Supra*, § VII.A.1.a.

a. Hope-Simpson Does Not Disclose Limitation 11.1

Like Limitation 1.1, Limitation 11.1 recites “a single static set of raw ultrasound radio frequency (RF) data . . . forming a single frame.” Ex. 1001 at 16:2-5. The Petition refers back to its analysis of Limitation 1.1 and repeats the same assertions regarding Hope-Simpson. Petition at 33-34. However, as discussed above, Petitioner failed to show that Hope-Simpson discloses a single static set of raw ultrasound RF data forming a single frame as recited in Limitation 11.1. *Supra*, § VII.A.1.b.

b. Hope-Simpson Does Not Disclose Limitation 11.2

Like Limitation 1.5, Limitation 11.2 recites “processing the single static set of ultrasound RF data as an input to a machine learning mode.” Ex. 1001 at 16:6-7. However, as discussed above, Petitioner failed to show that Hope-Simpson discloses a machine learning model processing a single static set of raw ultrasound RF data forming a single frame. *Supra*, § VII.A.1.a. Notably, the section of the Petition addressing Limitation 11.2 does not contain any citations to Dr. Papanicolau's declaration. Petition at 34-36.

3. Dependent Claims 2, 4, 5, 14, and 16

Petitioner failed to meet its burden for dependent claims 2, 4, and 5 for at least the same reasons as independent claim 1. *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1344 (Fed. Cir. 2009). Likewise, Petitioner failed to meet its burden for dependent claims 14 and 16 for at least the same reasons as independent claim 11.

B. Ground 2: Purported Obviousness Over Hope-Simpson (Claims 1, 2, 4, 5, 11, 14, and 16)

In Ground 2, Petitioner alleges that claims 1, 2, 4, 5, 11, 14, and 16 are obvious over Hope-Simpson. Petition at 38-41. Petitioner argues that “although Hope-Simpson discloses every element of claims 1, 2, 4, 5, 11, 14, and 16 of the ‘330 Patent, each of the elements of these claims were also separately known and obvious in view of the knowledge of a POSA.” Petition at 39. However, Petitioner only specifically alleges that two limitations would have been obvious over Hope-Simpson in view of the knowledge of a POSITA: (i) the requirement that the transducer is configured to generate a single static set of raw ultrasound RF data forming a single frame (*id.* at 40); and (ii) the output classification limitations (*id.* at 40-41).

Petitioner argues that “to the extent that Hope-Simpson does not already expressly acquire raw RF data in discrete static sets comprising single frames, it would have been obvious to do so, i.e., to use the normal manner of acquiring raw ultrasound data.” Petition at 40. Tellingly, Petitioner provides no citation for this

argument. *Id.* That is because Dr. Papanicolau's declaration does not support Petitioner's arguments for Ground 2. Indeed, the Petition does not cite *any* of the paragraphs of Dr. Papanicolau's declaration discussing Ground 2. *See* Petition at 39-41 (citing Ex. 1002 at ¶¶ 102, 110); *see also* Ex. 1002 at ¶¶ 128-134 (discussing Ground 2). Petitioner cannot satisfy its burden based on this single conclusory and unsupported assertion that using a single static set of raw ultrasound RF data forming a single frame would have been obvious. *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016) (holding that obviousness theories based on a single reference require "reasoned analysis and evidentiary support"); *see also In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (holding that "obviousness grounds cannot be sustained by mere conclusory statements").

Moreover, Petitioner's obviousness theory in Ground 2 is limited to arguing that it would have been obvious for Hope-Simpson's transducer to RF data in discrete static sets comprising single frames. Petition at 40. Importantly, Petitioner does not argue that it would have been obvious for Hope-Simpson's neural network to process a single static set of ultrasound RF data that is both not pre-processed and forms a single frame as required in Limitations 1.5 and 11.2. *Id.* As discussed above, Hope-Simpson does not expressly or inherently disclose this. *Supra*, § VII.A.1.c.

