

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRECISION CANCER TECHNOLOGIES INC.

Petitioner,

v.

ONCOUSTICS INC.,

Patent Owner

Case IPR2024-_____

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

**DECLARATION OF NAUM PAPANICOLAU, PH.D. IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO.
11,602,330**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND AND QUALIFICATIONS.....	1
III.	MATERIALS CONSIDERED	3
IV.	LEGAL UNDERSTANDING.....	4
	A. Anticipation	5
	B. Obviousness.....	6
	C. Claim Construction.....	10
	1. Single Static Set of Raw Ultrasound Radio Frequency (RF) Data Forming a Single Frame.....	10
	2. Output Classification / Outputting a Classification	11
	3. Processing the Single Static Set of Ultrasound RF Data as an Input to a Machine Learning Model.....	11
V.	LEVEL OF ORDINARY SKILL IN THE ART.....	12
VI.	THE 330 PATENT	13
	A. The 330 Patent (Ex. 1001).....	13
	B. Prosecution History of the 330 Patent (Ex. 1004)	20
VII.	PRIOR ART	33
	A. World Publication No. WO 2018/127498 A1 (Exhibit 1005)	33
	B. U.S. Patent Publication No. 2014/0180273 (Exhibit 1006).....	33
	C. “Detection and Grading of Prostate Cancer Using Temporal Enhanced Ultrasound: Combining Deep Neural Networks and Tissue Mimicking Simulations” (Exhibit 1007)	34
VIII.	SUMMARY OF OPINIONS.....	35
IX.	GROUND 1: HOPE-SIMPSON ANTICIPATES CLAIMS 1, 2, 4, 5, 11, 14, AND 16.....	36
	A. Independent Claim 1	36
	1. 1.P: Preamble - An ultrasound system.....	36

2.	1.1: a transducer configured to output a single static set of raw ultrasound [RF] data forming a single frame of a tissue area	42
3.	1.2: a memory containing machine readable medium comprising machine executable code having stored thereon instructions	44
4.	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 the cause the one or more processors to.....	45
5.	1.4: receive the single static set of raw ultrasound RF data	46
6.	1.5: process the single static set of raw RF ultrasound data with a machine learning model.....	50
7.	1.6: output classification of the raw RF ultrasound data from an output of the machine learning model	52
B.	Dependent Claims 2, 4, and 5	53
C.	Independent Claim 11	56
1.	11.P: Preamble - A method.....	57
2.	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.....	57
3.	11.2: processing the single static set of ultrasound RF data as an input to a machine learning model	61
4.	11.3: outputting a classification of the tissue area from the machine learning model	63
D.	Dependent Claims 14 and 16	64
X.	GROUND 2: HOPE-SIMPSON IN VIEW OF THE KNOWLEDGE OF A POSA RENDERS OBVIOUS CLAIMS 1, 2, 4, 5, 11, 14, AND 16 OF THE 330 PATENT	65
XI.	GROUND 3: HOPE-SIMPSON SMD NAIR RENDER OBVIOUS CLAIMS 3, 6-9, 12, 13, 15, AND 17-20 OF THE 330 PATENT	71
A.	Dependent Claim 3	71

B.	Independent Claim 6	72
1.	6.P: Preamble - A method.....	73
2.	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	73
3.	6.2: processing the single static set of raw ultrasound RF data set of windows to determine a power spectrum	77
4.	6.3: processing the determined power spectrum as an input into a machine learning model	80
5.	6.4: outputting a classification of the tissue area from the machine learning model	81
C.	Dependent Claims 7-9, 12, 13, 15, 17, and 18.....	82
D.	Independent Claim 19	93
1.	19.P: Preamble - An ultrasound system comprising:.....	94
2.	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.....	94
3.	19.2: a signal processing unit operable to:.....	95
4.	19.3: receive the single static set of raw ultrasound RF data; 96	
5.	19.4: process the set of single static set of raw ultrasound RF data to determine a raw power spectrum.....	99
6.	19.5: process the raw power spectrum as an input to a machine learning model; and	100
7.	19.6: “output a classification of the raw power from an output of the machine learning model.....	100
E.	Dependent Claim 20.....	101
XII.	GROUND 4: HOPE-SIMPSON IN VIEW OF NAIR IN FURTHER VIEW OF AZIZI RENDERS OBVIOUS DEPENDENT CLAIM 10 OF THE 330 PATENT	102
A.	Dependent Claim 10.....	103
XIII.	CONCLUSION	104

Declaration of Naum Papanicolau, Ph.D. in Support of
Petition for Inter Partes Review of U.S. Patent No. 11,602,330

I, Naum Papanicolau, declare as follows:

I. INTRODUCTION

1. I have been retained in this matter by McAndrews, Held & Malloy, Ltd. on behalf of Precision Cancer Technologies Inc. (“PCT”) to provide technical assistance in the *inter partes* review (“IPR”) of certain claims of U.S. Patent No. 11,602,330 (“the 330 Patent”). The 330 Patent is generally directed to an ultrasound system for classification and identification of various physiological aspects of a living organism using a machine learning model.

2. I understand that Petitioner PCT petitions for *inter partes* review of the 330 Patent and requests that the Patent Trial and Appeal Board (“Board”) cancel Claims 1-20 of the 330 Patent. I further understand that the 330 Patent is purportedly owned by Oncoustics Inc. (“Oncoustics”).

3. This declaration is a statement of my opinions on issues related to the unpatentability of certain claims of the 330 Patent.

II. BACKGROUND AND QUALIFICATIONS

4. In forming my opinions, I relied upon my education, knowledge, and experience and considered the level of ordinary skill in the art as discussed below. A copy of my current *curriculum vitae* is submitted herewith (Ex. 1003), and it provides a comprehensive description of my academic and employment history along with peer-reviewed journal articles that I have authored. I am being

compensated for my time in connection with this matter at my standard consulting rate, which is \$300 Canadian per hour, plus actual expenses. My compensation is not dependent in any way upon the outcome of this matter.

5. I earned my Ph.D. in Computer Science from Ryerson University in 2018, following an M.Sc. in Computer and Electrical Engineering in 2009 and a B.Sc. in Computer Science in 2006, both from Ryerson University. My graduate research, completed in collaboration with Sunnybrook Research Institute, focused on developing spectral computational models to detect cell death induced by cancer treatments using conventional frequency ultrasound.

