

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRECISION CANCER TECHNOLOGIES INC.

Petitioner,

v.

ONCOUSTICS INC.,

Patent Owner

Case IPR2025-00242

U.S. Patent No. 11,602,330

PETITION FOR *INTER PARTES* REVIEW

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EXHIBITS

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1002	Declaration of Dr. Naum Papanicolau, Ph.D.
1003	Curriculum Vitae of Dr. Naum Papanicolau, Ph.D.
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1006	U.S. Patent Publication No. 2014/0180273 (“Nair”)
1007	Azizi et al., “Detection and grading of prostate cancer using temporal enhanced ultrasound: combining deep neural networks and tissue mimicking simulations,” International Journal of Computer Assisted Radiology and Surgery (“Azizi”)
1008	Buhmann et al., “Unsupervised And Supervised Data Clustering With Competitive Neural Networks,” IJCNN International Joint Conference on Neural Networks, vol. 4 (1992) (“Buhmann”)
1009	Al-shamasneh et al., “Artificial Intelligence Techniques for Cancer Detection and Classification: Review Study,” European Scientific Journal, vol. 13 (Jan. 2017) (“Al-shamasneh”)
1010	U.S. Patent Publication No. 2016/0120502 (“Sadeghi-Naini”)
1011	U.S. Patent Publication No. 2017/0249739 (“Kallenberg”)
1012	Uniyal et al., “Ultrasound RF Time Series for Classification of Breast Lesions” (“Uniyal”)
1013	U.S. Provisional Application No. 62/442,691
1014	U.S. Provisional Application No. 62/522,136
1015	U.S. Patent No. 6,238,342 (“Feleppa”)
1016	U.S. Patent Publication No. 2010/0063393A1 (“Moradi”)
1017	U.S. Patent No. 10,499,857 (“Nguyen”)
1018	U.S. Patent Publication No. 2017/0307741 (“Ralston”)
1019	Palaz et al., “Analysis of CNN-based Speech Recognition System using Raw Speech as Input” (“Palaz”)
1020	Allen et al., “A Unified Approach to Short-Time Fourier Analysis and Synthesis” (“Allen”)

LIST OF CHALLENGED CLAIMS

Independent Claims

Claim 1 of the 330 Patent	
1.P	An ultrasound system comprising:
1.1	a transducer configured to output a single static set of raw ultrasound radio frequency (RF) data forming a single frame of a tissue area;
1.2	a memory containing machine readable medium comprising machine executable code having stored thereon instructions;
1.3	a signal processing unit comprising one or more processors coupled to the memory, the one or more processors configured to execute the machine executable code to [sic] the cause the one or more processors to:
1.4	receive the single static set of raw ultrasound RF data;
1.5	process the single static set of raw RF ultrasound data with a machine learning model; and
1.6	output classification of the raw RF ultrasound data from an output of the machine learning model.
Claim 6 of the 330 Patent	
6.P	A method comprising:
6.1	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;
6.2	processing the single static set of raw ultrasound RF data set of windows to determine a power spectrum;
6.3	processing the determined power spectrum as an input into a machine learning model; and

6.4	outputting a classification of the tissue area from the machine learning model.
Claim 11 of the 330 Patent	
11.P	A method comprising:
11.1	receiving a single static set of raw ultrasound radio frequency (RF) data output from at least one ultrasound transducer forming a single frame representing a tissue area of a patient;
11.2	processing the single static set of ultrasound RF data as an input to a machine learning model; and
11.3	outputting a classification of the tissue area from the machine learning model.
Claim 19 of the 330 Patent	
19.P	An ultrasound system comprising:
19.1	a transducer configured to output a single static set of raw ultrasound radio frequency (RF) data forming a single frame of a tissue area; and
19.2	a signal processing unit operable to:
19.3	receive the single static set of raw ultrasound RF data
19.4	process the set of single static set of raw ultrasound RF data to determine a raw power spectrum;
19.5	process the raw power spectrum as an input to a machine learning model; and
19.6	output a classification of the raw power from an output of the machine learning model.

Dependent Claims

Claim	Limitation
2	The ultrasound system of claim 1, wherein the machine learning model is a k-means model or a model from a deep learning network comprising but not limited to one or a combination to the algorithm types of CNN (Convolutional Neural Network), RBM (Restricted Boltzmann Machine), LSTM (Long Short Term Memory) or CapsNet (Capsule Networks).
3	The ultrasound system of claim 1, wherein the machine learning model is trained using ultrasound images labeled by a radiologist.
4	The ultrasound system of claim 1, wherein the machine learning model is an unsupervised model.
5	The system of claim 1, wherein the processor is operable to display an image representing the set of ultrasound data using a unique identifier based on the output of the machine learning model.
7	The method of claim 6, wherein the classification is a cancer status of the tissue.
8	The method of claim 6, wherein the method further comprises processing the power spectrum to determine a normalized power spectrum.
9	The method of claim 6, wherein the power spectrum is taken using a continuous Fast Fourier Transform (FFT).
10	The method of claim 6, wherein the power spectrum is taken using a discrete FFT.
12	The method of claim 11 further comprising: partitioning the single static set of raw ultrasound RF data into a set of windows or bounding boxes; and processing the set of windows to output a power spectrum for each window of the set of windows.

Claim	Limitation
13	The method of claim 12, wherein the step of processing the set of windows comprises processing the set of windows to output a time frequency domain processing technique.
14	The method of claim 11, wherein the machine learning model is a k-means model or a model from a deep learning network comprising one or a combination to the algorithm types of CNN (Convolutional Neural Network), RBM (Restricted Boltzmann Machine), LSTM (Long Short Term Memory) or CapsNet (Capsule Networks).
15	The method of claim 11, wherein the machine learning model is trained using ultrasound images labeled by a radiologist.
16	The method of claim 11, wherein the machine learning model is an unsupervised model.
17	The method of claim 11, wherein the classification is a cancer status of the tissue.
18	The method of claim 11, further comprising outputting a specific multi-parametric biomarker from the machine learning model.
20	The system of claim 19, further comprising a display, wherein the signal processing unit is operable to display an image representing the set of power spectrum data using a unique identifier based on the output of the machine learning model on the display.

I. INTRODUCTION

Petitioner Precision Cancer Technologies Inc. (“PCT”) respectfully petitions for *inter partes* review of Claims 1-20 (“the Challenged Claims”) of U.S. Patent No. 11,602,330 (“the 330 Patent”), which is purportedly assigned to Oncoustics Inc. (“Oncoustics”). The 330 patent is directed to what Oncoustics claimed to be a new method for quantitatively analyzing ultrasound images in order to classify and identify tissue. Namely, Oncoustics alleged during prosecution of the 330 Patent that (a) applying machine learning processing to “raw” ultrasound signals (as opposed to ultrasound data that had been pre-processed) and (b) doing so one at a time to a “single static set of raw ultrasound [RF] data forming a single frame of a tissue area” was novel and non-obvious.

But, in fact, both of these concepts were exceedingly conventional. Prior art that was not before the Examiner, such as PCT Publication No. WO 2018/127498 A1 (“Hope-Simpson”), expressly disclose applying machine learning processing to raw ultrasound signals. And a “single static set of raw ultrasound [RF] data forming a single frame of a tissue area” is simply the standard, normal output from any conventional ultrasound transducer (as used in Hope-Simpson) and was widely-known in the art (analogous to how a camera takes images frame-by-frame). Indeed, **any** processing of the “raw” ultrasound signals would be on a single static set forming a single frame.

Further, none of the other added limitations in the various claims (*e.g.*, the requirement in independent claim 6 that the “raw” data is first converted to “power spectra” data before processing by machine learning, or limitations such as those in claims 3 and 15 specifying how the machine learning algorithm is trained) add anything patentable. Each of those limitations was likewise found in the prior art and was already conventionally used, such as in U.S. Patent Publication No. 2014/0180273 (“Nair”) or *Detection and grading of prostate cancer using temporal enhanced ultrasound: combining deep neural networks and tissue mimicking simulations* (“Azizi”) as discussed in more detail below.

For the reasons discussed herein, each of the claims of the 330 Patent is anticipated and/or obvious in view of the prior art. The Board should institute *inter partes* review on the Challenged Claims.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

The 330 Patent was filed on June 12, 2020 as a 371 U.S. National Stage entry of PCT/US2018/065226, which was filed December 12, 2018 and claims a priority date of December 12, 2017.

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner PCT is the real party-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Petitioner is aware that at least U.S. Patent App. Nos. 18/182,907 (abandoned) and 18/620,419 (pending) are continuation applications claiming priority to the 330 Patent.

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel.

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D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to the lead counsel at the address provided in Section I(C) of this Petition. Petitioner also consents to electronic service by email at: PCT-IPR@mcandrews-ip.com.

E. Payment of Fees (37 C.F.R. §§ 42.15(a) and 42.103(a))

The USPTO is authorized to charge Deposit Account No. 13-0017 for fees in 37 C.F.R. § 42.15(a) and any additional fees.

F. Grounds for Standing (37 C.F.R. § 42.104(a))

The 330 Patent is available for *inter partes* review (it issued more than nine months ago, on March 14, 2023) and Petitioner is not barred or estopped from requesting *inter partes* review on the grounds identified in this Petition.

III. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to 35 U.S.C. §§ 311-319, Petitioner requests *inter partes* review of claims 1-20 of the 330 Patent on the grounds below and request that each claim be found unpatentable. Additional support for each ground is set forth in the Declaration of Dr. Naum Papanicolau, Ph.D. (EX1002), which demonstrates the knowledge of a person of ordinary skill in the art (“POSA”) at the time of the claimed invention.

A. Prior Art Relied Upon

Exhibit 1005: PCT Publication No. WO 2018/127498 A1 (“Hope-Simpson”), published July 12, 2018 and claims priority to U.S. Provisional Application Nos. 62/442,691 (January 5, 2017) and 62/522,136 (June 20, 2017).

Exhibit 1006: U.S. Patent Publication No. 2014/0180273 (“Nair”) published on June 26, 2014 and claims priority to U.S. Provisional Application No. 61/745,476 (December 21, 2012).

Exhibit 1007: Shekoofeh Azizi et al., *Detection and grading of prostate cancer using temporal enhanced ultrasound: combining deep neural networks and tissue*

mimicking simulations, 12 Int’l J. Comput. Assisted Radiology & Surgery 1293-1305 (“Azizi”), published on June 20, 2017.

B. Grounds for Challenge

Petitioner requests cancellation of the Challenged Claims on the following grounds:

Ground	Reference(s)	Claim(s)	Basis
1	Hope-Simpson	1, 2, 4, 5, 11, 14, 16	35 U.S.C. § 102
2	Hope-Simpson	1, 2, 4, 5, 11, 14, 16	35 U.S.C. § 103
3	Hope-Simpson, Nair	3, 6-9, 12-13, 15, 17-20	35 U.S.C. § 103
4	Hope-Simpson, Nair, Azizi	10	35 U.S.C. § 103

IV. TECHNOLOGY OVERVIEW AND THE 330 PATENT

A. Priority Date of the 330 Patent

The 330 Patent is a 371 U.S. National Stage entry of PCT/US2018/065226, which was filed December 12, 2018 and claims priority to U.S. Provisional Application No. 65/597,537 filed December 12, 2017.

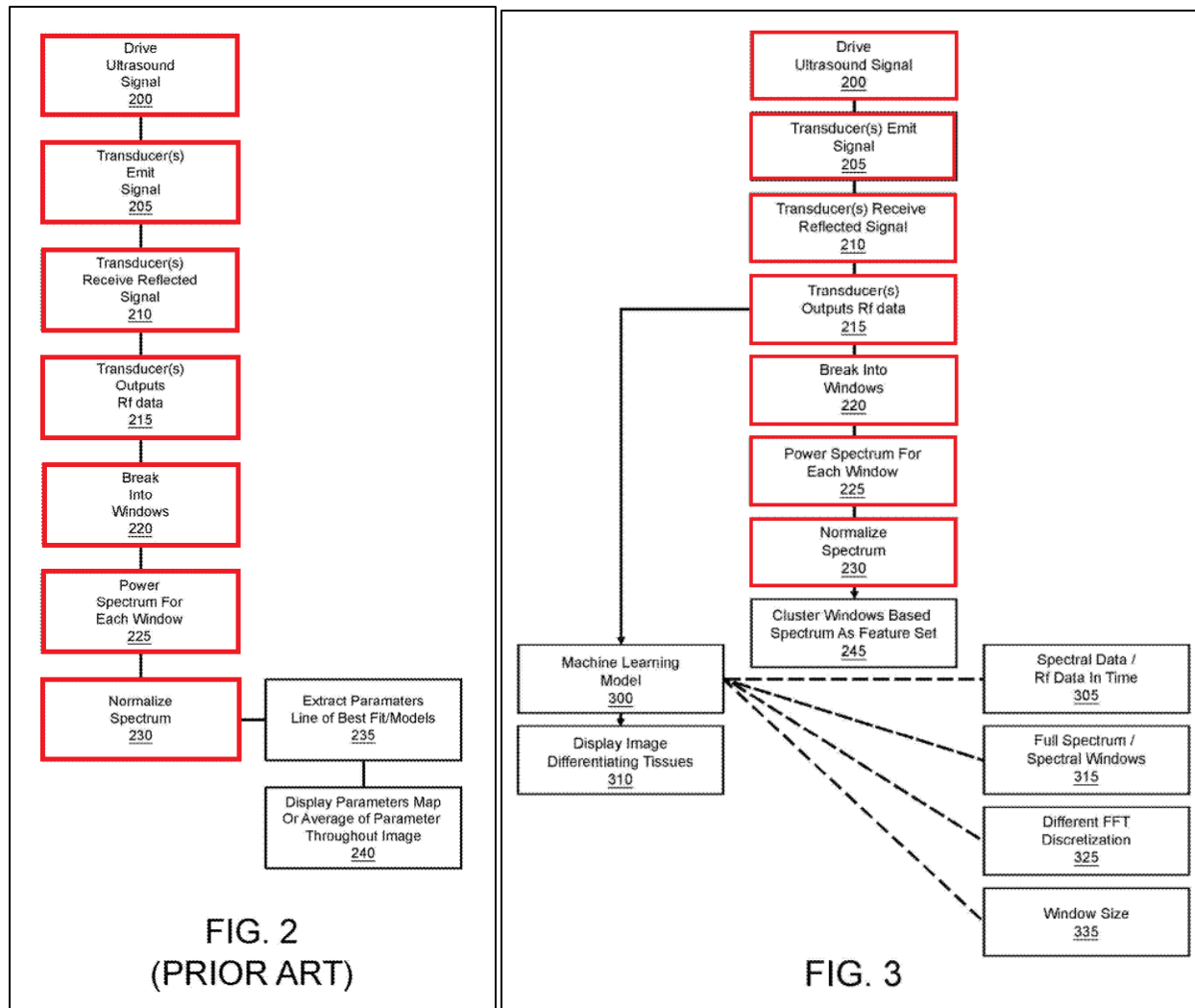
B. Subject Matter of the 330 Patent (EX1001)

The 330 Patent is directed to an ultrasound system that uses a machine learning model for the classification and identification of various physiological aspects of a living organism. *See* EX1001, 1:20-23.