C. Ground 3: Purported Obviousness Over Hope-Simpson in View of Nair (Claims 3, 6-9, 12, 13, 15 and 17-20)

In Ground 3, Petitioner alleges that claims 3, 6-9, 12, 13, 15, and 17-20 are obvious over Hope-Simpson in view of Nair. Petition, 42-68.

1. Independent Claim 6

Petitioner failed to meet its burden for independent claim 6 for at least the same reasons as independent claim 1, including its improper mixing and matching of embodiments in Hope-Simpson and its failure to apply its own proposed claim constructions. *Supra*, § VII.A.1.a.

a. Limitation 6.1

Like Limitation 1.1, Limitation 6.1 recites “receiving a single static set of raw ultrasound radio frequency (RF) data output from at least one ultrasound transducer, the single static set of raw ultrasound RF data forming a single frame representing a tissue area of a patient.” Ex. 1001 at 15:35-39. Petitioner refers to and repeats the same arguments as for Limitations 1.1 and 11.1. Petition at 44-45. However, as discussed above, Hope-Simpson does not disclose a single static set of ultrasound RF data that is not pre-processed that forms a single frame representing a tissue area of a patient. *Supra*, §§ VII.A.1.b, VII.A.2.a.

b. Limitation 6.2

Limitation 6.2 recites “processing the single static set of raw ultrasound RF data [into a]³ set of windows to determine a power spectrum.” Ex. 1001 at 15:40-41. Petitioner argues that this limitation is disclosed by alleged applicant admitted prior art (“AAPA”) and Nair. Petition at 46-50.

First, Petitioner argues that “Figure 2 of the 330 Patent . . . shows the steps of breaking the RF data into windows (220) and determining a power spectrum for each window (225).” Petition at 46 (citing Ex. 1001 at FIG. 2). However, nowhere does FIG. 2 or its corresponding description state that the RF data that is broken into windows and subsequently processed is a single static set of ultrasound RF data forming a single frame as claimed. Ex. 1001 at FIG. 2, 6:29-45. In fact, the Petition does not even allege that the RF data referenced in FIG. 2 is a single static set of ultrasound RF data forming a single frame. Petition at 46-47.

Second, Petitioner argues that Figures 7 and 8 of Nair disclose this limitation. Petition at 47-48. Specifically, Petitioner argues that in Nair “a scan line is ‘analyzed in segments represented by the windows illustrated in the figure [7], such as window 555.’” *Id.* at 47 (quoting Ex. 1006 at ¶ [0088]). The Petition does not explain how

³ Claim 6 appears to have inadvertently omitted the phrase “into a.” Petitioner appears to agree with this understanding of claim 6. Petition at 46.

Nair's "scan line" is a single static set of ultrasound RF data that is not pre-processed and forms a single frame as claimed. Petition at 47-48.

Nair describes tissue ablation and "guiding, monitoring, and assessing the ablation procedure in real-time." Ex. 1006 at ¶ [0048]. FIG. 7 represents an RF signal as one-dimensional waveform in the time dimension, and there is no indication that this is based on single static set of raw ultrasound radio frequency (RF) data forming a single frame of a tissue area. Ex. 1006 at ¶ [0088], FIG. 7. The windows in FIG. 7 (e.g., window 555) defining the data for determining the power spectrum are taken over a duration of time, as shown by their relative location to the y-axis representing time. *Id.* Further, the data is collected by the imaging apparatus in the form of raw data of the reflected signals along each individual scan line, and that data is analyzed in segments. Ex. 1006 at ¶¶ [0078]-[0079]. That is, in Nair, the data is temporal in nature and the power spectrum is not determined from a single *static* set of raw ultrasound RF data.

Petitioner also argues that this limitation is obvious "to the extent that Hope-Simpson does not already inherently do so." Petition at 49. Petitioner, however, provides no evidence or argument that Hope-Simpson inherently discloses Limitation 6.2. *See* Petition at 46-50; *PersonalWeb Techs., LLC v. Apple, Inc.*, 917 F.3d 1376, 1382 (Fed. Cir. 2019) (the "mere possibility" that reference discloses a feature is insufficient for inherency).