6. Throughout my studies and work experience, I designed and conducted pre-clinical experiments in various in vitro and in vivo models and oversaw all phases of a clinical trial—from initiation and recruitment to ultrasound data collection, application, processing, and implementation. My research in ultrasound analysis techniques and algorithm design led to four software-related invention disclosures. With over a decade of experience conducting pre-clinical and clinical studies in a biophysics laboratory, I have developed numerous unique software platforms for quantitative ultrasound analysis of ultrasound radiofrequency and spectral data. In fact, as set forth in my CV, I am a named inventor on a patent directed to quantitative-ultrasound (QUS) system for characterizing a specimen. My work extends to pre-clinical and commercial medical device development,

particularly in ultrasound and ophthalmic imaging applications.

III. MATERIALS CONSIDERED

7. In preparing this Declaration, I have reviewed the 330 Patent and considered the following documents in light of the general knowledge in the relevant art.

Exhibit	Description
1001	U.S. Patent No. 11,602,330 (“the 330 Patent”)
1002	Declaration of Dr. Naum Papanicolau, Ph.D.
1003	Curriculum Vitae of Dr. Naum Papanicolau, Ph.D.
1004	Prosecution History of U.S. Patent No. 11,602,330
1005	PCT Publication No. WO 2018/127498 A1 (“Hope-Simpson”)
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

Declaration of Naum Papanicolau, Ph.D. in Support of
Petition for Inter Partes Review of U.S. Patent No. 11,602,330

Exhibit	Description
	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”)

IV. LEGAL UNDERSTANDING

8. I am not an attorney, and I render no opinions on the law itself. My opinions are informed by my understanding of the relevant law as has been provided to me by counsel. I understand that the patentability analysis is conducted on a claim-by-claim and element-by-element basis, and that there are several possible reasons that a patent claim can be found to be unpatentable.

9. I understand that earlier patents and publications may render a patent unpatentable as anticipated under 35 U.S.C. § 102 or obvious under 35 U.S.C. §

103.¹

A. Anticipation

10. I understand that a patent claim is unpatentable and invalid if the claim is “anticipated” by the prior art. I understand that a claimed invention is not novel or is anticipated if:

(i) the invention was known or used by others in this country, or was patented or described in a printed publication in this or a foreign country, before the invention by the patent applicant;

(ii) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States; or

(iii) the invention was described in a published patent application by another filed in the United States before the invention by the applicant for patent; or

(iv) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the Patent Cooperation

¹ I understand from counsel that this proceeding is limited to issues of invalidity under 35 U.S.C. §§ 102 (anticipation) and 103 (obviousness). Thus, I have not performed any analysis of whether the claims of the 330 Patent are supported by and/enabled by the disclosure of the specification. My opinions should not be seen as an admission that the claims of the 330 Patent satisfy the requirements of 35 U.S.C. § 112.

Treaty shall serve as prior art only if the international application designated the United States and was published under the treaty in the English language.

11. I understand that anticipation occurs when a single piece of prior art describes every element of the claimed invention, either expressly or inherently, arranged in the same way as in the claim. I understand that, for inherent anticipation, it is required that the missing descriptive material is necessarily present in the prior art.

B. Obviousness

12. I further understand that a patent claim is unpatentable and invalid if the subject matter of the claim as a whole would have been obvious to a person of ordinary skill in the art (“POSA”) of the claimed subject matter as of the time of the invention at issue. I understand that obviousness may be shown by considering more than one item of prior art and/or the knowledge of a POSA.

13. I understand that the following factors should be evaluated to determine whether the claimed subject matter is obvious: (1) the scope and content of the prior art; (2) the difference or differences, if any, between each claim of the patent and the prior art; (3) the level of ordinary skill in the art at the time the patent was filed; and (4) objective evidence of non-obviousness, also referred to as secondary considerations (described below).

14. I understand that a prior art reference is proper to use in an obviousness

analysis if the prior art is analogous art to the claimed invention. I understand that a prior art reference is analogous art if at least one of the following two considerations is met: (1) the prior art reference is from the same field of endeavor as the claimed invention, even if the prior art reference addresses a different problem and/or arrives at a different solution; and/or (2) the prior art reference is reasonably pertinent to the problem faced by the inventor, even if it is not in the same field of endeavor as the claimed invention.

15. I understand that it must be shown that a POSA at the time of the invention would have had a reasonable expectation that a modification or combination of one or more prior art references would have succeeded. I further understand that a claim may be obvious in view of a single prior art reference, without the need to combine references, if the elements of the claim that are not found in the reference can be supplied by the knowledge or common sense of one of ordinary skill in the relevant art.

16. I also understand that there should be a reason, suggestion, or motivation in the prior art that would lead a POSA to combine the prior art references, and that would also suggest a reasonable likelihood of success. The reasons for combining references stem (explicitly or implicitly) from, for example: (a) the prior art references themselves; (b) the prior art as a whole; (c) the knowledge, common sense, and creativity of those of ordinary skill in the art; (d) the nature of

the problem to be solved; (e) the demands in the design community and/or the market place; (f) the simple and predictable substitution of one known element for another in accordance with their known functions; (g) the application of a known technique or method to a piece of prior art ready for improvement; (h) the obviousness of trying the combination; and/or (i) the general needs and problems in the field. For example, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a POSA has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. I also understand that, if a technique has been used to improve one device, and a POSA would recognize that it would improve similar devices in the same way, using the technique is obvious unless its application is beyond his or her skill.

17. I understand that so-called “objective indicia of non-obviousness,” also known as “secondary considerations,” are also to be considered when assessing obviousness, if present. These include commercial success; long-felt but unresolved need; failure of others to solve the problem that the inventor solved; unexpected results; copying of the invention by others; and industry recognition or expressions of disbelief by experts in the field of the claimed invention. I also understand that a nexus, i.e., a tie, must exist between objective indicia of non-obviousness and the novel aspects of the claimed subject matter. I understand from counsel that the Patent

Owner bears the burden of showing the existence and effect of secondary considerations of non-obviousness, after which the burden of coming forward with rebuttal evidence shifts to Petitioner.

18. I understand that the test of obviousness is whether the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art as of the date of the invention in light of the prior art. I understand that the use of hindsight must be avoided when considering whether the alleged invention would have been obvious to the POSA.

19. I understand that in determining obviousness, the POSA is a person of ordinary creativity, not an automaton. I understand that, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a POSA has good reason to pursue the known options within his or her technical grasp.

20. I understand that a dependent claim incorporates each and every limitation of the independent claim from which it depends. Thus, I understand that if a prior art reference fails to anticipate an independent claim, then that prior art also necessarily fails to anticipate all dependent claims that depend from the independent claim. Similarly, I understand that if a prior art reference or combination of prior art reference fails to render obvious an independent claim, then that prior art reference or combination of prior art references also necessarily fails to render obvious all

dependent claims that depend from that independent claim.