The 330 Patent explains that “[c]onventional ultrasound spectroscopy uses ultrasound frequency spectrums from ultrasound RF data (raw sound signal as it returns into a transducer) to extract specific, pre-defined quantitative parameters that can describe tissue state (e.g., information on the ultrasound scatter size, concentration, and change in impedance in tissue).” *Id.*, 4:22-27.

The 330 Patent purports to use “machine learning to take ultrasound images and to train machine learning models to recognize certain pathologies based on these conventionally qualitative images.” *Id.*, 4:61-64. The 330 Patent alleges that “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[.]” *Id.*, 5:12-15.

Figure 3 of the 330 Patent provides “an example of a flowchart showing a method for classification of tissue using machine learning analysis of ultrasound data.” *Id.*, 3:3-5. The steps bounded in red are applicant-admitted prior art because they overlap with the prior art flow chart of Figure 2. *Id.*, Fig. 2.



Compare *id.*, Fig. 2 (annotated), with Fig. 3 (annotated).

The claims of the 330 Patent recite a signal processing unit that receives a single static set of raw RF ultrasound data and processes that single static set of raw RF ultrasound data with a machine learning model. *See, e.g., id.*, Claim 1.

C. Prosecution History of the 330 Patent (EX1004)

On June 12, 2020, Oncoustics filed the application as a 371 U.S. National Stage entry of PCT/US2018/065226 with twelve claims generally directed to an

ultrasound system for classification and identification of various physiological aspects of a living organism using a machine learning model.

The Examiner rejected original application claims 1-2 and 5-12 under 35 U.S.C. § 102 as anticipated by U.S. Patent Publication No. 2016/0120502A1 by Sadeghi-Naini (“Sadeghi-Naini”) and claims 3-4 under 35 U.S.C. § 103 as obvious over Sadeghi-Naini in view of U.S. Patent Publication No. 2017/0249739A1 by Kallenberg (“Kallenberg”). EX1004, p. 132-138; *see also* EX1010, EX1011.

On October 20, 2022, Oncoustics and the named inventor held an interview with the examiner to discuss Sadeghi-Naini and a newly-cited reference, *Ultrasound RF Time Series for Classification of Breast Lesions* by Uniyal (“Uniyal”). EX1004, p. 185-191; *see also* EX1012. During the interview, “[t]he examiner suggested incorporating [0036] of the specification (‘The RF ultrasound data may be converted to a normalized power spectrum which may then be fed into a trained (supervised, unsupervised or deep learning method) ML model(s) to classify tissues for specific applications, or to find specific multi-parametric biomarkers, or to identify and apply previously unknown parameters of normal and pathological physiology.’)” into the claims. EX1004, p. 191.

Thereafter, on October 21, 2022, Oncoustics added new claims 13-20 and amended existing claims 1, 5, and 10 “to recite that the transducer is ‘configured to output a single static set of raw ultrasound radio frequency (RF) data forming a

single frame of a tissue area.” *Id.*, p. 181-184, 186. In its remarks, Oncoustics distinguished Sadeghi-Naini as a “process that depends on pre-processing the RF ultrasound data” and “does not disclose inputting raw ultrasound RF data into the machine learning model as Sadeghi-Naini requires a two stage parameterization of raw data for input in the LDA/machine learning model.” *Id.*, p. 186. To distinguish Uniyal, which allegedly “relies on a time series of ultrasound data,” Oncoustics amended the claims “to recite a single static set of ultrasound RF data in a single frame of the tissue area.” *Id.*, p. 186-187. Oncoustics argued that “the claims rely on a single [sic] ‘snapshot’ frame of the ultrasound RF data rather than a time series or RF data as disclosed in Uniyal.” *Id.*, p. 187.

Following these amendments, the claims were allowed on November 10, 2022. *Id.*, p. 196.

D. Level of Skill in the Art

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. EX1002, ¶29.

V. CLAIM CONSTRUCTION

Claim terms should generally be construed according to their ordinary and customary meaning, which is the meaning they would have to a POSA at the time of invention, in light of the specification and file history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-14 (Fed. Cir. 2005) (*en banc*); 37 C.F.R. § 42.100(b). Where the construction of specific terms is not necessary to resolve the issues before the Board, the Board need not construe those terms. *See Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1352-53 (Fed. Cir. 2013); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that the Board need only construe terms “that are in controversy, and only to the extent necessary to resolve the controversy”).

For purposes of this Petition, Petitioner requests that the Board apply the following claim constructions.¹

A. Single Static Set of Raw Ultrasound Radio Frequency (RF) Data Forming a Single Frame

The Board should construe the phrase a “single static set of raw ultrasound radio frequency (RF) data forming a single frame,” to mean “a single static set of

¹ Petitioner reserves the right to respond to any proposed constructions raised by Patent Owner, or to revise its claim constructions in light of developments in related proceedings.

ultrasound radio frequency (RF) data that is not pre-processed, forming a single frame.” EX1004, p. 186-87; *see also id.*, p. 181-184, 191. Indeed, a POSA would understand “raw ultrasound radio frequency (RF) data” to mean “ultrasound radio frequency (RF) data that is not pre-processed.” EX1002, ¶24; *see also* EX1001, 5:13:14 (differentiating raw RF data from data or images after processing).

B. Output Classification / Outputting A Classification

The Board should construe the phrases “output classification” and “outputting a classification” to mean “output/outputting information indicating the class or classes of tissue type for the tissue area in the frame.” *Id.*, p. 187; *see also id.*, p. 181-184, 186, 191; EX1002, ¶25.

C. Processing the Single Static Set of Ultrasound RF Data as an Input to a Machine Learning Model

The Board should construe the phrase “processing the single static set of ultrasound RF data as an input to a machine learning model” to mean “processing the single static set of ultrasound RF data using a machine learning model.” The 330 Patent explains that inputting raw data into a machine learning model, rather than inputting pre-processed data into the machine learning model, is beneficial. For example, the 330 Patent states that “it has been discovered that 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 have much of the important ultrasound data filtered out, including

that which is useful for diagnosis and classification (e.g., a lot of the microstructure of tissue is lost when processing the data to form images.)” EX1001, 5:11-19; *see also* EX1002, ¶26. Indeed, as discussed above, Patent Owner distinguished Sadeghi-Naini cited by the Examiner during prosecution of the 330 Patent by summarizing Sadeghi-Naini as a “process that *depends on pre-processing the RF ultrasound data*” and “does not disclose inputting *raw* ultrasound RF data into the machine learning model.” EX1004, p. 186 (emphasis added).

VI. SUMMARY OF THE PRIMARY PRIOR ART REFERENCES

The Challenged Claims are directed to features that were well-known in the art before the 330 Patent’s priority date of December 12, 2017. The prior art references relied upon herein are directed to the same field as the 330 Patent, namely, ultrasound systems and machine learning. EX1002, ¶31. Petitioner is not aware of any secondary considerations supporting a finding of non-obviousness.

A. Hope-Simpson (EX1005)

Hope-Simpson discloses exactly what Oncoustics claimed during prosecution was allegedly not present in the prior art—applying machine learning to raw, unprocessed ultrasound RF signal data, and doing so one-at-a-time to single static sets of data forming single frames (*i.e.*, the standard transducer output of any conventional ultrasound). Indeed, Hope-Simpson discloses very similar—if not

identical—structure and operations for doing so compared to the 330 Patent. Hope-Simpson was not cited during the prosecution of the 330 Patent.

Hope-Simpson, titled “Ultrasound Imaging System with a Neural Network for Image Formation and Tissue Characterization,” was filed January 3, 2018 and claims priority to Provisional Patent Application Nos. 62/442,691 (filed January 5, 2017) and 62/522,136 (filed June 20, 2017) (collectively, “Priority Provisionals”). EX1013, EX1014. Hope-Simpson shares the same figures and written description as U.S. Provisional Patent App. No. 62/522,136. *Compare* EX1005, *with* EX1014. The Priority Provisionals, each of which predate the earliest priority date of the 330 Patent, therefore provide written description support for at least the portions of the disclosure for which Hope-Simpson is relied upon.

Hope-Simpson teaches an ultrasound imaging system that uses a neural network to generate imaging and characterize tissue based on the echo signals that the ultrasound imaging system receives. EX1005, Abstract. The ultrasound system of Hope-Simpson includes a transducer 113 which transmits ultrasound and detects echo signals (also referred to as radio frequency or RF signals) from targeted tissue, and a signal processing unit 126 which is configured to execute instructions (which may be stored in a computer-readable medium) and acquires the echo signals (RF data). *Id.*, ¶[028]-[029]. The signal processing unit 126 uses a machine learning network 710 (in this case, a neural network) 710 to output “imaging data and/or

tissue information directly from the raw RF signals.” *Id.*, ¶[066], Fig. 7. The neural network may output tissue characterization from the raw RF signals. *Id.*, ¶¶[026], [066].

Figure 1 (reproduced below) depicts a block diagram of the ultrasound system disclosed in Hope-Simpson. In Figure 1, the ultrasound system 100 includes channel memory 110 (or a memory containing machine readable medium), a machine learning model 160 (neural network), a display processor 140, and a user interface 124. *Id.*, ¶[028]. Additionally, Figure 1 shows a transducer 113, a transmit/receive controller 120, beamformer 122, beamformer memory 123, signal processor 126 (or signal processing unit), imaging data processor 121, scan converter and multiplaner reformatter 133, input data selector 162, and a storage component 150. *Id.* The transducer 113 transmits pulses of ultrasound toward a medium and detects echoes of the transmitted pulses. *Id.*, ¶[029]. The channel memory 110 receives the echoed signals, also called the RF data, and couples it to a neural network 160 which can then produce imaging data and tissue information and classification “directly from the RF signals.” *Id.*, ¶[030]. The system of Hope-System produces imaging data and/or tissue information from raw RF signals, “without the need for conventional beamforming or downstream signal processing.” *Id.*, ¶[030]. Hope-Simpson describes that tissue information includes “tissue characterization or diagnostic

information,” such as “fat content or other type[s] of tissue content.” *Id.*, ¶¶[026], [071].

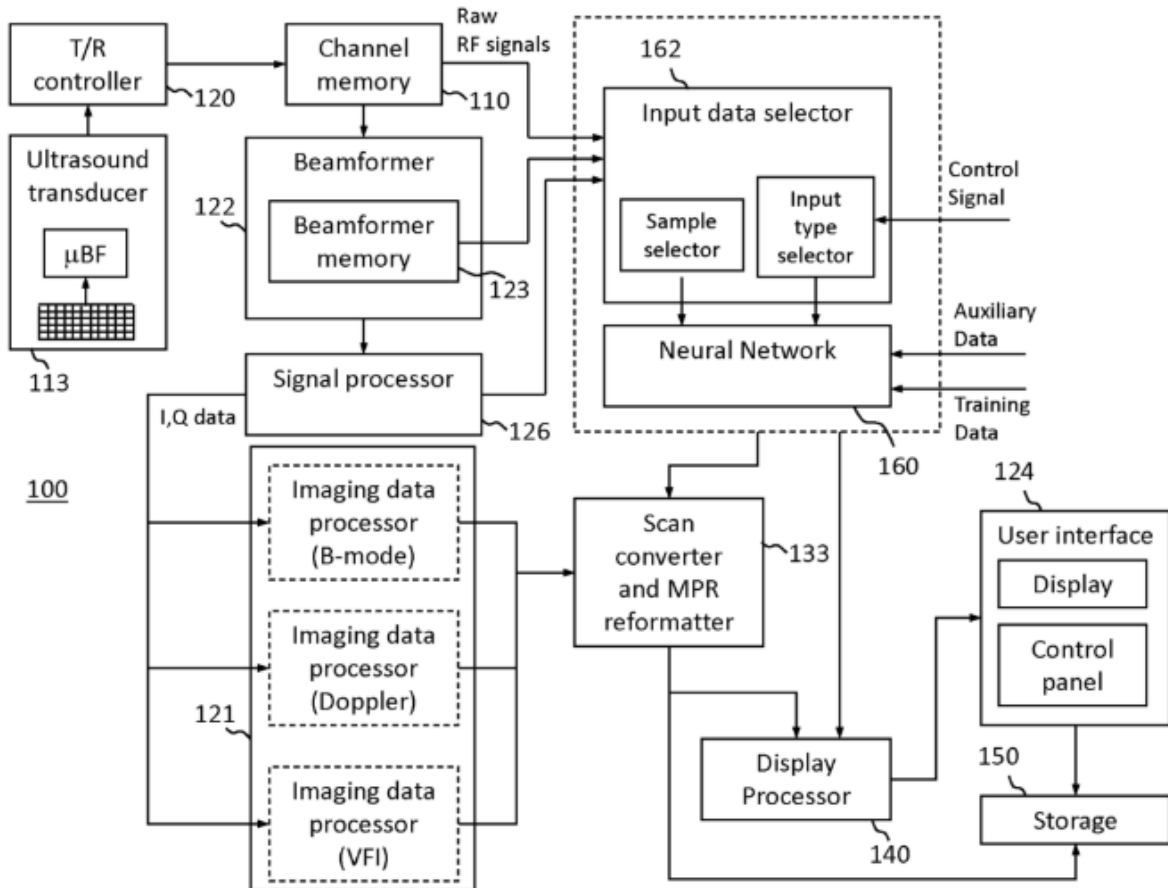


FIG. 1

Id., Fig. 1.

Figure 7 (reproduced below) depicts a flow diagram of the process disclosed by Hope-Simpson. As shown, Figure 7 illustrates the process of storing the acquired raw RF signals 702 and processing the raw RF data using a neural network 710 before providing imaging data and/or tissue information based on the raw RF signals 712.