As to an alleged motivation to combine Hope-Simpson and Nair (and/or the AAPA), Petitioner merely alleges that “[i]t would have been obvious that Hope-Simpson could include at least pre-processing the data into windows and a power spectrum for each window . . . in order to have the data in a format that can be predictably and easily analyzed in a neural network.” Petition at 50. This conclusory assertion is insufficient to establish *why* a POSITA allegedly would have been motivated to modify Hope-Simpson. *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (obviousness requires a showing as to “why one of ordinary skill in the art at the time of the invention would have sought to combine or modify the references”). For example, Petitioner does not explain why using a determined power spectrum results in “a format that can be predictably and easily analyzed in a neural network” or what it means for data to be “predictably and easily analyzed.” Petition at 50. Notably, the Petition cites only paragraph 152 of the Papanicolau Declaration, but that citation does not support the assertion in the Petition. *Id.* at 49-50 (citing Ex. 1002 at ¶ 152 (discussing only FIG. 2 of the ‘330 Patent and not obviousness)).

c. Limitation 6.3

Limitation 6.3 recites “processing the determined power spectrum as an input into a machine learning model.” Ex. 1001 at 15:42-43. None of the cited references disclose, teach, or suggest processing a determined power spectrum as an input into

a machine learning model that outputs a classification of the tissue area. Each of Petitioner's arguments for Limitation 6.3 are addressed in turn below.

First, Petitioner argues that "Hope-Simpson demonstrates that ultrasound tissue classification can be performed on complete data sets without the need for pre-processing signal properties." Petition at 50. However, as discussed above, Petitioner failed to show that the ultrasound RF data processed by the neural network in Hope-Simpson "not pre-processed." *Supra*, §§ VII.A.1.b-c. Moreover, even if Petitioner's characterization of Hope-Simpson were correct, its argument that "using this method on more-heavily processed signals . . . whose properties were well demonstrated tissue classifiers would yield similar results" is conclusory, as Petitioner does not explain why this is allegedly the case. Petition at 50; *Kahn*, 441 F.3d at 988. Dr. Papanicolau fares no better as merely repeats the same assertions as the Petition while at most adding, without explanation or support, that "[i]t would be intuitive . . . to process the power spectrum . . . as input into the machine learning model." Ex. 1002 at ¶ 157; *Xerox*, IPR2022-00624, Paper 9 at 15-17; 37 C.F.R. § 42.65(a).

Second, Petitioner argues that "as shown by Nair and as admitted by the '330 Patent, using determined power spectrum as an input into a machine learning model was a well-understood and conventional process in the art at the time of the '330 Patent." Petition at 51. Both assertions are incorrect. Tellingly, the Petition does not identify where the '330 Patent supposedly admits that inputting a determined power

spectrum as an input into a machine learning model is prior art. *Id.*⁴ That is because the '330 Patent makes no such admission. The “prior art” method illustrated in FIG. 2 does not use a machine learning model. Ex. 1001 at 6:29-45.

Petitioner also fails to identify where Nair supposedly discloses using a determined power spectrum from a single set of static data as an input into a machine learning model. Petition at 51. That is because Nair does not disclose this.⁵ Elsewhere in the Petition, Petitioner alleges, without citing any support (whether from Nair, its expert, or otherwise), that Nair discloses a “machine learning algorithm.” Petition at 16. But the phrases “machine learning algorithm” and “machine learning model” do not appear anywhere in Nair. *See generally* Ex. 1006. Put simply, even if Nair discloses the claimed determined power spectrum (which it does not), Petitioner does not identify anything in Nair that discloses, teaches, or suggests using the determined power spectrum as an input to a machine learning model as recited in Limitation 6.3.

⁴ Dr. Papanicolau's declaration does not support Petitioner's arguments for Limitation 6.3. *See* Ex. 1002 at ¶¶ 156-157.