C. Claim Construction

21. I understand that “claim construction” is the interpretation of the meaning of patent claims. I understand that claims in this *inter partes* review proceeding are generally given their ordinary and customary meaning, which is the meaning they would have to a POSA at the time of the invention, in light of the specification and file history.

22. I understand that many sources can be used to assist in understanding the meaning of a claim including the claims themselves, the specification, the prosecution history, and extrinsic evidence concerning scientific principles, the meaning of technical terms, and the state of the art.

23. I have been asked to review the claims and ascertain the meaning of the claims from the perspective of one of ordinary skill in the art. My opinions on claim construction expressed in this declaration are from the perspective of a POSA as of December 12, 2017, the earliest priority date of the 330 Patent, and are consistent with my understanding as stated above with regards to this *inter partes* review.

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

24. 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 ultrasound radio frequency (RF) data that is not pre-processed, forming a single frame.” *See* EX1004, pp. 186-87; *see also id.*, pp. 181-184, 191. A POSA would understand “raw ultrasound radio frequency (RF) data” to mean “ultrasound radio frequency (RF) data that is not pre-processed.”

2. Output Classification / Outputting a Classification

25. 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.” *See id.*, p. 187; *see also id.*, pp. 181-184, 186, 191.

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

26. 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. In addition, as discussed in more detail below, Patent Owner distinguished a reference cited by the Examiner during prosecution of the 330 Patent by explaining that, in contrast to the claimed subject matter, the cited reference disclosed a “process that *depend[ed] on pre-processing the RF ultrasound data*” and did “not disclose inputting *raw* ultrasound RF data into the machine learning model.” EX1004, p. 186.

V. LEVEL OF ORDINARY SKILL IN THE ART

27. I have been asked to analyze the 330 Patent and the references discussed herein from the perspective of a POSA at the time of invention. I understand that, for purposes of this *inter partes* review, the time of invention is assumed to be the 330 Patent’s earliest priority date, which is December 12, 2017.

28. I understand that a POSA of the 330 Patent is a hypothetical person who is presumed to be aware of pertinent art including knowledge in the art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. I understand that this hypothetical POSA is considered to have the normal skills and knowledge of a person in the technical field. I understand that factors that may be considered in determining the level of ordinary skill in the art include: (1) the education level of the inventor; (2) the types of problems encountered in the art; (3) the prior art

solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the education level of active workers in the field.

29. In my opinion, a POSA relating to the subject matter of the 330 Patent would be an individual having 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.

30. I believe that I am qualified to provide opinions about how one of ordinary skill in the art on December 12, 2017, would have interpreted and understood the 330 Patent and the prior art relied upon by the Petitioners.

VI. THE 330 PATENT

A. The 330 Patent (Ex. 1001)

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

32. The 330 Patent explains that “[c]onventional ultrasound spectroscopy uses ultrasound frequency spectrums from ultrasound RF data (raw sound signal as it returns into 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 uses “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.

33. Fig. 3 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. *See id.*, Fig. 2.

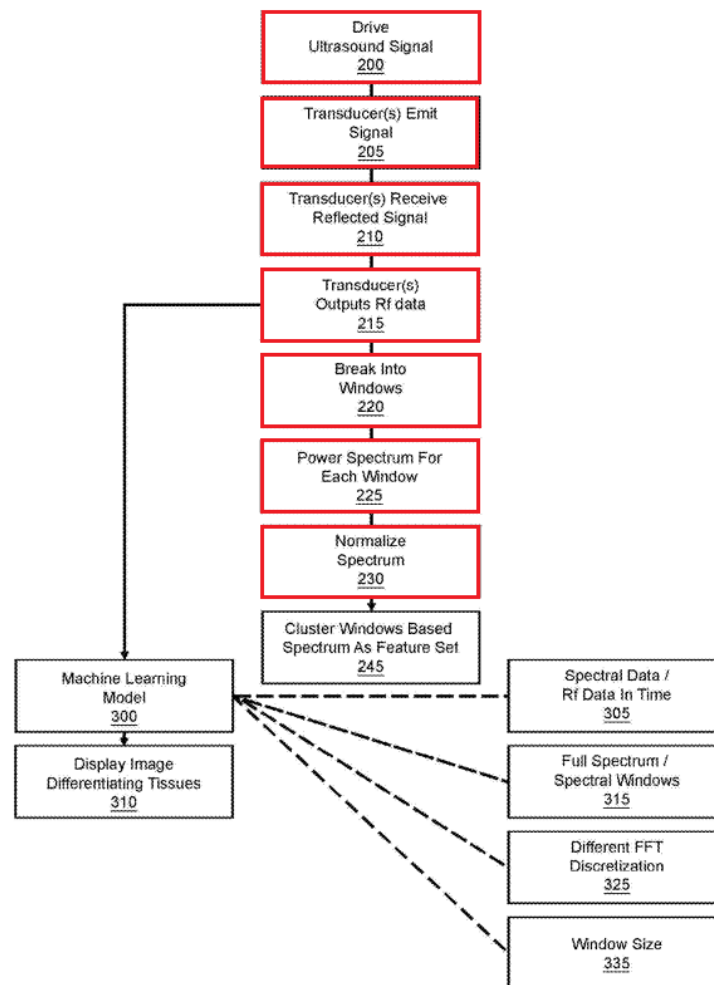


FIG. 3

EX1001, Fig. 3 (annotated).

34. In the claimed embodiments, a signal processing unit uses one or more processors to “receive [and] process the single static set of raw RF ultrasound data with a machine learning model.” *Id.*, 15:13-15.

35. The 330 Patent includes four independent claims and sixteen dependent claims.

36. **Claim 1** recites:

An ultrasound system comprising:

- a transducer configured to output a single static set of raw ultrasound radio frequency (RF) data forming a single frame of a tissue area;

- a memory containing machine readable medium comprising machine executable code having stored thereon instructions;

- 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 cause the one or more processors to:

 - receive the single static set of raw ultrasound RF data;

 - process the single static set of raw RF ultrasound data with a machine learning model; and

 - output classification of the raw RF ultrasound data from an output of the machine learning model.

37. **Claim 6** is directed to a method of receiving the RF data, processing it into a set of windows, determining a power spectrum, and using a machine learning model to output a classification based on that power spectrum:

A method comprising:

- 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;

- processing the single static set of raw ultrasound RF data set of windows to determine a power spectrum;

- processing the determined power spectrum as an input into a machine learning model; and

- outputting a classification of the tissue area from the machine learning model.