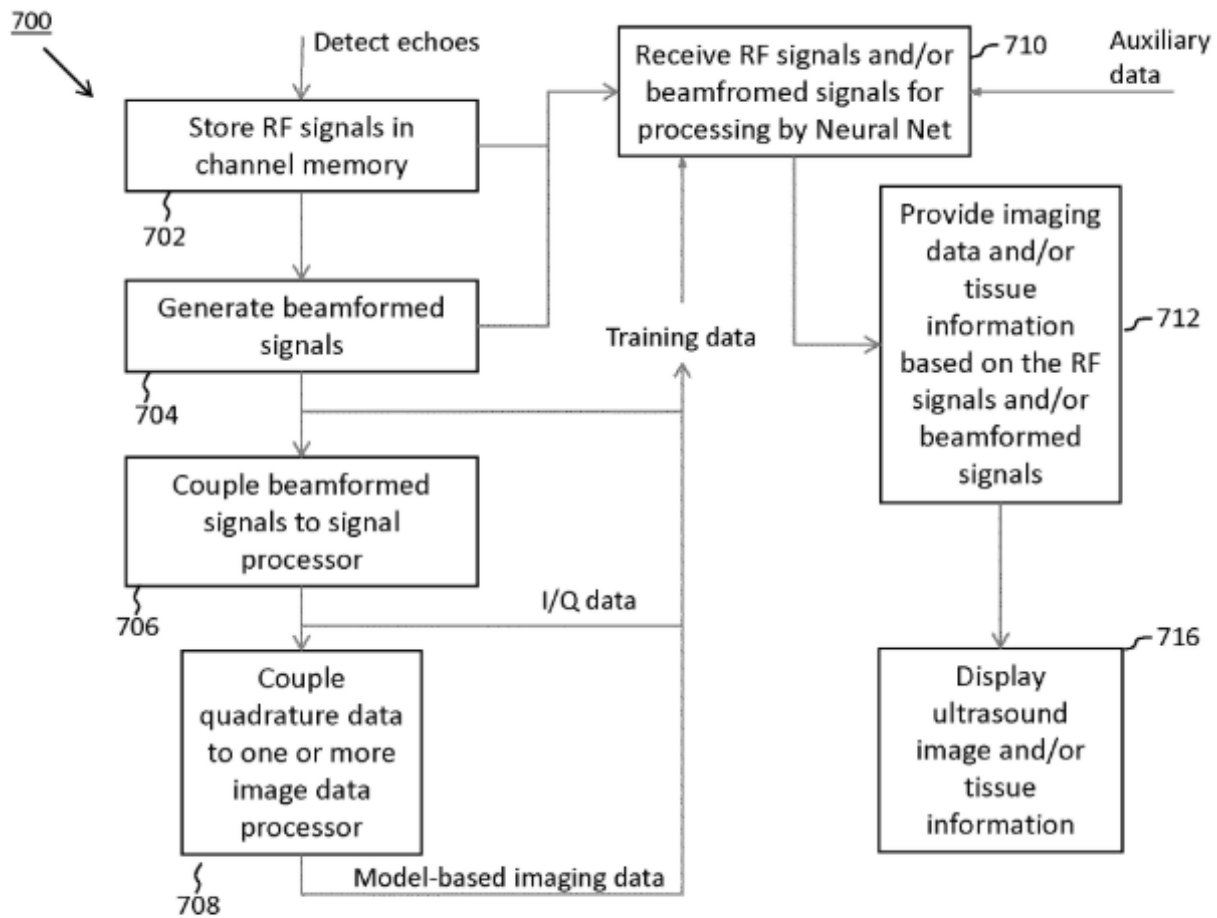


FIG. 7

Id., Fig. 7.

B. Nair (EX1006)

Nair discloses additional details known in the prior art relating to the use of machine learning for analyzing ultrasound imaging data, such as how the data is processed and how a machine learning algorithm is trained. Nair was not cited during prosecution of the 330 Patent.

Nair, titled “Device, System, and Method for Imaging and Tissue Characterization of Ablated Tissue,” published June 26, 2014 and claims priority to Provisional Patent App. No. 61/745,476 (December 21, 2012). Nair teaches a system for classifying tissue that utilizes a signal analyzer to determine one or more signal properties from reflected signals and associates those signal properties to pre-determined tissue signal properties via pattern recognition. EX1006, Abstract. Figure 10 of Nair, reproduced below, is a simplified flow diagram illustrating a methodology for characterizing tissue components:

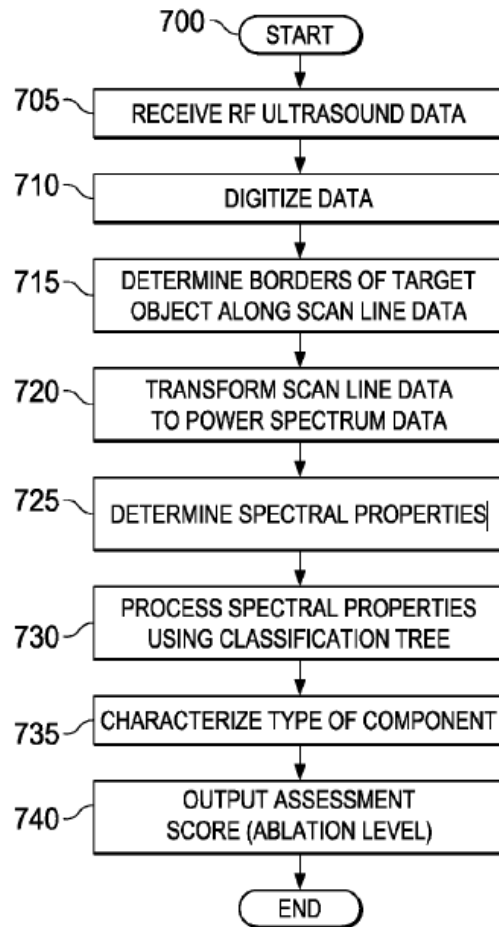


Fig. 10

EX1006, Fig. 10.

C. Azizi (EX1007)

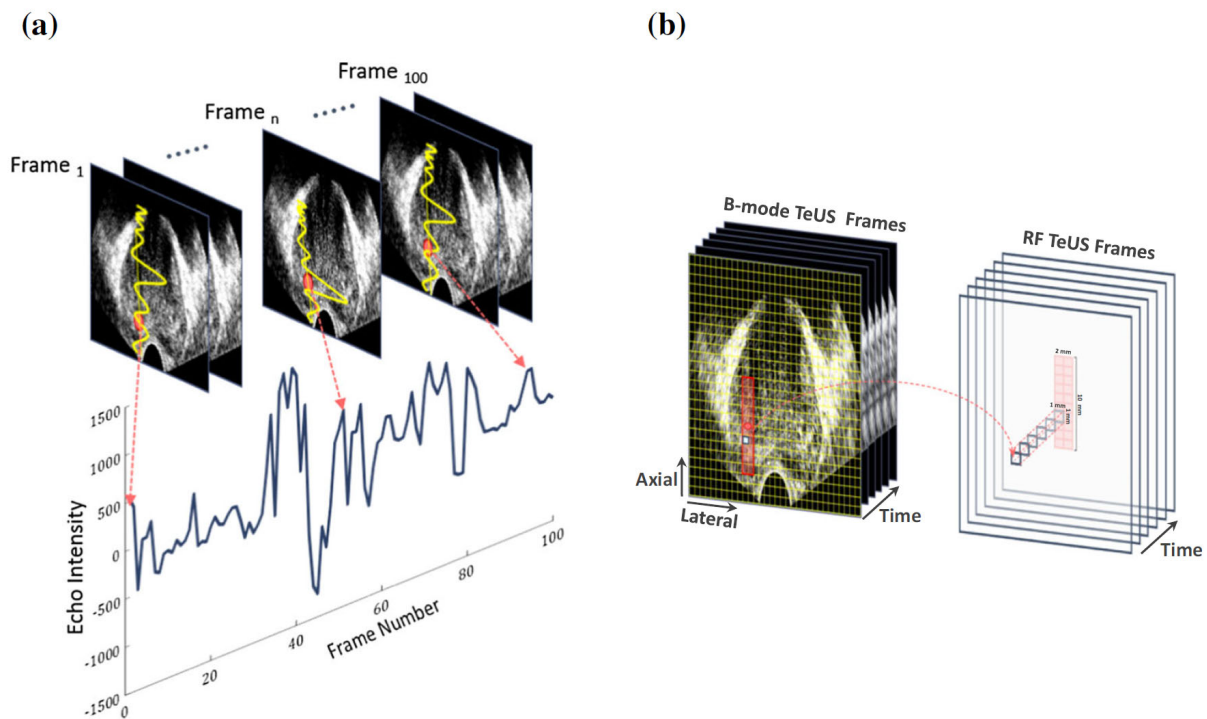
Azizi discloses further detail regarding known methods for processing ultrasound signal data. In particular, Azizi discloses the use of discrete Fast Fourier Transform (DFFT) to process ultrasound signal data. EX1007, p. 1295-96. Azizi was not cited by the examiner during prosecution of the 330 Patent.

Azizi, titled “Detection and grading of prostate cancer using temporal enhanced ultrasound: combining deep neural networks and tissue mimicking

simulations,” was published online June 20, 2017. Azizi generally teaches the use of Temporal Enhanced Ultrasound (TeUS) for tissue characterization based on RF data.

Id., Abstract.

Azizi computes the spectrum of TeUS data obtained from each biopsy target and in each region of interest (ROI). *Id.*, p. 1295-96. To make data workable in their implementation, a Discrete Fourier Transform (DFT) of all zero-mean US time series corresponding to the RF samples in each ROI, normalized to the frame rate is taken. *Id.*



Id., Figs. 1a, 1b.

As can be appreciated, the time series data processed by Azizi is made up of a plurality of static frames—each of which gets analyzed. EX1002, ¶73. Each of the

individual RF frames is a single sample within the time series. *Id.* Then, Azizi calculates the mean absolute values of the Fourier transforms of the RF time series in each ROI. *Id.* Finally, each ROI is represented by 50 positive frequency components. *Id.*

In other words, Figures 1a and 1b in Azizi demonstrate that passing a single frame of RF data directly into a machine learning model allows for spatial analysis in both the X and Y dimensions. EX1002, ¶¶73.

VII. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM IS UNPATENTABLE

A. Ground 1: Hope-Simpson Anticipates Claims 1, 2, 4, 5, 11, 14, and 16

As shown below and in the accompanying Declaration, Hope-Simpson discloses each element of claims 1, 2, 4, 5, 11, 14, and 16, and thus anticipates these claims under 35 U.S.C. § 102. EX1002, ¶¶75, 79-128.

i. Claim 1

a. 1.P: Preamble - An ultrasound system comprising:

Whether or not the preamble is limiting, Hope-Simpson discloses an ultrasound system. Hope-Simpson is entitled “Ultrasound Imaging System with a Neural Network for Image Formation and Tissue Characterization.” EX1005, Title. Figures 1, 4, 5, and 6 of Hope-Simpson are also exemplary ultrasound system designs. For example, Figure 1 of Hope-Simpson, reproduced below, depicts an

ultrasound system that includes channel memory 110, a neural network 160, an ultrasound transducer 113, a signal processor 126, an imaging data processor 121, and a storage component 150, among other components. EX1005, Fig. 1; EX1002, ¶¶81-82.

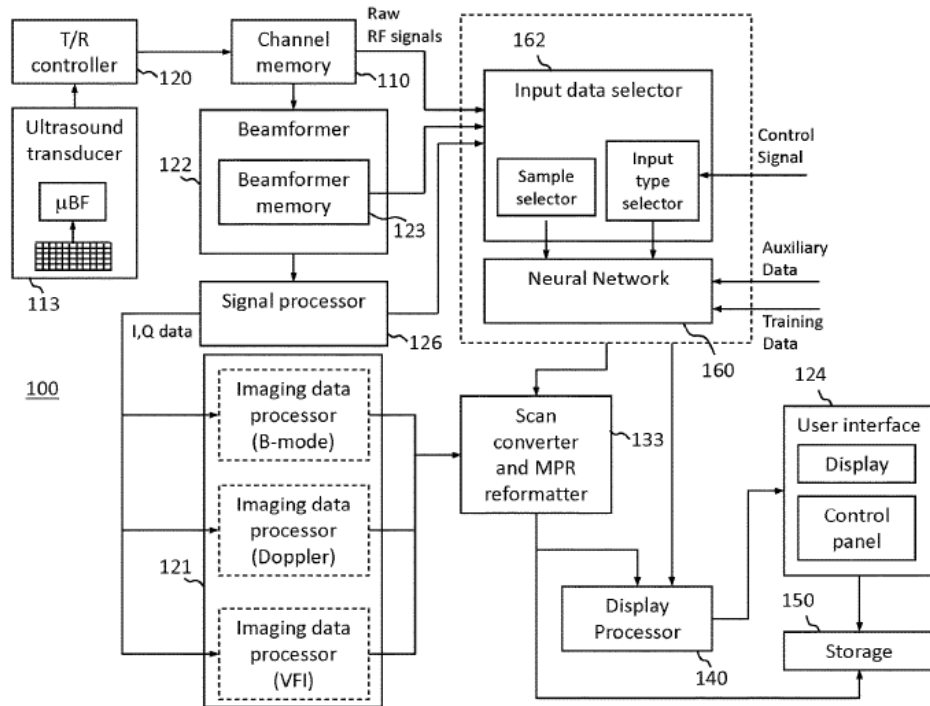


FIG. 1

EX1005, Fig. 1.

- b. 1.1: a transducer configured to output a single static set of raw ultrasound [RF] data forming a single frame of a tissue area;**

This limitation describes a conventional ultrasound transducer that acquires raw RF data in discrete sets. EX1002, ¶84. Indeed, “data forming a single frame of tissue area” is standard transducer output when imaging tissue using ultrasound. *Id.*,

¶85. This is analogous to how a standard video camera captures video at a given frame-rate, *i.e.*, one frame at a time. *Id.*, ¶84. Hope-Simpson discloses this conventional output. In particular, Hope-Simpson discloses an output of “acquired echo signals,” or raw RF data, through a transducer. EX1005, ¶¶[002], [030]; EX1002, ¶86. Thus, it was known in the art at the time of filing to use a transducer configured to output a single static set of raw RF data forming a single frame of a tissue area. EX1002, ¶86.

Moreover, Hope-Simpson further discloses that its transducer is configured to acquire echo signals (a single static set of raw RF data) and feed it to a neural network which is capable of “analyzing patterns using a with a [sic] multidimensional (2-or more dimensional) data set, which may also be thought of as localized data sets....” EX1005, ¶[005]; *see also id.*, ¶[030]; EX1002, ¶86. The localized data sets described by Hope-Simpson are equivalent to the claimed “single static set of raw ultrasound [RF] data forming single frame of a tissue area.” EX1002, ¶86. Indeed, Hope-Simpson describes that “the system may include a data selector configured to select a subset of echo signals from the acquired echo signals stored in the channel memory and provide the subset of echo signals to the neural network, wherein the echo signals in the subset are associated with adjacent points within a region of imaged tissue.” EX1005, ¶[007]. Therefore, 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. EX1005, ¶¶[005]-[006], [026], [030]; EX1002, ¶86.

c. 1.2: a memory containing machine readable medium comprising machine executable code having stored thereon instructions;

Hope-Simpson discloses an ultrasound system that includes a “computer-readable medium comprising executable instructions.” EX1005, Claim 12. Hope-Simpson also contemplates that when those instructions are executed, they cause the processor to “perform a machine-trained algorithm for...outputting tissue information.” *Id.*, ¶[027]. Thus, Hope-Simpson discloses “a memory containing machine readable medium comprising machine executable code having stored thereon instructions”—Hope-Simpson’s “executable instructions” would be “machine executable code” because they are stored on a computer readable medium and processed by a processor—“having stored thereon instructions.” EX1002, ¶87.

d. 1.3: a signal processing unit comprising one or more processors coupled to the memory, the one or more processors configured to execute the machine executable code to [sic] the cause the one or more processors to:

Hope-Simpson also discloses a neural network that may be implemented using a processor (or processing unit), which may be multiple processors arranged in parallel. EX1005, ¶[027]. The processing unit may be stored in a computer-readable medium and is “configured to execute instructions” that may be stored in

the computer-readable medium. *Id.*, ¶[027], Claim 12. Therefore, Hope-Simpson discloses a signal processing unit comprising one or more processors that are configured to execute the machine executable code.