⁵ Dr. Papanicolau does not allege that Nair discloses a machine learning model. *See* Ex. 1002 at ¶¶ 156-157.

Third, Petitioner argues that implementing Nair's alleged determined power spectrum "in Hope-Simpson would have been obvious in order to provide a predictable and easily analyzed data form for the neural network of Hope-Simpson to analyze." Petition at 51. As an initial matter, this argument is based on the erroneous assumption that Nair discloses inputting a determined power spectrum into a machine learning model. But regardless, Petitioner's assertion is entirely conclusory and fails to explain *why* using a determined spectrum as an input to Hope-Simpson's neural network would allegedly provide "predictable and easily analyzed data form for the neural network" to analyze. Petition at 51; *InTouch Techs.*, 751 F.3d at 1352 (obviousness requires a showing as to "why one of ordinary skill in the art at the time of the invention would have sought to combine or modify the references").

Fourth, Petitioner argues that "application of methods of processing raw power spectra would be obvious to one of skill in the art, who would also understand its applicability to raw ultrasound RF image data" and that "the use of the determined power spectrum of the raw RF data as an input to a machine learning model would be obvious in view of Hope-Simpson." Petition at 51. This is entirely conclusory and insufficient for Petitioner to meet its burden. *Kahn*, 441 F.3d at 988 (holding that "obviousness grounds cannot be sustained by mere conclusory statements").

2. Independent Claim 19

Petitioner failed to meet its burden for independent claim 19 for at least the same reasons as independent claim 6. *Supra*, § VII.C.1. Additionally, Petitioner does not cite to the Panaicolau declaration as support for its arguments for Limitations 19.P, 19.1, 19.2, 19.3 or 19.4. *See* Petition at 65-66.

a. Limitation 19.1

Similar to claim 6, claim 19 recites “a single static set of raw ultrasound radio frequency (RF) data forming a single frame.” Ex. 1001 at 16:38-40. As discussed for claim 6, Petitioner failed to show that the combination of Hope-Simpson and Nair discloses this limitation. *Supra*, § VII.C.1.a.

b. Limitation 19.3

Similar to claim 6, claim 19, limitation 19.3 recites “receiv[ing] the single static set of raw ultrasound RF data.” Ex. 1001 at 16:42. Because Hope-Simpson and Nair do not disclose the “single static set of raw ultrasound radio frequency (RF) data forming a single frame,” they necessarily fail to disclose Limitation 19.1. *Supra*, § VII.C.2.a.

Moreover, Limitation 19.2, Petitioner identifies Hope-Simpson's neural network as the claimed “signal processing unit.” Petition at 65. Thus, Petitioner alleges that Hope-Simpson's neural network receives the “single static set of raw ultrasound radio frequency (RF) data forming a single frame.” *Id.* As discussed for claim 1, even if Hope-Simpson disclose that the transducer generates this data,

Hope-Simpson does not disclose that it is received by the neural network; rather, it would only be received by the input data selector 162. *Supra*, § VII.A.1.c.

c. Limitation 19.4

Similar to claim 6, claim 19 recites “process[ing] the set of single static set of raw ultrasound RF data to determine a raw power spectrum.” Ex. 1001 at 16:45-46. Petitioner failed to meet its burden for the same reasons discussed above for Limitation 6.2. *Supra*, § VII.C.1.b.

d. Limitation 19.5

Similar to claim 6, claim 19 recites “process[ing] the raw power spectrum as an input to the machine learning model.” Ex. 1001 at 16:47-48. Petitioner failed to meet its burden for the same reasons discussed above for Limitation 6.3. *Supra*, § VII.C.1.c.

3. Dependent Claims 3, 7-9, 12-13, 15, 17-19 and 20

Petitioner failed to meet its burden for dependent claims 3, 7-9, 12-13, 15, and 17-20 for at least the same reasons as the independent claims from which these claims depend. *Callaway*, 576 F.3d at 1344.