38. **Claim 11** recites a similar method to claim 6, but omits the steps of forming windows and determining a power spectrum for the set of RF data. Instead, the method of claim 11 discloses feeding the single static set of ultrasound RF data directly into the machine learning model:

A method comprising:

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;

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

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

39. **Claim 19** is similar to claim 1, but, similar to how claim 6 differs from claim 11, claim 19 discloses using the raw ultrasound RF data to determine a raw power spectrum and inputting that raw power spectrum into the machine learning model, whereas claim 1 discloses processing the raw ultrasound RF data directly *with* the machine learning model. Claim 19 reads:

An ultrasound system comprising:

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

a signal processing unit operable to:

receive the single static set of raw ultrasound RF data

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

process the raw power spectrum as an input to a machine learning model; and

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

40. Dependent claims 2 and 14 depend from claims 1 and 11, respectively, and add the claim element:

[W]herein 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).²

41. Dependent claims 3 and 15 depend from claims 1 and 11, respectively, and add the claim element “wherein the machine learning model is trained using ultrasound images labeled by a radiologist.”

42. Dependent claims 4 and 16 depend from claims 1 and 11, respectively, and add the claim element “wherein the machine learning model is an unsupervised model.”

43. Dependent claims 5 and 20 depend from claims 1 and 19, respectively. Claim 5 adds the element “wherein the processor is operable to display an image

² Claim 2 includes the underlined term “but not limited to,” while claim 14 does not. This is the only difference in the limitations that these claims add.

representing the set of ultrasound data using a unique identifier based on the output of the machine learning model.” Claim 20 adds the similar, but not identical, element “further comprising a display, wherein the signal processing unit is operable to display an image representing the raw power spectrum data using a unique identifier based on the output of the machine learning model on the display.”³

44. Dependent claims 7 and 17 depend from claims 6 and 11, respectively, and add the element “wherein the classification is a cancer status of the tissue.”

45. Claim 8 depends from claim 6 and adds the element “wherein the method further comprises processing the power spectrum to determine a normalized power spectrum.”

46. Claim 9 depends from claim 6 and adds the element “wherein the power spectrum is taken using a continuous Fast Fourier Transform (FFT).”

47. Claim 10 depends from claim 6 and adds the element “wherein the power spectrum is taken using a discrete FFT.”

48. Claim 12 depends from claim 11 and adds steps of partitioning the RF data into windows and processing those windows to output a power spectrum:

...further comprising:

partitioning the single static set of raw ultrasound RF data into a set of windows or bounding boxes; and

³ The underlined portions indicate the differences between claim 20 and claim 5.

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

49. Claim 13 depends from claim 12, and ultimately claim 11, and adds the limitation “wherein the step of processing the set of windows comprising processing the set of windows to output a time frequency domain processing technique.”

50. Claim 18 depends from claim 11 and adds the limitation “further comprising outputting a specific multi-parametric biomarker from the machine learning tool.”

B. Prosecution History of the 330 Patent (Ex. 1004)

51. On June 12, 2020, Ahmed El Kaffas and Oncoustics, Inc. (“Patent Owner” or “Applicant”) filed U.S. Patent Application No. 16/772,304 (“Application”) as a 371 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. Originally, the Application contained 12 claims. Original claims 1, 5, and 10 were independent, and original claims 2-4, 6-9, and 11-12 depended from claims 1, 5, and 10, respectively.

52. The original claims in the Application differ from the claims that eventually issued with the 330 Patent in several ways, which will be addressed below. The original independent claims read:

Original Claim 1:

An ultrasound system comprising:

a transducer configured to output a set of ultrasound data;

a memory containing machine readable medium comprising machine executable code having stored thereon instructions;

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 cause the one or more processors to:

receive the set of ultrasound data and partition the set of ultrasound data into a set of windows;

process the set of windows to determine a power spectrum for each window of the set of windows;

process the power spectrum for each window of the set of windows to determine a normalized power spectrum for each window of the set of windows; and

process the normalized power spectrum for each window of the set of windows with a machine learning model; and

display an image where each window of the set of windows is displayed using a unique identifier based on the output of the machine learning model.

Original Claim 5:

A method comprising:

receiving a set of ultrasound data output from at least one ultrasound transducer representing a tissue of a patient and partitioning the set of ultrasound data into a set of windows or bounding boxes;

processing the set of windows to determine a power spectrum for each window of the set of windows;

processing the power spectrum for each window of the set of windows with a machine learning model; and

outputting a classification of the tissue.

Original Claim 10:

A method comprising:

receiving a set of ultrasound data output from at least one ultrasound transducer representing a tissue of a patient and partitioning the set of ultrasound data into a set of windows;

processing the set of windows with a machine learning model; and

outputting a classification of the tissue.

EX1004, pp. 51-52.

53. The original dependent claims bore limitations similar to those in the dependent claims of the 330 Patent. Original claim 2 depends from original claim 1 and specifies different types of machine learning models that can be used, this is similar to claims 2 and 14 of the 330 Patent. Original claim 3 depends from original claim 1 and discusses training the machine learning model using ultrasound images labeled by a radiologist, this is similar to claims 3 and 15 of the 330 Patent. Original claim 4 depends from original claim 1 and limits the machine learning model to an unsupervised model, identical to the limitation of claims 4 and 16 of the 330 Patent.

54. Original claim 6 depends from original claim 5 and limits the

classification to the cancer status of a tissue, identical to claims 7 and 17 of the 330 Patent. Original claim 7 depends from original claim 5 and discloses the further step of “processing the power spectrum for each window of the set of windows to determine a normalized power spectrum for each window of the set of windows.” This is similar to claim 8 of the 330 Patent, although it was amended substantially during prosecution as will be discussed below. Original claim 8 depends from original claim 5 and specifies that the power spectrum of original claim 5 is taken using a continuous Fast Fourier Transform (FFT). This is identical to claim 9 of the 330 Patent. Original claim 9 depends from original claim 5 and specifies that the power spectrum of original claim 5 is taken using a discrete FFT. This is identical to claim 10 of the 330 Patent.

55. Original claim 11 depends from original claim 10 and adds “wherein the step of processing the set of windows with a machine learning model first comprises processing the set of windows to output a power spectrum for each window of the set of windows.” This was later incorporated as an element of claim 12 of the 330 Patent. Original claim 12 depends from original claim 10 and adds “wherein the step of processing the set of windows with a machine learning model first comprises processing the set of windows to output a time frequency domain processing technique.” This is similar to claim 13 of the 330 Patent.

56. On August 28, 2020, Applicant filed an Information Disclosure

Statement (IDS) citing U.S. Patent No. 6,238,342 (“Feleppa 342”) and U.S. Patent Publication No. 2016/0238568 (“Feleppa 568”) for consideration by the Examiner. EX1004, p. 113.