Hope-Simpson also discloses having the one or more processors coupled to the memory, stating the system may include “a computer-readable medium comprising executable instructions which when executed by a processor coupled to the channel memory, the beamformer, or both, cause the processor to perform a machine trained algorithm to produce the imaging data based on the one or more samples of the acquired echo signals....” *Id.*, ¶[010]. Thus, Hope-Simpson discloses a signal processing unit comprising one or more processors coupled to the memory, and those processors are configured to execute the machine executable code.

e. 1.4: receive the single static set of raw ultrasound RF data;

Figures 1 and 2 of Hope-Simpson demonstrate that the ultrasound system of Hope-Simpson produces and processes localized, static data sets composed of raw ultrasound RF data. EX1005, Figs. 1-2; EX1002, ¶92. For example, Figure 1 of Hope-Simpson shows raw RF data acquisition from a transducer 113 into channel memory 110 as input to data selector 162 which is configured to select a discrete set of echo samples from the input raw RF signals. EX1005, Fig. 1; EX1002, ¶92.

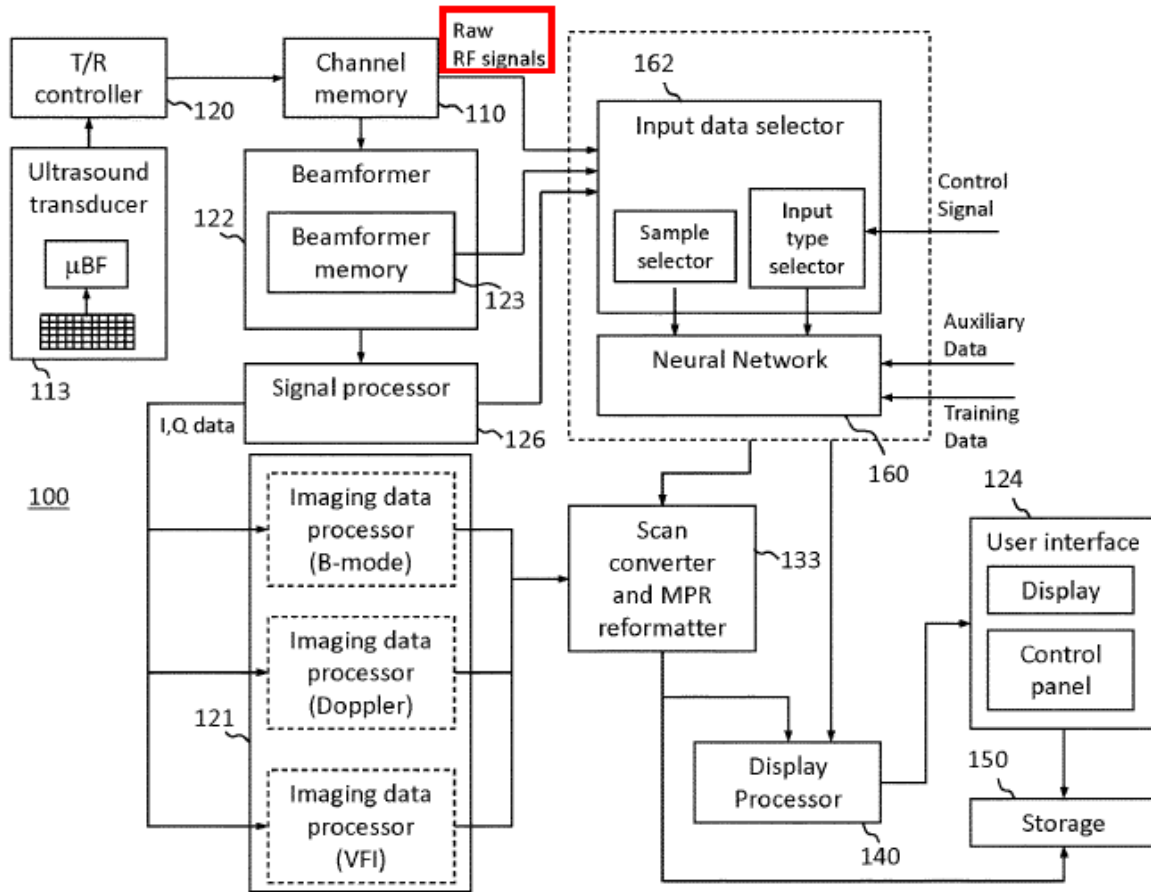


FIG. 1

EX1005, Fig. 1 (annotated).

Indeed, the signals that are fed from the transducer to the channel memory and, ultimately, into the signal processing unit, are raw RF signals. EX1002, ¶93. “The ultrasound transducer 113 is communicatively coupled to channel memory 110, which receives and stores the echo signals acquired by the ultrasound transducer 113. The channel memory 110 may be configured to store per-element or group (in the case of microbeamformed signals) echo signals (also referred to as raw

RF signals or simply RF signals, or per-channel data).” EX1005, ¶[029]; *see also id.*, ¶[030].

Additionally, Hope-Simpson discloses a transducer 113 that may acquire echo signals (raw RF data) “responsive to ultrasound signals transmitted toward a medium to be imaged (e.g., tissue).” *Id.*, ¶[029]. Figure 7 of Hope-Simpson demonstrates that the ultrasound system, specifically the signal processor (or signal processing unit), receives the single static set of raw ultrasound data that has been stored in the system memory after being output by the transducer. *Id.*, Fig. 7.

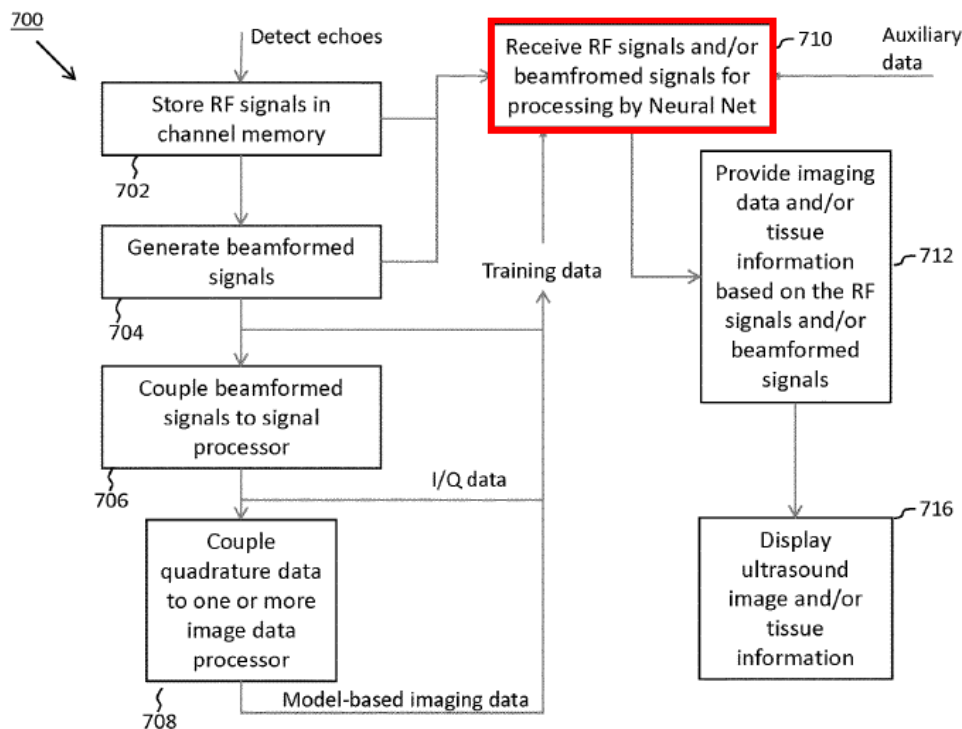


FIG. 7

Id., Fig. 7 (annotated).

As discussed below in § VII(A)(i)(f), the processors recited in Claim 1 of the 330 Patent are responsible for both processing raw RF data with a machine learning model and receiving the static set of raw ultrasound RF data. EX1001, Claim 1. In the same way, Step 710 of Figure 7 of Hope-Simpson describes “[r]eceiv[ing] RF signals and/or beamformed [sic] signals for processing by the Neural Net.” EX1005, Fig. 1. This indicates that the processors of Hope-Simpson are responsible for processing raw RF data with a machine learning model, such as a neural network, and are also configured to receive the static set of raw ultrasound RF data. EX1002, ¶¶96. Thus, Hope-Simpson discloses processors that are configured to receive the static set of raw ultrasound RF data. *Id.*

f. 1.5: process the single static set of raw RF ultrasound data with a machine learning model; and

Hope-Simpson discloses multiple examples of processing raw RF ultrasound data with a machine learning model. EX1002, ¶¶97. For example, as discussed above, Figure 7 of Hope-Simpson includes the step of “[r]eceiv[ing] RF signals...for processing by Neural Net.” EX1005, Fig. 7. Hope-Simpson also discloses the use of a processor configured to execute instructions, “which when executed cause the processor to perform a machine-trained algorithm for producing ultrasound images and/or outputting tissue information.” *Id.*, ¶¶[027]. In this case, a machine-trained algorithm is synonymous with a machine learning model. *Id.*, ¶¶[025] (“[T]he neural network may be trained using any variety of currently known or later developed

machine learning techniques to obtain a neural network (e.g., a machine-trained algorithm or hardware-based system of nodes)...”); EX1002, ¶99. As established previously, the processors in question are those implicated by Step 710 of Figure 7 and process the single static set of raw RF ultrasound data with a machine learning model. EX1005, Fig. 7.

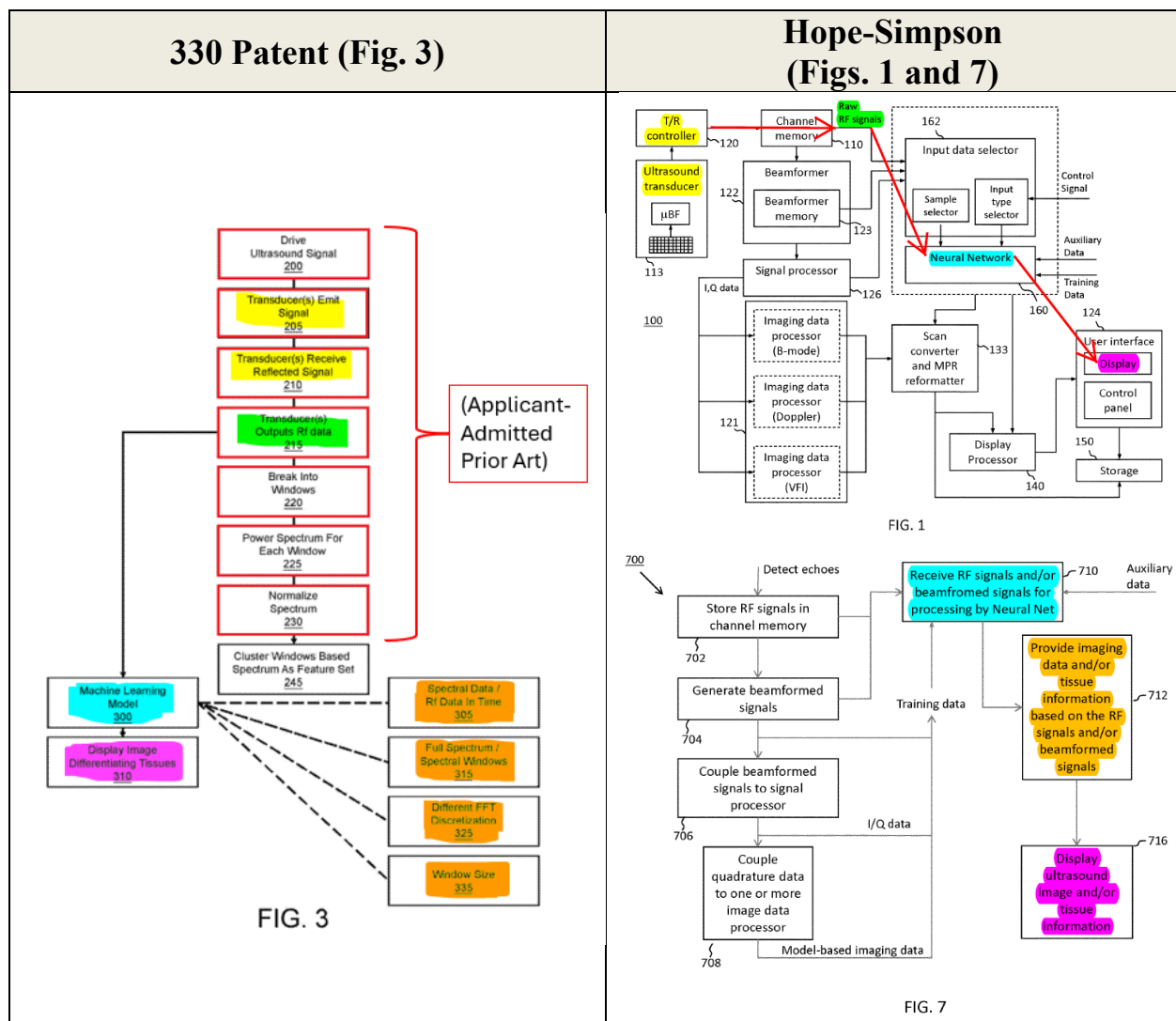
g. 1.6: output classification of the raw RF ultrasound data from an output of the machine learning model.

Hope-Simpson discloses outputting a variety of “tissue characterization or diagnostic information (collectively referred to as tissue information) from raw RF signals....” *Id.*, ¶[026]. For example, Figure 7 details the process of performing tissue characterization using machine learning algorithms to process raw ultrasound RF data. *Id.*, ¶[066]. “Samples of the per-channel RF signals may be coupled to a neural network (e.g., neural net 160), as shown in 710, and may then propagate through the nodes of the network to output...tissue information directly from the raw RF signals...as shown in block 712.” *Id.*

The process of determining tissue characteristics in Hope-Simpson is a classifying process. For example, Hope-Simpson discloses the use of its ultrasound system to characterize fat content and plaque within tissue, *i.e.*, its characterization process classifies tissue as either fat, plaque, etc. EX1005, ¶¶[069]-[071]; EX1002, ¶102. Thus, as shown in Step 712 of Figure 7 of Hope-Simpson, the processors responsible for receiving raw RF data and processing that raw RF data using a

machine learning model also output tissue classification information based on the raw RF signals. EX1005, Fig. 7.

For at least these reasons, claim 1 of the 330 Patent is anticipated by Hope-Simpson. Indeed, as is evident from comparing their respective figures (annotated below), Hope-Simpson's system and the system of the 330 Patent are structurally and operationally analogous:



As shown in Figure 3 of the 330 Patent and Figure 1 of Hope-Simpson, and as discussed in more detail herein, both systems include a transducer (yellow) which outputs raw RF signals (green) directly to a machine learning model (blue). Both machine learning models then generate imaging data as well as classifications of the scanned tissue (orange) and output/display that information (magenta).