D. Ground 4: Purported Obviousness Over Hope-Simpson in View of Nair, and Azizi (Claim 10)

In Ground 4, Petitioner alleges that dependent claim 10 is obvious over Hope-Simpson in view of Nair and Azizi. Petition, 68-69.

1. Azizi Does Not Cure the Deficiencies in Hope-Simpson

Dependent claim 10 recites “wherein the power spectrum is taken using a discrete FFT.” Ex. 1001 at 15:53-54. Petitioner refers to its arguments for claim 6 and alleges that (i) “Nair would include a foundational mathematic concept such as discrete FFT (DFFT)” and (ii) “to the extent that the combination of Hope-Simpson and Nair do not fully disclose use of a DFFT to determine the power spectrum, Azizi discloses an example of an ultrasound tissue classification application which uses DFFT to compute power spectra from raw RF signal data.” Petition at 68-69. However, as discussed above, Hope-Simpson and Nair fail to render obvious independent claim 6 as alleged in Ground 3. *Supra*, § VII.C. Petitioner’s arguments in Ground 4 address only the additional limitations of claim 10 and do not cure any of the deficiencies in Ground 3. Petition at 68-69. Thus, Petitioner failed to meet its burden for claim 10 for at least the same reasons as for independent claim 6.

2. Petitioner Provides No Evidence Azizi Qualifies as Printed Publication Prior Art

Petitioner did not meet its burden for Ground 4 for another reason: it failed to establish that Azizi qualifies as printed publication prior art. The Petition alleges that Azizi “was published online June 20, 2017” but cites no evidence. Petition at 19. To the extent Petitioner is relying on the fact that Azizi states “Published online: 20 June 2017” on its first page, the Board has found that similar evidence is insufficient, even at the institution stage. *Victoria’s Secret Stores LLC v. Andra Grp.*, IPR2020-

00853, Paper 12 at 24-25 (PTAB Oct. 22, 2020) (finding copyright date alone was insufficient to show public accessibility at institution stage); *In-Depth Geophysical, Inc. v. Conocophillips Co.*, IPR2019-00849, Paper 14 at 10-11 (PTAB Sept. 6, 2019) (finding that “vague date listed on a website page” was insufficient).

The Petition does not explain where Azizi was allegedly published online, let alone how a POSITA in the relevant subject matter would have been able to locate Azizi through reasonable diligence. *Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 772 (Fed. Cir. 2018) (affirming Board finding that a reference on a website was not publicly available prior art because petitioner failed to show how a POSITA exercising reasonable diligence would locate it); *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1369 (Fed. Cir. 2019) (same); *see also Salesforce.com, Inc. v. WSOU Investments, LLC*, IPR2022-00428, Paper 10 at 13-14 (PTAB July 13, 2022). Because there is no evidence that Azizi would have been accessible to a POSITA in the relevant timeframe, Petitioner failed to show that Azizi qualifies as prior art to the ‘330 Patent.

VII. CONCLUSION

For at least the foregoing reasons, the Petition should be denied as to each of the requested grounds. For brevity, Patent Owner may not have addressed all characterizations of the applied references and the challenged claims and reserves the right to do so should institution be granted. The absence of a response by Patent

Owner to any of the positions presented in the Petition or the associated expert declaration does not constitute a concession to those positions. The fact that Patent Owner's Preliminary Response has focused on particular arguments is not a concession that there are no other arguments for patentability of the challenged claims.

Respectfully submitted,

Dated: March 12, 2025

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CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the foregoing Patent Owner's Preliminary Response is produced using a 14-point Times New Roman font and contains approximately 7,279 words, which is less than the 14,000 total words permitted by the U.S. Patent Trial and Appeal Board rules. Counsel relies on the word count of the computer program used to prepare the response on March 12, 2025.

Dated: March 12, 2025

By: /s/ Angelo J. Christopher
Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Preliminary Response** was served on March 12, 2025, via email:

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