57. Feleppa 342 issued on May 29, 2001, and is titled “Ultrasonic Tissue-type Classification and Imaging Methods and Apparatus.” It generally discloses methods and apparatus for classifying tissue-type in accordance with spectral and clinical data.

58. Feleppa 568 was published on August 18, 2016, and is titled “Typing and Imaging of Biological and Non-biological Materials Using Quantitative Ultrasound.” It generally discloses improved typing and imaging of biological and non-biological materials by combining quantitative-ultrasound (QUS) estimates based on the statistics of the envelope of echo signals generated using pulse-echo ultrasound with QUS estimates based on the normalized power spectra of echo signals generated using pulse-echo ultrasound and global variables associated with the material of interest.

59. On June 21, 2022, the Examiner issued a non-final rejection, rejecting claims 1-2 and 5-12 under 35 U.S.C. § 102 as anticipated by U.S. Patent Publication No. 2016/0120502 (“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 (“Kallenberg”). *Id.*, pp. 132-138.

60. Sadeghi-Naini, titled “System and Method for Classifying and Characterizing Tissues Using First-Order and Second-Order Statistics of Quantitative Ultrasound Parametric Maps,” published on May 5, 2016, and generally relates to systems and methods of classifying and characterizing tissues as being associated with a particular histological state using QUS. Kallenberg, titled “Computer Analysis of Mammograms,” was published on August 31, 2017, and generally relates to an improved method of analyzing mammograms to screen for breast cancer.

61. In the rejection, the Examiner stated that Sadeghi-Naini teaches each element of original claims 1-2 and 5-12. *Id.*, pp. 132-136. The Examiner stated that Sadeghi-Naini may not fully anticipate original claims 3 and 4 because, in regard to original claim 3, “Sadeghi-Naini does not appear to explicitly teach that the labeling is performed by a radiologist.” *Id.*, p. 137. Regarding claim 4, the Examiner stated that Sadeghi-Naini “does not appear to explicitly teach that the machine learning model is an unsupervised model.” *Id.*, p. 138. The Examiner then cited Kallenberg as teaching both of these limitations; “Pertaining to the same field of endeavor, Kallenberg teaches that the labeling is performed by a radiologist (Kallenberg ¶0080: ‘A trained radiologist annotated the skin-air boundary and the pectoral muscle by a polygon tool ...’).” *Id.*, p. 137. For original claim 4, “Kallenberg teaches that the machine learning model is an unsupervised model (Kallenberg ¶0050: ‘The

features can also be learned in an unsupervised way, e.g. using Restricted Boltzmann Machine...’).” *Id.*, p. 138.

62. The Examiner further stated:

It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have modified the system and method for classifying and characterizing tissue using quantitative ultrasound parametric maps (as taught by Sadeghi-Naini) to use radiologist-labeled data for training (as taught by Kallenberg) because the combination allows the use of autoencoders (Kallenberg ¶0066).

Id., p. 138.

63. On October 20, 2022, the Applicant held an interview with the Examiner to discuss the § 102 rejections in view of Sadeghi-Naini. The Applicant summarized this interview in their response to the Office Action which was filed the next day:

The undersigned expresses appreciation for the telephone interview conducted with the Examiner and inventor Ahmed Al-Kaffas on Oct. 20, 2022. The Sadeghi-Naini reference was discussed as well as the Uniyal reference sent by the Examiner. The Examiner agreed that the proposed claim amendments distinguished over the Sadeghi-Naini reference. The Examiner indicated a new search would be conducted. Applicants agreed to further amend the claims to distinguish the Uniyal reference and submit further written arguments.

Id., p. 164. The Examiner’s summary of the interview was:

The proposed amendment has been discussed. A new prior art reference (Uniyal et al.) appears to teach the amended limitations. Inventor noted that Uniyal uses a time series US data whereas the invention uses images that are non-coherent in time (e.g., a static frame). Inventor further noted that Uniyal performs parameterization, but is not required in the invention. The 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.”)

Id., p. 191.

64. Uniyal, the new reference discussed above, is an article titled “Ultrasound RF Time Series for Classification of Breast Lesions.” IEEE TRANSACTIONS ON MEDICAL IMAGING, Vol. 34, No. 2, February 2015.

65. The claim amendments which overcame Sadeghi-Naini and Uniyal are summarized below:

Declaration of Naum Papanicolau, Ph.D. in Support of
Petition for Inter Partes Review of U.S. Patent No. 11,602,330

1. (Currently Amended) An ultrasound system comprising:
 - a transducer configured to output a single static set of raw ultrasound radio frequency (RF) data from a tissue area;
 - a memory containing machine readable medium comprising machine executable code having stored thereon instructions;
 - 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 cause the one or more processors to:
 - receive the single static set of raw ultrasound RF data ~~and partition the set of ultrasound data into a set of windows;~~
 - ~~process the set of windows to determine a power spectrum for each window of the set of windows;~~
 - ~~process the power spectrum for each window of the set of windows to determine a normalized power spectrum for each window of the set of windows; and~~
 - process the single static set of raw RF ultrasound data ~~normalized power spectrum for each window of the set of windows~~ with a machine learning model; and
 - output classification of the raw RF ultrasound data from an output of the machine learning model.
2. (Currently Amended) 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).

Declaration of Naum Papanicolau, Ph.D. in Support of
Petition for Inter Partes Review of U.S. Patent No. 11,602,330

5. (Currently Amended) A method comprising:

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 representing a tissue area of a patient ~~and partitioning the set of ultrasound data into a set of windows or bounding boxes;~~

processing the single static set of raw ultrasound RF data ~~set of windows~~ to determine a power spectrum ~~for each window of the set of windows;~~

processing the determined power spectrum as an input into ~~for each window of the set of windows~~ with a machine learning model; and

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

7. (Currently Amended) The method of claim 5, wherein the method further comprises processing the power spectrum ~~for each window of the set of windows~~ to determine a normalized power spectrum ~~for each window of the set of windows.~~

10. (Currently Amended) A method comprising:

receiving a single static set of raw ultrasound radio frequency (RF) data output from at least one ultrasound transducer representing a tissue area of a patient ~~and partitioning the set of ultrasound data into a set of windows;~~

processing the single static set of ultrasound RF data as an input to ~~set of windows~~ with a machine learning model; and

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

Declaration of Naum Papanicolau, Ph.D. in Support of
Petition for Inter Partes Review of U.S. Patent No. 11,602,330

11. (Currently Amended) The method of claim 10, ~~wherein the step of processing the set of windows with a machine learning model first comprises~~ 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.