- ii. **Claim 2: The ultrasound system of claim 1, wherein the machine learning model is a k-means model or a model from a deep learning network comprising but not limited to one or a combination to the algorithm types of CNN (Convolutional Neural Network), RBM (Restricted Boltzmann Machine), LSTM (Long Short Term Memory) or CapsNet (Capsule Networks).**

Hope-Simpson further discloses the use of a deep neural network (DNN), a convolutional neural network (CNN), or a combination thereof. EX1005, ¶[066]. Hope-Simpson also discloses that the DNN and CNN may be trained using any variety of currently known or later developed machine learning techniques. *Id.*, ¶[025]. In this context, the machine learning model is used for determining the characteristics (here, tissue classification) of an image for display from raw RF channel data. *Id.*

Because claim 1 is anticipated by Hope-Simpson (as discussed in Section VII(A)(i)) and Hope-Simpson demonstrates that the use of a wide array of machine learning models, including at least CNNs, to classify tissue was well-known in the

art before to the 330 Patent, claim 2 of the 330 Patent is also anticipated by Hope-Simpson.

iii. Claim 4: The ultrasound system of claim 1, wherein the machine learning model is an unsupervised model.

Hope-Simpson outlines the use of an unsupervised machine learning model. For example, Hope-Simpson discloses that its algorithm can “directly estimate or output imaging data or other tissue properties based on the raw measurement data (i.e., raw acquired RF signals) *without reliance on an explicit model of the input/output relationship...*” *Id.*, ¶[032] (emphasis added). While the term “unsupervised” is not used by Hope-Simpson to describe this model, a POSA would understand that its use of an algorithm that does not rely on direct input from a user is a description of the same thing. EX1002, ¶108. Additionally, Hope-Simpson incorporates all “currently known” machine learning techniques, which includes unsupervised models, which were known in the art. *Id.*; EX1005, ¶[025]. Indeed, unsupervised machine learning algorithms were known long before Hope-Simpson or the 330 Patent. *See, e.g.*, EX1008, p. 796-801 (discussing the use of unsupervised machine learning algorithms at least as early as 1992).

Claim 1 is anticipated by Hope-Simpson (as discussed in Section VII(A)(i)). As shown in Hope-Simpson, an unsupervised machine learning model for tissue classification was also known in the prior art at the time of the 330 Patent. Therefore, claim 4 of the 330 Patent is likewise anticipated by Hope-Simpson.

- iv. **Claim 5: The system of claim 1, wherein the processor is operable to display an image representing the set of ultrasound data using a unique identifier based on the output of the machine learning model.**

Hope-Simpson describes several embodiments that perform a classification process and display an output image containing tissue classification output from the machine learning model. EX1005, ¶¶[027], [064]. Specifically, Hope-Simpson discloses outputs of the ultrasound system that “may be graphically represented, with each quantitative value being color-coded.” *Id.*, ¶[070]. Thus, Hope-Simpson discloses the display of an image representing the set of ultrasound data using a unique identifier (color-coding) based on the output (tissue classification) of the machine learning model.

Indeed, this feature is nothing unique. The use of a display to visualize tissue classification is intuitive to the person of skill in the art—it is necessary. EX1002, ¶110. This visualization is typically in the form of full frame parametric frames or regions overlaid onto conventional ultrasound images. *Id.* Each color in the parametric image is associated with a value in a corresponding color scale. *Id.* Thus, each color on the corresponding color scale is a unique identifier of a particular property of the power spectra. *Id.*

Claim 1 is anticipated by Hope-Simpson (as discussed in Section VII(A)(i)) and Hope-Simpson also discloses displaying an image representing the set of

ultrasound data using a unique identifier based on the output of the machine learning model, Hope-Simpson anticipates claim 5 of the 330 Patent.

v. Claim 11

a. 11.P: Preamble - A method comprising:

Whether or not the preamble is limiting, Hope-Simpson discloses a method. EX1005, ¶[001]. (“The present disclosure pertains to ultrasound systems and methods....”).

b. 11.1: receiving a single static set of raw ultrasound [RF] data output from at least one ultrasound transducer forming a single frame representing a tissue area of a patient;

As discussed above in Section VII(A)(i)(e), Hope-Simpson discloses a transducer 113 that acquires echo signals (raw RF data) “responsive to ultrasound signals transmitted toward a medium to be imaged (e.g., tissue).” *Id.*, ¶[029]. Indeed, Hope-Simpson discloses the output of “acquired echo signals,” or raw RF data, through a transducer. *Id.*, ¶¶[002], [025]. The transducer disclosed in Hope-Simpson is also configured to output a single static set of raw ultrasound RF data forming a single frame of a tissue area. *Id.*, ¶¶[005]-[006], [026]; EX1002, ¶84.

As discussed in Section VII(A)(i)(e), Figure 7 of Hope-Simpson demonstrates in Step 710 that the ultrasound system of Hope-Simpson, specifically the signal processor or signal processing unit, receives the single static set of raw ultrasound data that has been stored in the system memory after being output by the transducer.

EX1005, Fig. 7. Step 710 of Figure 7 states “[r]eceive RF signals and/or beamformed [sic] signals for processing by the Neural Net.” *Id.* This indicates that the processors of Hope-Simpson responsible for processing raw RF data with a machine learning model, such as a neural network, are also configured to receive the static set of raw ultrasound RF data. In the same way, as discussed in Section VII(A)(v)(c), the processors recited of the 330 Patent are also responsible for both processing the raw RF data with a machine learning model and receiving the static set of raw ultrasound RF data. EX1001, Claim 11. Thus, the processors of Hope-Simpson which are represented in Step 710 of Figure 7, are configured to receive the static set of raw ultrasound RF data, as was known in the prior art.

Moreover, as discussed above in Section VII(A)(i)(b), an “ultrasound transducer forming a single frame representing a tissue area” describes a normal ultrasound transducer which acquires raw RF data in discrete sets. EX1002, ¶84. For example, “[d]ata forming a single frame of tissue area” is standard transducer output when imaging tissue using ultrasound. *Id.*, ¶119.

c. 11.2: processing the single static set of ultrasound RF data as an input to a machine learning model; and

Hope-Simpson discloses multiple examples of processing the single static set of raw ultrasound RF data using a machine learning model. For example, Figure 7 (reproduced below) of Hope-Simpson includes the step of “[r]eceive[ing] RF

signals...for processing by Neural Net.” EX1005, Fig. 7. Potential inputs to that step include raw ultrasound RF data.

Indeed, Hope-Simpson describes “a neural network...that [is] able to derive or calculate the characteristics of an image for display from raw channel data (i.e., acquired radio frequency (RF) echo signals)....” *Id.*, ¶[025]; *see also id.*, ¶¶[026] (“[T]he neural network may be trained to output ultrasound images and/or a variety of tissue characterization or diagnostic information (collectively referred to herein as tissue information) from raw RF signals, beamformed signals, or combinations thereof.”), [030] (“[A] neural network 160, which is trained to produce imaging data, extract tissue information, or any combinations thereof, directly from the RF signals, e.g., without the need for conventional beamforming or downstream signal processing.”), [047] (“The neural network 460...may be trained for example as described herein to produce the pixel data directly from the input array, e.g., bypassing conventional signal processing steps such as beamforming, RF filtering, demodulation and I/Q data extraction, amplitude detection, etc.”), [066] (“Samples of the per-channel RF signals may be coupled to a neural network (e.g., neural net 160), as shown in 710, and may then propagate through the nodes of the network to output produce [sic] imaging data and/or tissue information directly from the raw RF signals or beamformed RF signals, as shown in block 712.”). Figure 7 shows that

this unprocessed data may then be used as input to the machine learning model (Step 710). *Id.*, Fig. 7.

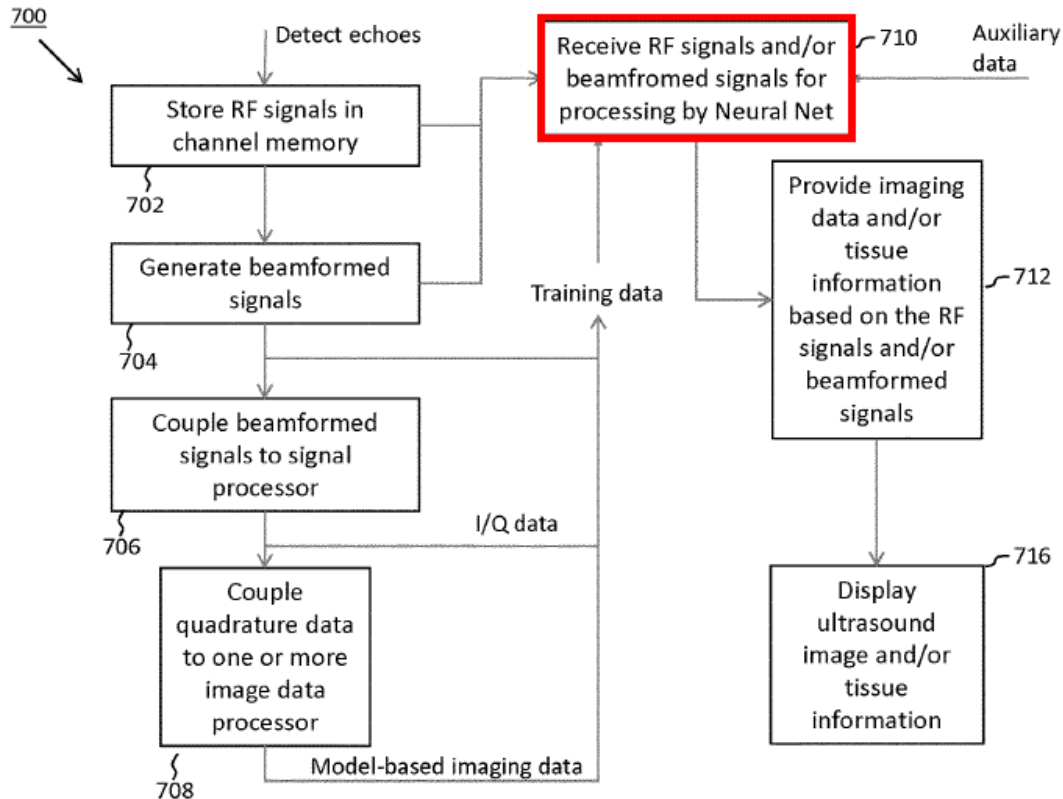


FIG. 7

d. 11.3: outputting a classification of the tissue area from the machine learning model.

As discussed above in VII(A)(i)(g), Hope-Simpson discloses outputting a classification of the tissue area (*e.g.*, tissue information) from raw RF signals. *Id.*, ¶[026]. Figure 7 details the process of performing tissue classification using machine learning algorithms processing raw ultrasound RF data. *Id.*, ¶[066]. “Samples of the per-channel RF signals may be coupled to a neural network (*e.g.*, neural net 160), as

shown in 710, and may then propagate through the nodes of the network to output...tissue information directly from the raw RF signals...as shown in block 712.” *Id.* The process of outputting tissue information in Hope-Simpson is a classifying process. *Id.* For example, Hope-Simpson discloses the use of its ultrasound system to characterize fat content and plaque within tissue, *i.e.*, its characterization process classifies tissue as either fat, plaque, etc. *Id.*, ¶[069]; EX1002, ¶102.

Additionally, as shown in Step 712 of Figure 7 of Hope-Simpson, the processors which are also responsible for receiving raw RF data and processing that raw RF data using a machine learning model will also output tissue information (*e.g.*, a classification) based on the RF signals. EX1005, Fig. 7.

For at least these reasons, claim 11 of the 330 Patent is anticipated by Hope-Simpson.

- vi. **Claim 14: The method of claim 11, wherein the machine learning model is a k-means model or a model from a deep learning network comprising one or a combination to the algorithm types of CNN (Convolutional Neural Network), RBM (Restricted Boltzmann Machine), LSTM (Long Short Term Memory) or CapsNet (Capsule Networks).**

As discussed above in VII(A)(ii), Hope-Simpson discloses the use of a deep neural network (DNN), a convolutional neural network (CNN), or a combination thereof. EX1005, ¶[025]. Hope-Simpson also discloses that the DNN and CNN may be trained using any variety of currently known or later developed machine learning

techniques. *Id.* In this context, the machine learning model is used for determining the characteristics (here, tissue classification) of an image for display from raw RF data. *Id.*

Because claim 11 is anticipated by Hope-Simpson (as discussed in Section VII(A)(v)) and Hope-Simpson demonstrates that the use of a wide array of machine learning models, including CNNs, to derive tissue information was well-known in the art prior to the 330 Patent, claim 14 of the 330 Patent is also anticipated by Hope-Simpson.

vii. Claim 16: The method of claim 11, wherein the machine learning model is an unsupervised model.

As discussed above in Section VII(A)(iii), Hope-Simpson outlines the use of an unsupervised algorithm to “directly estimate or output imaging data or other tissue properties based on the raw measurement data (i.e., raw acquired RF signals) *without reliance on an explicit model of the input/output relationship.*” *Id.*, ¶[032] (emphasis added). Again, while the term “unsupervised” is not used by Hope-Simpson to describe its model, its description of an algorithm that does not rely on direct input from a user is a description of the same thing. EX1002, ¶99. Additionally, Hope-Simpson incorporates all “currently known” machine learning techniques, which includes unsupervised models that were known in the art. EX1005, ¶[025]. Indeed, unsupervised machine learning algorithms were known long before Hope-Simpson or the 330 Patent. *See, e.g.*, EX1008, p. 796-801

(discussing the use of unsupervised machine learning algorithms at least as early as 1992).

Because claim 11 is anticipated by Hope-Simpson (as discussed in Section VII(A)(v)) and, as shown in Hope-Simpson, an unsupervised machine learning model was also known in the prior art at the time of the 330 Patent. Therefore, claim 16 does not add anything patentable to the subject matter of claim 11. As such, claim 16 of the 330 Patent is likewise anticipated by Hope-Simpson.

B. Ground 2: Claims 1, 2, 4, 5, 11, 14, and 16 are Obvious in View of Hope-Simpson and the Knowledge of a POSA

The knowledge within the art at the time of the 330 Patent's claimed priority date reinforces that Hope-Simpson anticipates the 330 Patent or, alternatively, renders the 330 Patent obvious in view of Hope-Simpson and the knowledge of a POSA that existed at the time. *See, e.g., Monsanto Tech. LLC v. E.I. DuPont De Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018) ("Extrinsic evidence may be used to interpret the allegedly anticipating reference and to shed light on what it would have meant to a PHOSITA"); *Koninklijke Philips v. Google*, 948 F.3d 1330, 1337-38 (Fed. Cir. 2020) (affirming PTAB finding of obviousness based on a single reference in view of the knowledge of a POSA). In particular, 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.

For example, it was well-known to a POSA that a normal ultrasound transducer acquires raw RF data in discrete sets of single “frames.” EX1002, ¶84; *see also* U.S. Patent Pub. No. 20100063393A1 by Moradi at ¶¶124-25 (describing operation of a standard commercial ultrasound, the Sonix RP, which collects discrete static frames of data, at 8 frames per second). At the very least, 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. Again, similar to how a camera works, a standard ultrasound detector collects signals for a single time for a single view. EX1002, ¶84. Utilizing such a setup with Hope-Simpson would have involved simply utilizing a known, conventional, and predictable process, with a reasonable expectation of success. *See id.*; *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-21 (2007) (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”).