12. (Currently Amended) The method of claim ~~11~~ 40, wherein the step of processing the set of windows ~~with a machine learning model first comprises~~ processing the set of windows to output a time frequency domain processing technique.

EX1004, pp. 160-162. The claims not shown above (original claims 3, 4, 6, 8, and 9) were not amended.

66. In its response, the Applicant also added eight new claims. Claim 13 depended from claim 10 and reflected the amended language of claim 2. Claim 14 depended from claim 10 and reflected the language of claim 3. Claim 15 depended from claim 10 and reflected the language of claim 4. Claim 16 depended from claim 10 and reflected the language of claim 6. Claim 17 depended from claim 10 and added the limitation “further comprising outputting a specific multi-parametric biomarker from the machine learning model.” Claim 18 depended from claim 1 and added the limitation “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.” Claim 19 was a new independent claim, stating:

An ultrasound system comprising:

a transducer configured to output a single static set of raw ultrasound radio frequency (RF) data from a tissue area; and

a signal processing unit operable to:

receive the single static set of raw ultrasound RF data

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

process the raw power spectrum as an input to a machine learning model; and

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

Id., p. 163. Claim 20 depended from claim 19 and adds the limitation “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. *Id.*, p. 163.

67. The Applicant described its amendments, listed above, as:

Claims 1, 5, and 10 have been amended to recite that the transducer is “configured to output a single static set of raw ultrasound radio frequency (RF) data from a tissue area.” Support for the amendments may be found in at least paragraphs 45, 54, and 56 of the printed publication. Claims 1 and 10 have been further amended to recite that the machine learning model processes the single static set of raw RF ultrasound data. Claim 5 has been amended to recite that a power spectrum is determined from the raw ultrasound RF data and the power spectrum is input into the machine learning model. Support for these amendments may be found in at least paragraph 45 of the printed publication.

Id., p. 165.

68. According to the Applicant, these amendments overcame the §§ 102 and 103 rejections because “Sadeghi-Naini 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.* The Applicant further asserted that “Sadeghi-Naini requires determination of mapped parameters and further processing as an input to the machine learning/LNA. Sadeghi-Naini does not disclose inputting raw RF data from the ultrasonic transducer or a power spectrum derived from the raw RF data as an input to the machine learning model as now required by claims 1, 5, and 10.” *Id.* (emphasis added).

69. In response to the newly cited Uniyal reference, which “relies on a time series of ultrasound data,” the Applicant stated “[i]n order to distinguish Uniyal, the claims have been amended to recite **a single static set of ultrasound RF data**. As explained in the Interview, the claims rely on a snapshot of the ultrasound RF data rather than a time series. Applicant respectfully submits the amended claims are allowable over all of [sic] the cited reference.” *Id.*, pp. 165-166 (emphasis added).

70. Following these amendments, the claims were allowed on November 10, 2022. *Id.*, p. 196. The Examiner noted in the allowance that:

The prior art of record teaches that it was known at the time the application was filed to process the raw ultrasound radiofrequency timeseries data with a machine learning model, e.g., SVM, to classify malignant vs. breast lesions.

However, the prior art, alone or in combination, does not appear to suggest that **a single static set of raw ultrasound radiofrequency data is processed with a machine learning model to output the classification results.**

Id., p. 201 (emphasis added).

VII. PRIOR ART

A. World Publication No. WO 2018/127498 A1 (Exhibit 1005)

71. World Publication No. WO 2018/127498 A1 (“Hope-Simpson”), entitled “Ultrasound Imaging System with a Neural Network for Image Formation and Tissue Characterization,” is directed to an ultrasound system and methods for obtaining ultrasonic images and/or tissue information using a neural network. EX1005, ¶[001]. In particular, Hope-Simpson discloses a system which utilizes a machine-trained neural network developed through one or more machine learning algorithms to output image data and/or a variety of tissue information. *Id.*, ¶[005]. Hope-Simpson was 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).

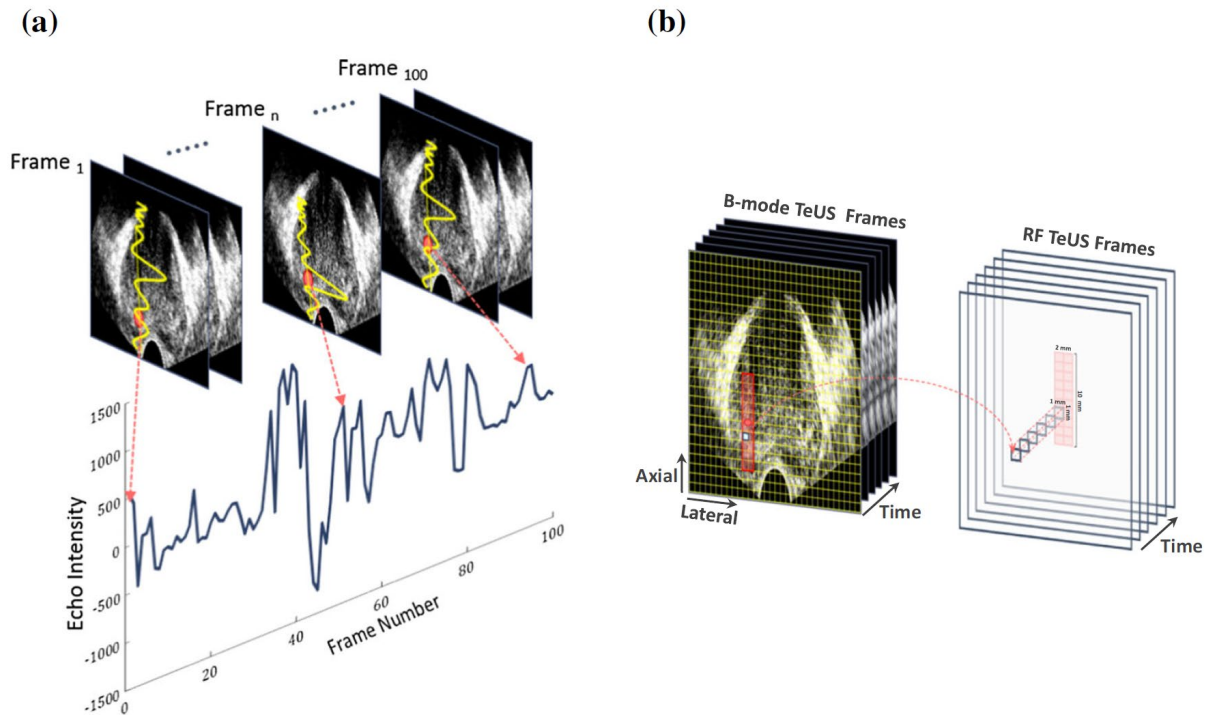
B. U.S. Patent Publication No. 2014/0180273 (Exhibit 1006)

72. U.S. Patent Publication No. 2014/0180273 (“Nair”), entitled “Device, System, and Method for Imaging and Tissue Characterization of Ablated Tissue,” is directed to tissue ablation procedures and imaging with tissue characterization to guide the ablation therapy. EX1006, ¶[0002]. In particular, Nair discloses a system and method for performing an ablation procedure on a patient’s tissue while utilizing

active tissue characterization to at least in part guide the ablation therapy. *Id.*, ¶[0009]. Nair was published on June 26, 2014 and claims priority to U.S. Provisional Application No. 61/745,476 (December 21, 2012).