As discussed above, Hope-Simpson describes that “[s]amples of the per-channel RF signals may be coupled to a neural network (e.g., neural net 160), as shown in 710, and may then propagate through the nodes of the network to output...tissue information directly from the raw RF signals...as shown in block 712.” EX1005, ¶[066]. As discussed above, the process of determining tissue characteristics in Hope-Simpson is a classifying process. And such a classification

process was well-known. EX1002, ¶102; *see also* EX1016, U.S. Patent No. 6,238,342 to Feleppa (“Feleppa”) at Title (“Ultrasonic tissue-type classification and imaging methods and apparatus”), 10:64-11:3 (“The present invention provides methods of characterizing various materials, such as various tissue-types, using ultrasound measurements and material-related data. Once characterized, methods of displaying a real-time image depicting different tissue types differently, e.g., suspect tissue differently than non-suspect tissue, are also provided by the present invention.”). For example, Feleppa discloses using ultrasound to classify tissue as “suspect” or “non-suspect” tissue. EX1016, 10:64-11:3.

Because such tissue classification techniques were known, it would have been obvious to employ these tissue classification techniques in Hope-Simpson, for example. EX1002, ¶102. Indeed, classifying tissue would aid a user in interpreting the ultrasound image (*e.g.*, for diagnosis and treatment), and would have involved simply choosing how to display the information already analyzed and output by the machine learning algorithm of Hope-Simpson. EX1002, ¶110; *see also* EX1016, 4:39-45. A POSA would have been able to predictably do so in an expected manner, given that it would have only involved choosing a display output and/or training the algorithm with specific information to identify specific tissue types. EX1002, ¶110.

C. Ground 3: Claims 3, 6-9, 12, 13, 15, and 17-20 are Obvious in View of Hope-Simpson, Nair, and the Knowledge of a POSA

i. Claim 3: The ultrasound system of claim 1, wherein the machine learning model is trained using ultrasound images labeled by a radiologist.

As discussed in Section VII(A)(ii), Hope-Simpson discloses the ultrasound system of claim 1 of the 330 Patent. Further, Hope-Simpson discloses the use of ultrasound images labeled by a radiologist to train the machine learning model.

For example, Hope-Simpson teaches a training algorithm that receives “an array of training inputs and known outputs, wherein the training inputs...[are] associated with a region of imaged tissue and the known outputs comprise known properties of the imaged tissue.” EX1005, Claim 5, ¶¶[010], [069]. Although Hope-Simpson does not expressly state that the labeled ultrasound images that are used for training have been labeled *by a radiologist*, Hope-Simpson does state that the training inputs may include “training data sets of input and known outputs, for example obtained through conventional ultrasound imaging....” *Id.*, ¶[069]. A POSA would understand that “training data sets of inputs and known outputs...obtained through conventional ultrasound imaging” would include labeled ultrasound images that were labeled by a radiologist (*e.g.*, to get training inputs associated with a region of imaged tissue). EX1002, ¶¶140-41. Indeed, the process of preparing and labeling training data for machine learning algorithms has a high impact on the success of a classifying system. EX1002, ¶141.

To the extent that Hope-Simpson does not disclose the labeling of images by a radiologist, Nair discloses such an input. For example, Nair discloses preparing a tissue specimen for slide review, wherein a clinician identifies and characterizes the tissue type(s). EX1006, ¶[0064]. Then, “[t]he identified tissue type(s) and/or characterization conclusions are provided to the characterization application 250 as characterization data.” *Id.*, ¶[0066], Claim 7 (signal properties used in characterization application include an artificial neural network). Nair’s “clinician” that identifies and characterizes tissue types, or labels the ultrasound images, would necessarily be, or include, a radiologist. EX1002, ¶¶141-42.

A person having ordinary skill in the art would have been motivated to combine the training data and inputs of Hope-Simpson with the labelling by a clinician (*e.g.*, a radiologist) disclosed by Nair. To the extent that neither Nair nor Hope-Simpson expressly disclose labeling performed by a *radiologist*, the choice of a radiologist for these purposes would be obvious, and a POSA would understand that such labeling is often done by a radiologist. *Id.*, ¶142. In particular, having a radiologist label the images would have been obvious to ensure that the labels are accurate and that the tissue identification of the system is successful. A radiologist would be qualified in terms of education, experience, and knowledge to perform such labeling to reliably discern the tissue types based on analyzing images. For example, U.S. Patent No. 10,499,857 by Nguyen describes that “studies are used

to train a network [e.g., a machine learning algorithm] to then be able to operate by analyzing studies not yet reviewed by a human radiologist” and that such studies “will contain a study-level label as normal or abnormal, provided by a human radiologist.” EX1017, 23:61-65; *see also id.*, 2:66-3:3, 4:25-27 (discussing availability of radiologists for interpretation of medical images for diagnoses).

Thus, it would be obvious to use a clinician, as described by Nair, to produce the labeled data of Hope-Simpson that is used for training the machine learning model of Hope-Simpson. Further, it would be obvious to select a clinician familiar with the labeling of ultrasound data; specifically, a radiologist. *Id.*, ¶¶140-42.

ii. Claim 6

a. 6.P: Preamble - A method comprising:

Whether or not the preamble is limiting, Hope-Simpson discloses a method. EX1005, ¶[001] (“The present disclosure pertains to ultrasound systems and methods....”). Nair also discloses a method. EX1006, ¶[0210] (“The systems and methods described herein....”).

b. 6.1: receiving a single static set of raw ultrasound [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;

As discussed above in Sections VII(A)(i)(e) and VII(A)(iv)(b), Hope-Simpson discloses a transducer 113 that acquires echo signals (raw RF data)

“responsive to ultrasound signals transmitted toward a medium to be imaged (e.g., tissue).” *Id.*, ¶[029]. As discussed above in Sections VII(A)(i)(b) and VII(A)(iv)(b), an “ultrasound transducer forming a single frame representing a tissue area of a patient” describes a normal ultrasound transducer which acquires raw RF data in discrete sets. *See* EX1002, ¶84.

Hope-Simpson discloses the output of “acquired echo signals,” also called raw RF data, through a transducer. EX1005, ¶¶[002], [025]-[026], [030]. The transducer disclosed in Hope-Simpson is also configured to output a single static set of raw ultrasound RF data forming a single frame of a tissue area. *Id.*, ¶¶[005]-[006], [026]; EX1002, ¶84. In fact, “[d]ata forming a single frame of tissue area” is standard transducer output when imaging tissue using ultrasound. *Id.*, ¶150.

As further discussed in Sections VII(A)(i)(e) and VII(A)(iv)(b), Figure 7 of Hope-Simpson demonstrates in Step 710 that the ultrasound system, specifically the signal processor or signal processing unit, receives the single static set of raw ultrasound data that has been stored in the system memory after being output by the transducer. EX1005, Fig. 7. Step 710 of Figure 7 shows “[r]eceiv[ing] RF signals and/or beamformed [sic] signals for processing by the Neural Net.” *Id.* This indicates that the processors of Hope-Simpson responsible for processing raw RF data with a machine learning model, such as a neural network, are also configured to receive the static set of raw ultrasound RF data. In the same way, as discussed below in Section

VII(C)(ii)(c), the processors recited in claim 6 of the 330 Patent are also responsible for both processing the raw RF data with a machine learning model and receiving the static set of raw ultrasound RF data. EX1001, Claim 6.

c. 6.2: processing the single static set of raw ultrasound RF data set of windows to determine a power spectrum;

Windows are not discussed previously in this claim, but the two-step method of (1) partitioning the RF data into windows and (2) determining a power spectrum for each window, would be consistent with conventional approaches to interpreting ultrasound data using machine learning. EX1002, ¶152. The separation of RF data into windows and subsequent determination of the power spectrum for each window is a standard approach to image processing in algorithms, such as sliding window analysis, and is well known in the art, as admitted in the 330 Patent. EX1001, Fig. 2. For example, Figure 2 of the 330 Patent, which is admitted prior art, shows the steps of breaking the RF data into windows (220) and determining a power spectrum for each window (225). *Id.*

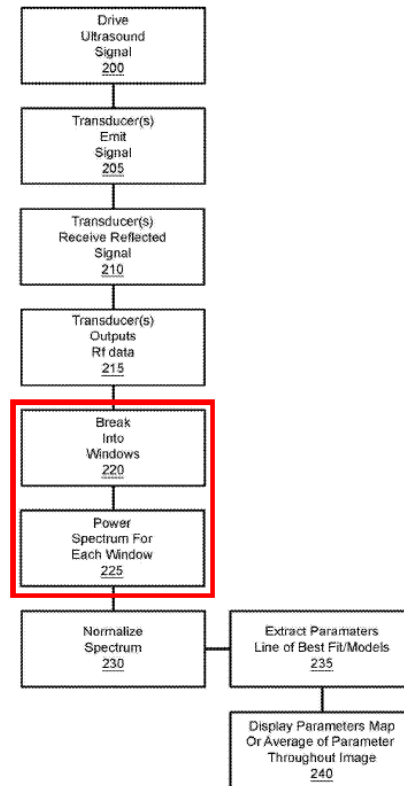


FIG. 2
(PRIOR ART)

Id. (annotated).

Similarly, this process is described in Figure 7 of Nair (reproduced below). According to Nair, a scan line is “analyzed in segments represented by the windows illustrated in the figure [7], such as window 555.” EX1006, ¶[0088]. The data within the window 555 is then transformed to “a power spectrum density plot,” as shown in Figure 8 of Nair (reproduced below). *Id.* Figure 8 of Nair is an illustration of a power spectrum plot generated from the data of Figure 7. *Id.*, ¶[0023].

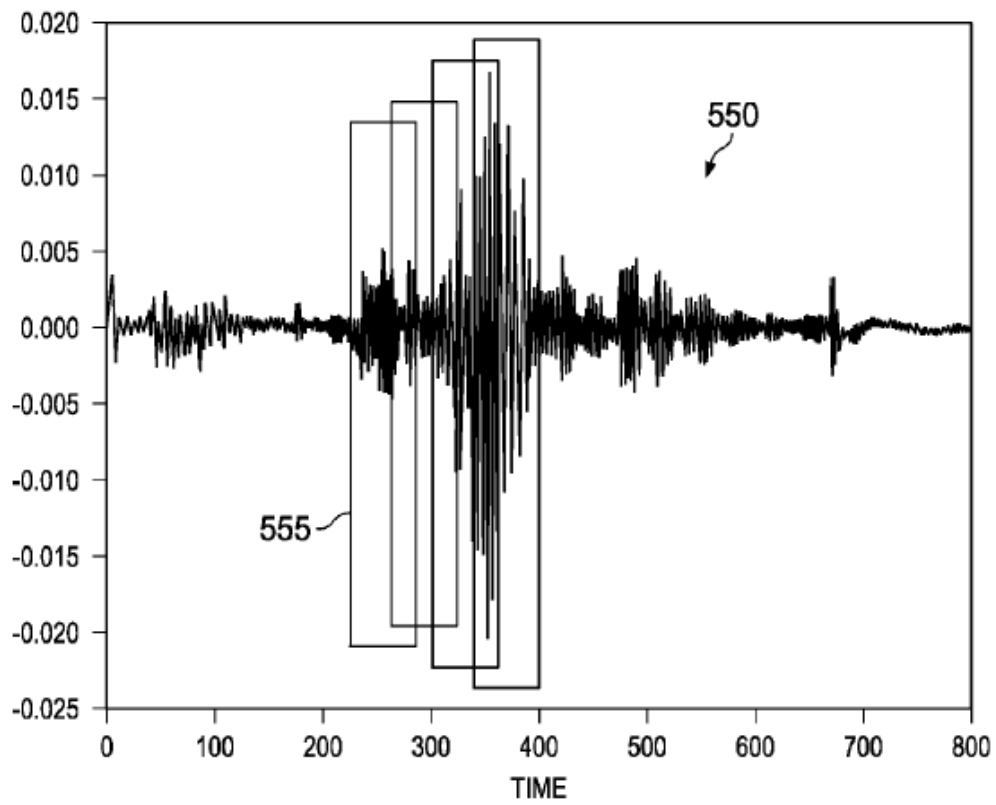


Fig. 7

Id., Fig. 7.

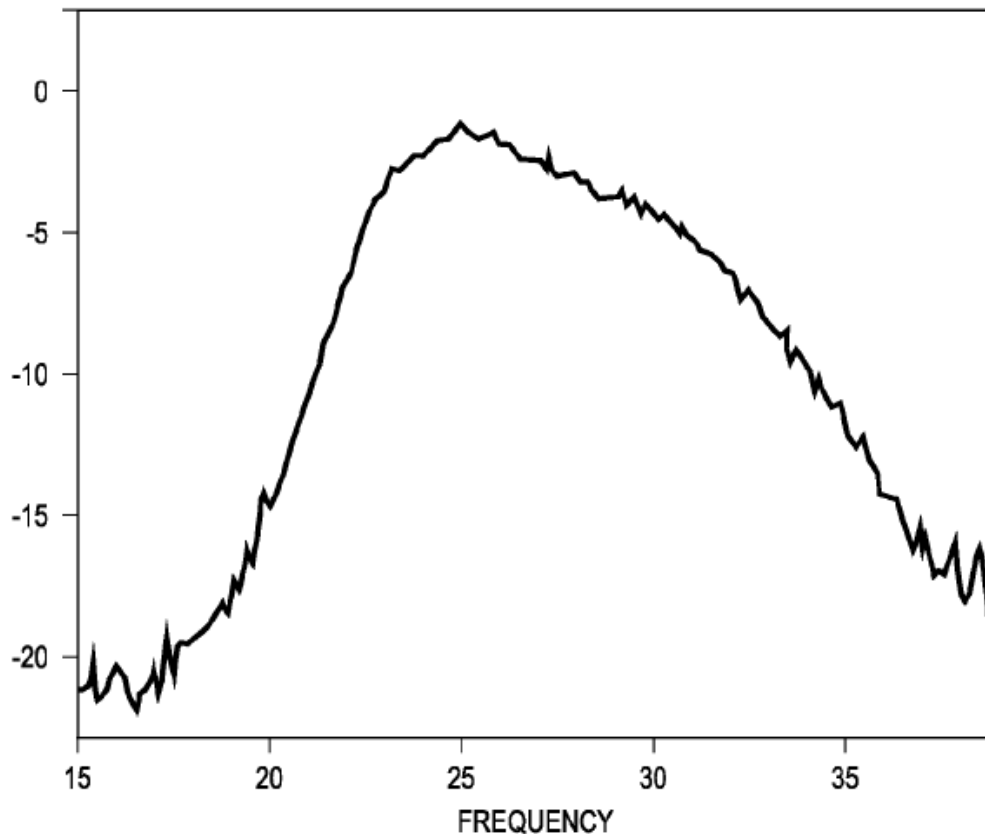


Fig. 8

Id., Fig. 8.