C. “Detection and Grading of Prostate Cancer Using Temporal Enhanced Ultrasound: Combining Deep Neural Networks and Tissue Mimicking Simulations” (Exhibit 1007)

73. “Detection and Grading of Prostate Cancer Using Temporal Enhanced Ultrasound: Combining Deep Neural Networks and Tissue Mimicking Simulations” (“Azizi”) was written by several authors and published in the International Journal of Computer Assisted Radiology and Surgery on June 20, 2017. Azizi generally discloses the use of Temporal Enhanced Ultrasound (TeUS) for tissue characterization based on a sequence of ultrasound RF data. EX1007, Abstract. Azizi discloses the use of a Discrete Fourier Transform (DFT) of RF samples from each ROI. EX1007, 1295-96 (“For this purpose, we take the Discrete Fourier Transforms (DFT) of all zero-mean US time series corresponding to the RF samples in each ROI, normalized to the frame rate. Then, we calculate the mean absolute values of the Fourier transforms of the RF time series in each ROI. Finally, each ROI is represented by 50 positive frequency components.”); *see also id.*, Figs. 1a & 1b (reproduced below).



VIII. SUMMARY OF OPINIONS

74. The following is a summary of my opinions regarding patentability of the challenged claims of the 330 Patent.

75. Ground 1: Hope-Simpson discloses all of the elements of claims 1, 2, 4, 5, 11, 14, and 16 of the 330 Patent and thus anticipates those claims.

76. Ground 2: Hope-Simpson discloses all of the elements of claims 1, 2, 4, 5, 11, 14, and 16 of the 330 Patent, and any differences between the 330 Patent and Hope-Simpson amount to nothing more than routine and conventional features that were known in the art. Thus, the 330 Patent would have further been obvious in view of Hope-Simpson and the knowledge of a POSA.

77. Ground 3: Claims 3, 6-9, 12-13, 15, and 17-20 would have been

obvious in view of Hope-Simpson and Nair.

78. Ground 4: Claim 10 would have been obvious in view of Hope-Simpson and Nair, in further view of Azizi.

IX. GROUND 1: HOPE-SIMPSON ANTICIPATES CLAIMS 1, 2, 4, 5, 11, 14, AND 16

79. In my opinion, Hope-Simpson discloses all of the elements of claims 1-2, 4, 5, 11, 14, and 16 of the 330 Patent.

A. Independent Claim 1

80. I have compared claim 1 to the disclosure of Hope-Simpson. As set forth in the following subsections, in my opinion, Hope-Simpson discloses all the elements of claim 1 of the 330 Patent and therefore anticipates claim 1.

1. 1.P: Preamble - An ultrasound system

81. Hope-Simpson plainly discloses an ultrasound system. There are many ultrasound system descriptions within the Hope-Simpson patent. Figures 1, 4, 5, and 6 are all exemplary ultrasound systems. Hope-Simpson is titled “**Ultrasound Imaging System** with a Neural Network for Image Formation and Tissue Characterization.” EX1005, Title (emphasis added); *see also id.*, ¶[001] (“The present disclosure pertains to **ultrasound systems** and methods for obtaining **ultrasonic images** and/or tissue information using a neural network.”), ¶[006] (“An **ultrasound imaging system** according to the present disclosure...”), ¶[011] (“According to further embodiments, an **ultrasound imaging system** of the present

disclosure...”), ¶[013] (“According to further embodiments, an ultrasound imaging system of the present disclosure...”), ¶[014] (“A method of ultrasound imaging according to the present disclosure may include...”), ¶[014] (“In some embodiments, the selecting of the operational mode may be... automatic by the system, such as based on an imaging mode of the ultrasound system during acquisition of the echo signals.”), ¶[025] (“An ultrasound system according to the present disclosure may utilize a neural network....”), ¶[025] (“[T]he neural network of an ultrasound system according to the present disclosure can be trained to produce images and/or tissue characterization....”), ¶[026] (“An ultrasound system in accordance with principles of the present invention....”), ¶[026] (“The ultrasound system may include....”), ¶[026] (“and a display for displaying ultrasound images generated by the ultrasound imaging system. The ultrasound imaging system may include a neural network....”), ¶[027] (“The ultrasound system may include a display or graphics processor, which is operable to arrange the ultrasound image and/or additional graphical information, which may include annotations, tissue information, which may also be output by the neural network, and other graphical components, in display window for display on the display of the ultrasound system.”), ¶[028] (“Fig. 1 shows an example ultrasound system according to principles of the present disclosure. The ultrasound system includes....”), ¶[031] (“The input [Xi] and output [Yi] data of the training data sets

may be acquired by an **ultrasound imaging system** which has components for conventional ultrasound imaging or an imaging system configured for another type of modality.”), ¶[033] (“As such, the **ultrasound system** may be configured to output ultrasound images.”), ¶[042] (“Further examples of **ultrasound systems according to embodiments of the present disclosure** will now be described with reference also to FIGS. 4-6.”).