Thus, as admitted prior art by the 330 Patent, and as confirmed by Nair, processing data into windows and subsequently determining a power spectrum for each window was a well-understood and conventional process in the art at the time of the 330 Patent. It would have been obvious—to the extent that Hope-Simpson does not already inherently do so—to use Nair’s conventional processing of data into windows and power spectrums for each window in the system of Hope-Simpson. Again, as discussed above, Figure 7 of Hope-Simpson includes the step “[r]eceive RF signals...for processing by Neural Net.” EX1005, Fig. 7. Hope-

Simpson also discloses the use of a processor configured to execute instructions, “which when executed cause the processor to perform a machine-trained algorithm for producing ultrasound images and/or outputting tissue information.” *Id.*, ¶[027]. It would have been obvious that Hope-Simpson could include at least pre-processing the data into windows and a power spectrum for each window, as conventionally known, in order to have the data in a format that can be predictably and easily analyzed by a neural network. EX1002, ¶152. Indeed, it was common knowledge in the art to pre-process data before inputting it into a machine learning network. *See, e.g.*, EX1012, p. 659 (“This method uses RF time series parameters within a machine learning framework.”), 654 (“We use the method...[of] summarizing the power spectrum of the RF time series in six parameters.”); EX1019, p. 11 (referencing study that used a “CNN-based system taking power spectrum as input....”). And because pre-processing ultrasound data into windows and a power spectrum for each window was conventional, a POSA would have known how to successfully do so. EX1002, ¶152.

d. 6.3: processing the determined power spectrum as an input into a machine learning model; and

Hope-Simpson demonstrates that ultrasound tissue classification can be performed on complete data sets without the need for pre-processing signal properties. EX1005, ¶[031]. A POSA would understand that using this method on more-heavily processed signals (such as power spectra) whose properties are well

demonstrated tissue classifiers would yield similar results. EX1002, ¶157. Again, 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, and doing so in Hope-Simpson would have been obvious in order to provide a predictable and easily analyzed data format for the neural network of Hope-Simpson to analyze. EX1002, ¶158; *see also* EX1012, p. 659 (“This method uses RF time series parameters within a machine learning framework.”), 654 (“We use the method...[of] summarizing the power spectrum of the RF time series in six parameters.”); EX1019, p. 11 (referencing study that used a “CNN-based system taking power spectrum as input....”).

In other words, 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 as described in the 330 Patent. *Id.* Thus 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.

e. 6.4: outputting a classification of the tissue area from the machine learning model.

Hope-Simpson discloses multiple examples of outputting a classification of the tissue area from the machine learning model. For example, Hope-Simpson discloses that its neural network can be trained to “produce images and/or tissue characterization and diagnostic information...without the need for a physically-

derived model to guide system operation.” EX1005, ¶[025]; *see also id.*, ¶[065] (“[The system] may process the received signals in accordance with conventional physics-based [sic] pre-programmed models to derive the imaging data for producing ultrasound images.”).

Nair also discloses the step of outputting a classification of the tissue area from the machine learning model. *See, e.g.*, EX1006, ¶[0204] (“[T]he image data obtained can be used by the characterization application 250 to output tissue characterization...in real time.”), Claim 7 (“[T]he predetermined tissue signal properties are embodied in the database as an artificial neural network having one or more nodes that identify a tissue component.”).

Additionally, as discussed above in Section VII(B), it was otherwise well-known to a POSA that tissue classification was a useful and desired output of a machine learning algorithm analyzing ultrasound data. For the same reasons discussed in that section, to the extent not disclosed by Hope-Simpson or Nair, it was obvious to output a classification the tissue area, for example, in order to aid a user in interpreting an ultrasound image, and would have involved simply choosing how to display the information analyzed and output by the machine learning algorithm of Hope-Simpson. EX1002, ¶110.

iii. Claim 7: The method of claim 6, wherein the classification is a cancer status of the tissue.

The term “cancer status” may refer to the presence or state of cancerous tissue

within a sample. *Id.*, ¶162. Both Hope-Simpson and Nair discuss tissue characterization. *See, e.g.*, EX1005, ¶[026]; EX1006, ¶[0048] (“The characterization data may include a variety of identifying and/or characterization information, such as...type of tissue, [or] the different cell components within the tissue....”). A POSA would understand that these descriptions would include classifying the *cancer* status of tissue, or, at the very least, that doing so is obvious. EX1002, ¶163. For example, a POSA would have known that classifying tissue as either cancerous or non-cancerous would assist a clinician in interpreting the image for purposes of cancer diagnosis, testing, or treatment. *Id.*

As one example, Feleppa discloses that it is desirable for an ultrasound system to be able to identify cancerous versus non-cancerous tissue. EX1016, 2:35-37 (“In one embodiment, the classification scores distinguish cancerous tissue from non-cancerous tissue.”). Because Hope-Simpson and Nair both already disclose classifying the tissue “type,” it would have been a straightforward and predictable exercise to train their machine learning algorithms to identify “cancerous” or “non-cancerous” (*e.g.*, cancer status) as the tissue type. EX1002, ¶163. Indeed, this sort of classification was done using machine learning methods much earlier than the priority date of the 330 Patent. *See, e.g.*, EX1009, Abstract (“These methods used for [cancer] diagnosis include artificial intelligence techniques, such as support vector machine neural network, artificial neural network, fuzzy logic, and adaptive

neuro-fuzzy interference system, with medical imaging like X-ray, *ultrasound*, magnetic resonance imaging, and computed tomography scan images.”) (emphasis added).

Accordingly, because Claim 6 is obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA, and the addition of Claim 7—that the classification is a cancer status of the tissue—contributes nothing novel or non-obvious in view of Hope-Simpson, Nair, or the general knowledge within the art, Claim 7 is also obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

iv. Claim 8: The method of claim 6, wherein the method further comprises processing the power spectrum to determine a normalized power spectrum.

The step of processing the power spectrum to determine a normalized power spectrum is admitted prior art in block 230 of Figure 2 of the 330 Patent. EX1001, Fig. 2, 6:38-42.

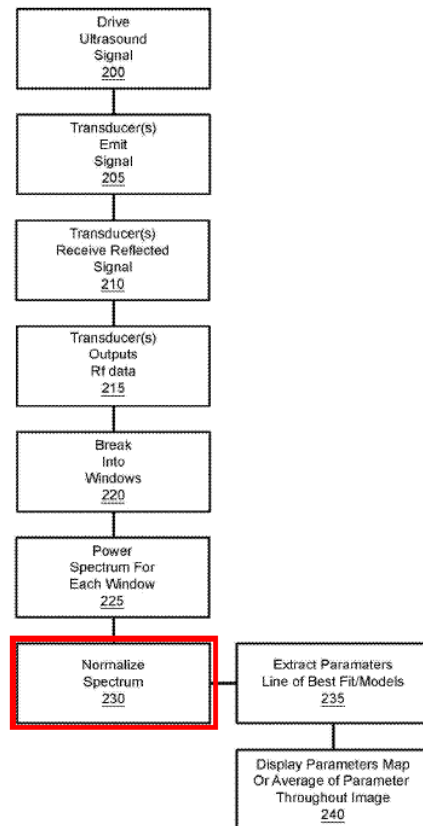


FIG. 2
(PRIOR ART)

Id., Fig. 2 (annotated).

Further, power spectrum normalization was often used as a calibration mechanism and is common in ultrasound tissue characterization applications and known to a POSA at the time of the 330 Patent. EX1002, ¶¶165-66. For example, U.S. Patent Pub. No. 2007/0167755 by Kolios discloses that normalized power spectrum can be used to easily calculate differences in tissue type:

The normalized power spectra can be calculated between bandwidth limits where the value of the reference Fourier power spectrum can be -15 dB or 3% of the maximum value at the center frequency of the ultrasound imaging system. Linear regression can be performed on the

normalized power spectrum from each A-scan line....Apoptosis or cellular death can be indicated by the slope of the average fitted normalized Fourier power spectrum versus frequency becoming significantly more positive during treatment.

EX1017, ¶71.

To the extent not already inherently present in Hope-Simpson and Nair, it would have been obvious in view of the knowledge of a POSA to process the power spectrum to determine a normalized power spectrum in order to calibrate the system and aid in tissue classification. *See* EX1002, ¶166.

Because Claim 6 is obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA, and because Claim 8 adds nothing novel or non-obvious, Claim 8 is also obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

v. Claim 9: The method of claim 6, wherein the power spectrum is taken using a continuous Fast Fourier Transform (FFT).

The use of an FFT is a standard method for computing power spectrum data for ultrasound tissue characterization applications. EX1002, ¶168. Nair discusses the use of various transformation algorithms to produce a power spectrum plot such as a Fourier transformation. EX1006, ¶[0090]. The difference between a Fourier Transformation (FT), as disclosed by Nair, and a Fast Fourier Transformation (FFT) as in Claim 9 of the 330 Patent is that “the Fourier transform is efficient (*e.g.*, fast).” EX1002, ¶168.

As discussed above in Sections VII(C)(ii)(b) and VII(C)(ii)(c), Hope-Simpson expressly discloses the use of a static single set of RF data, and it would have been obvious in view of Nair to determine a power spectrum of Hope-Simpson's RF data. Further, Nair discloses that the power spectrum is taken by a Fourier Transformation (EX1006, ¶[0090]), which would necessarily include a Fast Fourier Transformation. EX1002, ¶168. It would have been routine and obvious to a POSA to use "a continuous Fast Fourier Transform (FFT)" to compute a power spectrum as claimed, especially in view of Nair's discussion of producing power spectrums using a Fourier transform. *Id.* Thus, the step of taking the power spectrum using a continuous FFT is disclosed by the combination of Hope-Simpson and Nair.

This, combined with the finding above that Claim 6 is obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA, likewise renders Claim 9 of the 330 Patent obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

vi. Claim 12

a. 12.P: Preamble - The method of claim 11 further comprising:

As discussed in Section VII(A)(v), Hope-Simpson discloses each limitation of claim 11. The limitations added by claim 12, as follows, are obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

**b. 12.1: partitioning the single static set of raw
ultrasound RF data into a set of windows or bounding
boxes; and**

First, the 330 Patent itself admits “break into windows” is prior art, as seen in Step 220 of Figure 2. EX1001, Fig. 2. The 330 Patent also describes that “in previously described systems, the raw ultrasound data is typically broken up into various windows 220.” *Id.*, 6:36-38.

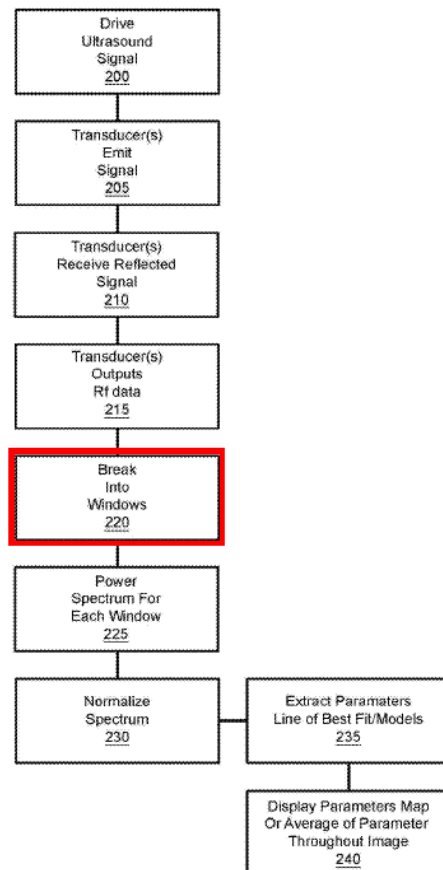


**FIG. 2
(PRIOR ART)**

Id., Fig. 2 (annotated).

Hope-Simpson and Nair confirm that “partitioning the single static set of raw ultrasound RF data into a set of windows or bounding boxes” was known in the art. For example, Hope-Simpson describes the process of partitioning raw RF input data into windows based on a depth of interest. EX1005, Fig. 2. Similarly, Nair describes the process of selecting windows of raw RF data from the acquired ultrasound RF data. EX1006, ¶[0088].

c. 12.2: processing the set of windows to output a power spectrum for each window of the set of windows.

Processing windowed RF data into power spectra was a known process in the art. EX1002, ¶170. Indeed, the 330 Patent admits this as prior art in box 225 of Figure 2, stating that in a conventional system (*e.g.*, in the prior art) after the raw RF data is broken into windows, “the power spectral for each window 225 may be determined....” EX1001, 6:36-39.

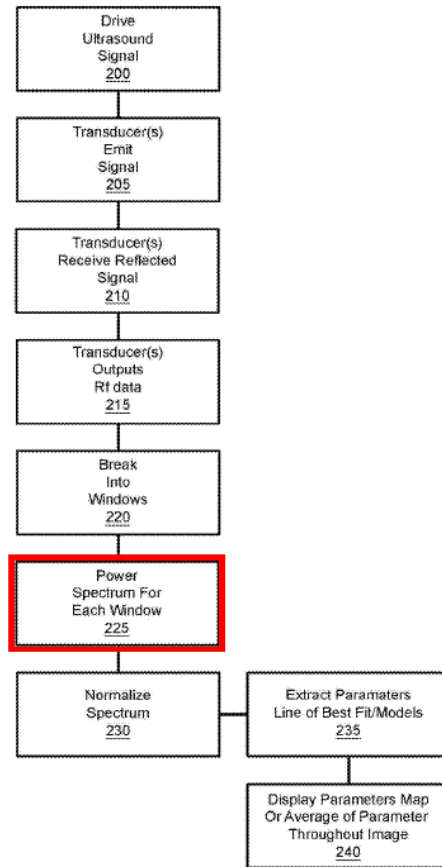


FIG. 2
(PRIOR ART)

Id., Fig. 2 (annotated). For at least the reasons discussed above in Section VII(C)(ii)(c) with respect to Claim 6, it would have been obvious to process the raw ultrasound data of Hope-Simpson into windows and subsequently determine a power spectrum. It further would have been obvious to determine a power spectrum for each window of the set of windows, because that was the typical and conventional way to process data into windows and determine a power spectrum, and was also within the knowledge of a POSA (as shown by the “Admitted Prior Art” of the 330 Patent). EX1002, ¶170.

Because Claim 11 is anticipated by Hope-Simpson, and because Claim 12 adds nothing novel or non-obvious, Claim 12 is obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

vii. Claim 13: The method of claim 12, wherein the step of processing the set of windows comprises processing the set of windows to output a time frequency domain processing technique.

A POSA would have known that it is common in signal processing to take segments of a signal (*e.g.*, windows) and analyze them using a technique that looks at both the time and frequency aspects of the signal. EX1002, ¶175. For example, U.S. Patent Publication No. 2017/0307741 by Ralston (“Ralston”) discloses that “one or more weighting functions may be applied in the time domain and one or more weighting functions may be applied in the frequency domain.” EX1018, Abstract.

Additionally, Hope-Simpson describes a system which uses neural networks to perform traditional physics-based models to derive imaging data. EX1005, ¶[065]. It also describes the same method being used to perform tissue classification. *Id.* These traditional physics-based models would obviously include a system which computes windowed power spectrum data from raw RF data and derives imaging data (*e.g.*, as discussed above with respect to Claim 6). EX1002, ¶175. A person of ordinary skill in the art would understand that a time frequency domain processing technique would be an obvious processing technique to use in computing windowed

power spectrum data from raw RF data. *Id.* For example, a POSA would select a time frequency domain processing technique to analyze a temporally localized version of a signal in the frequency domain. One example of a time frequency domain processing technique is a fast Fourier transform, which, as described above, was well-known and common in the art. *Id.* Indeed, this type of signal processing has been used since as early as at least 1977 and is used for many applications. *See, e.g.,* EX1020, p. 1558. Thus, in view of Hope-Simpson and/or Nair, a POSA would find it obvious to use the method of claim 12 to specifically output a time frequency domain processing technique.

viii. Claim 15: The method of claim 11, wherein the machine learning model is trained using ultrasound images labeled by a radiologist.

As discussed in Section VII(C)(i), Hope-Simpson inherently discloses the use of ultrasound images labeled by a radiologist to train the machine learning model. Hope-Simpson teaches a training algorithm that receives “an array of training inputs and known outputs, wherein the training inputs...[are] associated with a region of imaged tissue and the known outputs comprise known properties of the imaged tissue.” EX1005, Claim 5, ¶¶[010],[069]. Although Hope-Simpson does state that the training inputs may include “training data sets of input and known outputs, for example obtained through conventional ultrasound imaging....” *Id.*, ¶[069]. A POSA would understand that “training data sets of inputs and known outputs...obtained

through conventional ultrasound imaging” would include labeled ultrasound images that were labeled by a radiologist (*e.g.*, to get training inputs associated with a region of imaged tissue). EX1002, ¶¶177-78. Namely, for the same reasons discussed above in Section VII(C)(i), it would have been obvious to have a radiologist in particular label the images for training in order to increase their accuracy. It was known to a POSA that a radiologist would be qualified by virtue of experience and education to perform such labeling, and that the process of preparing and labeling training data for machine learning algorithms has a high impact on the success of a classifying system. *Id.*, ¶177.

Because Claim 11 is anticipated by Hope-Simpson, and because Claim 15 adds nothing novel or non-obvious, Claim 15 is obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

ix. Claim 17: The method of claim 11, wherein the classification is a cancer status of the tissue.

As discussed above in VII(C)(iii), the term “cancer status” may refer to the presence or state of cancerous tissue within a sample. EX1002, ¶180. Both Hope-Simpson and Nair discuss tissue classification. *See, e.g.*, EX1005, ¶[026]; EX1006, [0048] (“The characterization data may include a variety of identifying and/or characterization information, such as...type of tissue [or] the different cell components within the tissue....”). And as discussed above in Section VII(C)(iii)

with respect to Claim 7, it would have been obvious to utilize the combination of Hope-Simpson and Nair to classify the cancer status of tissue.

Claim 11 is anticipated by Hope-Simpson, and the addition of the limitation of Claim 17—that the classification is a cancer status of the tissue—contributes nothing novel or non-obvious in view of Hope-Simpson, Nair, and/or general knowledge within the art at the time of the 330 Patent. Therefore, Claim 17 is obvious in view of Hope-Simpson, Nair, and/or the knowledge of a POSA.

x. Claim 18: The method of claim 11, further comprising outputting a specific multi-parametric biomarker from the machine learning model.

Hope-Simpson discloses a system which uses multiple propagation pathways to result in multiple different pixel data predicting different aspects of the tissue. EX1005, ¶[057]. Nair also describes a system which performs tissue classification using secondary parameters. EX1006, Claims 10-11. The “multiple different pixel data predicting different aspects of the tissue” of Hope-Simpson and the secondary parameters of Nair illustrate that both of these references disclose the output of a multi-parametric biomarker. EX1002, ¶¶183-84. This, in addition to the finding above that Claim 11 is anticipated by Hope-Simpson, establishes that Claim 18 is obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

xi. Claim 19

a. 19.P: Preamble - An ultrasound system comprising:

Whether or not the preamble is limiting, and as discussed in regard to claim 1 above, Hope-Simpson discloses an “Ultrasound Imaging System with a Neural Network for Image Formation and Tissue Characterization.” EX1005, Title. Figures 1, 4, 5, and 6 of Hope-Simpson are also exemplary ultrasound system designs.

b. 19.1: a transducer configured to output a single static set of raw ultrasound [RF] data forming a single frame of a tissue area; and

For the reasons discussed above in Section VII(C)(ii)(b) with respect to Claim 6, a transducer configured to output a single static set of raw ultrasound (RF) data forming a single frame of a tissue area was disclosed in and/or obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA. It further would have at least been obvious to a POSA to have Hope-Simpson output a single static set of raw ultrasound RF data forming a single frame of a tissue area for the reasons discussed above in Section VII(B).

c. 19.2: a signal processing unit operable to:

Hope-Simpson discloses a neural network that may be implemented using a processor (or processing unit), which may be multiple processors arranged in parallel. EX1005, ¶[027], Claim 14. Therefore, Hope-Simpson discloses a signal processing unit.

d. 19.3: receive the single static set of raw ultrasound RF data;

For the reasons discussed above in Section VII(C)(ii)(b) with respect to Claim 6, receiving the single static set of raw ultrasound RF data was disclosed in and/or at least obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

e. 19.4: process the set of single static set of raw ultrasound RF data to determine a raw power spectrum;

For the reasons discussed above in Section VII(C)(ii)(c) with respect to Claim 6, determining a raw power spectrum was at least obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

f. 19.5: process the raw power spectrum as an input to a machine learning model; and

For the reasons discussed above in Section VII(C)(ii)(d) with respect to Claim 6, processing the raw power spectrum as an input to a machine learning model was disclosed in and/or obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA. A POSA would have understood that Claim 19's reference to a "raw power spectrum" is the same thing as Claim 6's reference to a "determined power spectrum," given that in this context the power spectrum is "determined" from the raw RF signal data. EX1002, ¶199. In other words, a POSA would understand "determined power spectrum" to be synonymous with a measured power spectrum,

and measured power spectrum is the same as a raw, unprocessed power spectrum.

Id.

g. 19.6: output a classification of the raw power from an output of the machine learning model.

For the reasons discussed above in Section VII(C)(ii)(e) with respect to Claim 6, outputting a classification of the raw power from an output of the machine learning model was disclosed in and/or obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA. A POSA would have understood that Claim 19's reference to a "classification of the raw power" is the same thing as Claim 6's reference to a "classification of the tissue area," given that in this context the raw power spectrum is dependent on and/or represents the characteristics of the tissue area; therefore a classification of the raw power spectrum is also a classification of the tissue area. EX1002, ¶200.

D. Claim 20: The system of claim 19, further comprising a display, wherein the signal processing unit is operable to display an image representing the set of power spectrum data using a unique identifier based on the output of the machine learning model on the display.

Claim 20 is obvious over Hope-Simpson in view of Nair. For example, as discussed with respect to claim 5, Hope-Simpson describes several embodiments that perform a classification process and display an output image containing tissue classification output from the machine learning model. EX1005, ¶¶[027], [064]. Specifically, Hope-Simpson discloses outputs of the ultrasound system that "may be

graphically represented, with each quantitative value being color-coded.” *Id.*, ¶[070]; *see also* EX1002, ¶203.

Moreover, such a feature is not novel or non-obvious. The use of a display to visualize tissue classification is intuitive to the person of skill in the art—it is necessary. EX1002, ¶202. This visualization is typically in the form of full frame parametric frames or regions overlaid onto conventional ultrasound images. *Id.* Each color in the parametric image is associated with a value in a corresponding color scale. *Id.* Thus, each color on the corresponding color scale is a unique identifier of a particular property of the power spectra. *Id.*

Thus, claim 20 is obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA.

E. Ground 4: Claim 10 is Obvious in View of Hope-Simpson, Nair, and Azizi

i. Claim 10: The method of claim 6, wherein the power spectrum is taken using a discrete FFT.

As discussed above in Section VII(C), claim 6 is obvious in view of Hope-Simpson and Nair and/or the knowledge of a POSA. Nair also discloses the use of various transformation algorithms to produce a power spectrum plot such as a Fourier transformation. EX1006, ¶[0090]. It would have been obvious to a POSA that the “various transformation algorithms” of Nair would include a foundational mathematical concept such as a discrete FFT (DFFT). EX1002, ¶205.

However, to the extent that the combination of Hope-Simpson and Nair do not fully disclose the 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. EX1007, p. 1295-96. Azizi, like Hope-Simpson and Nair, involves the interpretation of raw RF data from an ultrasound system. *Id.* Specifically, Azizi discusses the detection and grading of cancer tissue by using machine learning techniques to interpret ultrasound data. *Id.*, Abstract.

It would have been obvious to a POSA to use Azizi's DFFT with the teachings of Hope-Simpson and Nair, *i.e.*, use a DFFT instead of a continuous FFT, because a DFFT offers several advantages, such as that it can efficiently process sequences of any size, is particularly suited for digital signal processing that uses discretely sampled time inputs (*e.g.*, static windows in this context). EX1002, ¶206. As such, a POSA would understand that it would be obvious in view of Hope-Simpson, Nair, and Azizi to use a DFFT to take the power spectrum.

VIII. THE BOARD SHOULD REACH THE MERITS OF THIS PETITION

A. 35 U.S.C. § 325(d) Does Not Favor Denial of Institution

The Board applies a two-part framework in considering whether to exercise its discretion to deny institution under § 325(d). *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13,

2020) (precedential). Section 325(d) does not apply here because the same or substantially the same prior art and arguments presented in this Petition were not previously presented to the Office.

First, none of Hope-Simpson, Nair, or Azizi were cited in an IDS or otherwise presented to the Office during prosecution, nor were they cited by the examiner. EX1004. Indeed, even if any of these references had been merely cited, none were the basis for a rejection. In closer circumstances, the Board has still declined to exercise its discretion to deny institution. *See, e.g., Celco Partnership v. Huawei Device Co.*, IPR2020-01117, Paper 10 at 13 (P.T.A.B. Feb. 3, 2021) (“[T]he fact that Wen was not the basis of rejection weighs strongly against exercising our discretion to deny institution under 35 U.S.C. § 325(d).”); *Apple Inc. v. Qualcomm Inc.*, IPR2018-01315, Paper 7 at 25 (P.T.A.B. Jan. 18, 2019) (“The fact that neither AAPA nor Majcherczak was the basis of rejection weighs strongly against exercising our discretion to deny under 35 U.S.C. § 325(d)”); *see also Oticon Medical AB v. Cochlear Limited*, IPR2019-00975, Paper 15 at 20 (P.T.A.B. Oct. 16, 2019) (precedential) (declining to exercise its discretion where one prior art reference was new and noncumulative).

Second, the prior art and arguments that were presented to the Examiner are not substantially the same as Hope-Simpson, Nair, or Azizi. For example, as discussed above, Oncoustics distinguished Sadeghi-Naini as being a “process that

depends on pre-processing the RF ultrasound data [and] does not disclose inputting raw ultrasound RF data into the machine learning model as Sadeghi-Naini requires a two stage parameterization of raw data for input in the LDA/machine learning model.” EX1004, p. 186. And in order to distinguish Uniyal, which allegedly “relies on a time series of ultrasound data,” Oncoustics amended the claims “to recite a single static set of ultrasound RF data in a single frame of the tissue area.” EX1004, p. 186-187. Oncoustics argued that “the claims rely on a single [sic] ‘snapshot’ frame of the ultrasound RF data rather than a time series or RF data as disclosed in Uniyal.” EX1004, p. 187.² In contrast, Hope-Simpson (which was not before the Examiner) discloses both of these limitations, while Nair and Azizi (which were also not before the Examiner) disclose additional limitations.

In short, it appears that the Office was simply unaware of the existence of Hope-Simpson, Nair, and Azizi (or anything similar to these references) and was unaware that they disclose each and every limitation of the claims. Since the Petition presents different prior art than the Office was aware of, a discretionary denial of institution is inappropriate here. *See, e.g., Oticon Medical AB*, IPR2019-00975, Paper 15 at 20.

² The only other reference addressed during prosecution, Kallenberg (US 2017/0249739) was cited for disclosure that labeling of ultrasound classifications is performed by a “radiologist.”

B. 35 U.S.C. § 314(a) Does Not Favor Denial of Institution

The decision whether to exercise discretion to deny institution under Section 314(a) is based on “a balanced assessment of all relevant circumstances in the case, including the merits.” P.T.A.B. Consolidated Trial Practice Guide at 58 (Nov. 2019). This case does not involve follow-on petitions, as the present Petition is the only petition for IPR that Petitioner has ever filed relating to the 330 Patent.

Petitioner is not involved in any litigation involving the 330 Patent and is not aware of any co-pending litigation involving the 330 Patent. As such, discretionary denial under § 314(a) fails in view the factors identified in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential), as applied in *CommScope Technologies LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 (P.T.A.B. Fed. 27, 2023) and *OpenSky Indus., LLC v. VLSI Tech. LLC*, IPR2021-01064, Paper 102 at 49 (P.T.A.B. Oct. 4, 2022) (precedential).

C. Other Circumstances

Petitioner diligently filed the present Petition as soon as Petitioner became aware of the 330 Patent and the invalidity thereof. Moreover, Petitioner has established a reasonable likelihood that it will prevail with respect to the challenged claims, with multiple references anticipating or rendering obvious the challenged claims. Where, as here, the merits of the challenges presented in the Petition are strong, this factor favors institution. *See Celco Partnership*, IPR2020-01117, Paper

10 at 26-27. Additionally, the lack of any parallel district court proceedings combined with the strength of Petitioner's showing of unpatentability strongly favor institution of *inter partes* review. *Id.*, Paper 10 at 27.

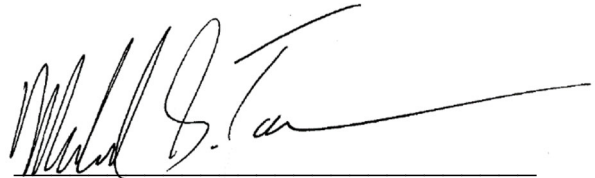
IX. CONCLUSION

Petitioner respectfully requests institution of *inter partes* review of Claims 1-20 of the 330 Patent.

Respectfully submitted,

Dated: November 27, 2024

By:

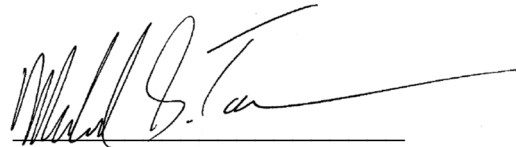
A handwritten signature in black ink, appearing to read "Michael S. Tomsa", written over a horizontal line.

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CERTIFICATE OF WORD COUNT

I hereby certify that this Petition complies with the word count limit of 37 CFR § 42.24. The argument sections of this Petition (Sections I through IX) have a total of 13,627, less than 14,000 words, as measured by Microsoft Word™.

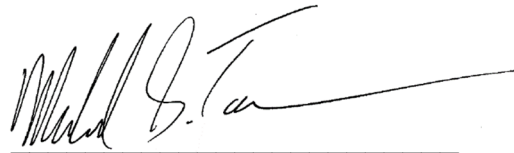
Dated: November 27, 2024

A handwritten signature in black ink, appearing to read 'Michael S. Tomsa', written over a horizontal line.

Michael S. Tomsa
Registration No. 64,264

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 11,602,330 (IPR2025-00242) was served on November 27, 2024, via pre-paid, overnight Express Mail to the correspondence address of record for the subject patent pursuant to 37 C.F.R. § 42.105:

A handwritten signature in black ink, appearing to read 'Michael S. Tomsa', written over a horizontal line.

Michael S. Tomsa
Registration No. 64,264