82. Figure 1 of Hope-Simpson (reproduced below) depicts an ultrasound system. *Id.*, ¶[016].

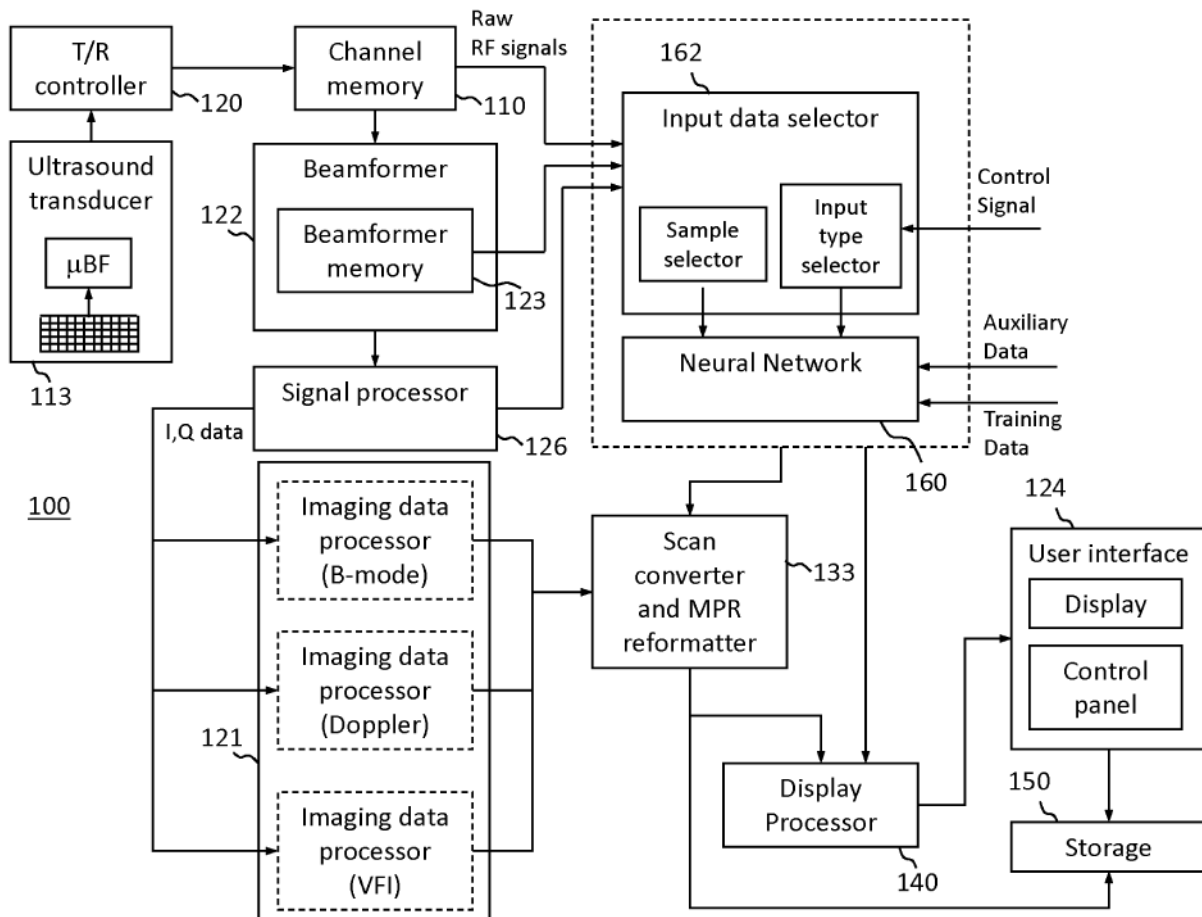
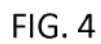


FIG. 1

Id., Fig. 1.

83. Figures 4, 5, and 6 (reproduced below) also depict ultrasound systems.

Id., ¶¶[019]-[021] (“FIG. 4 is block diagram of **an ultrasound system**.... FIG. 5 is block diagram of **another ultrasound system**.... FIG. 6 is block diagram of **yet another ultrasound system**....”).



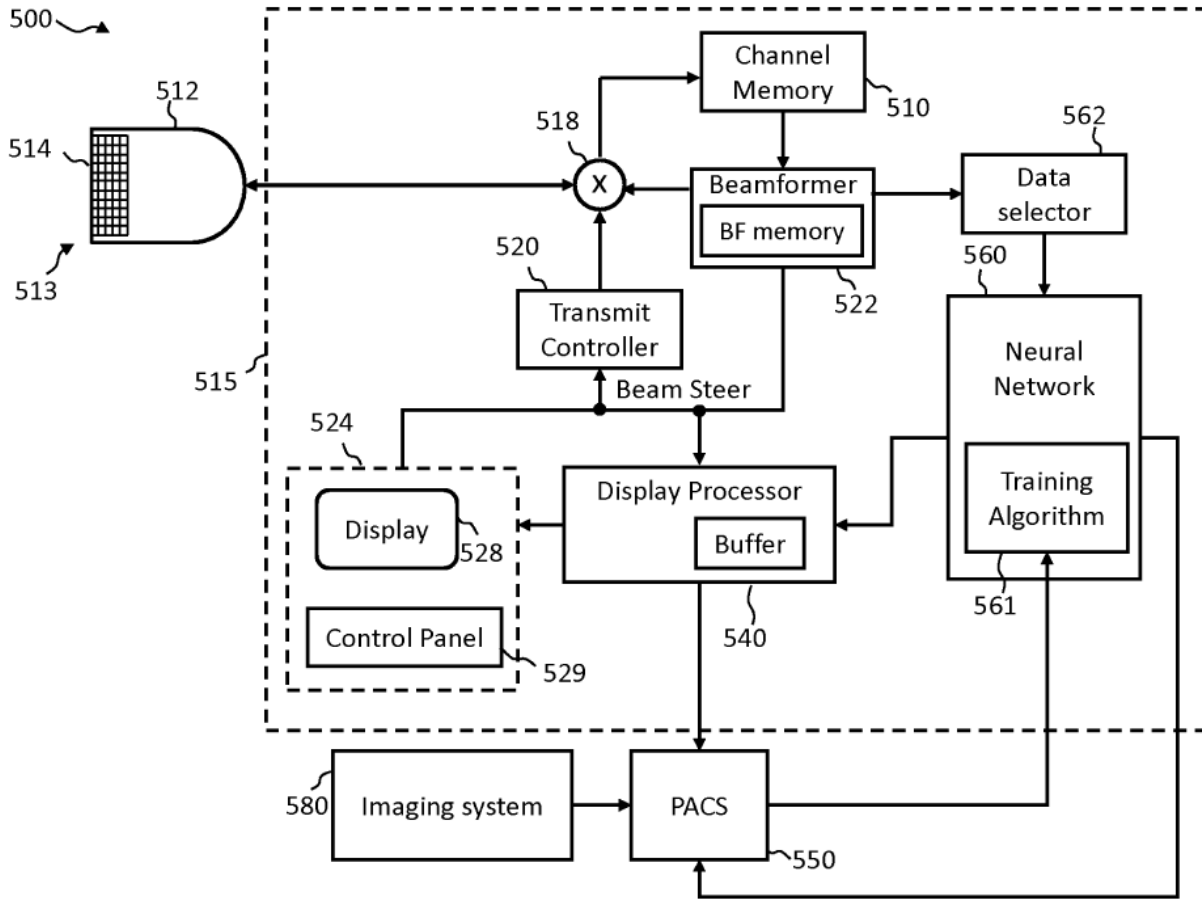


FIG. 5

Id., Fig. 5.

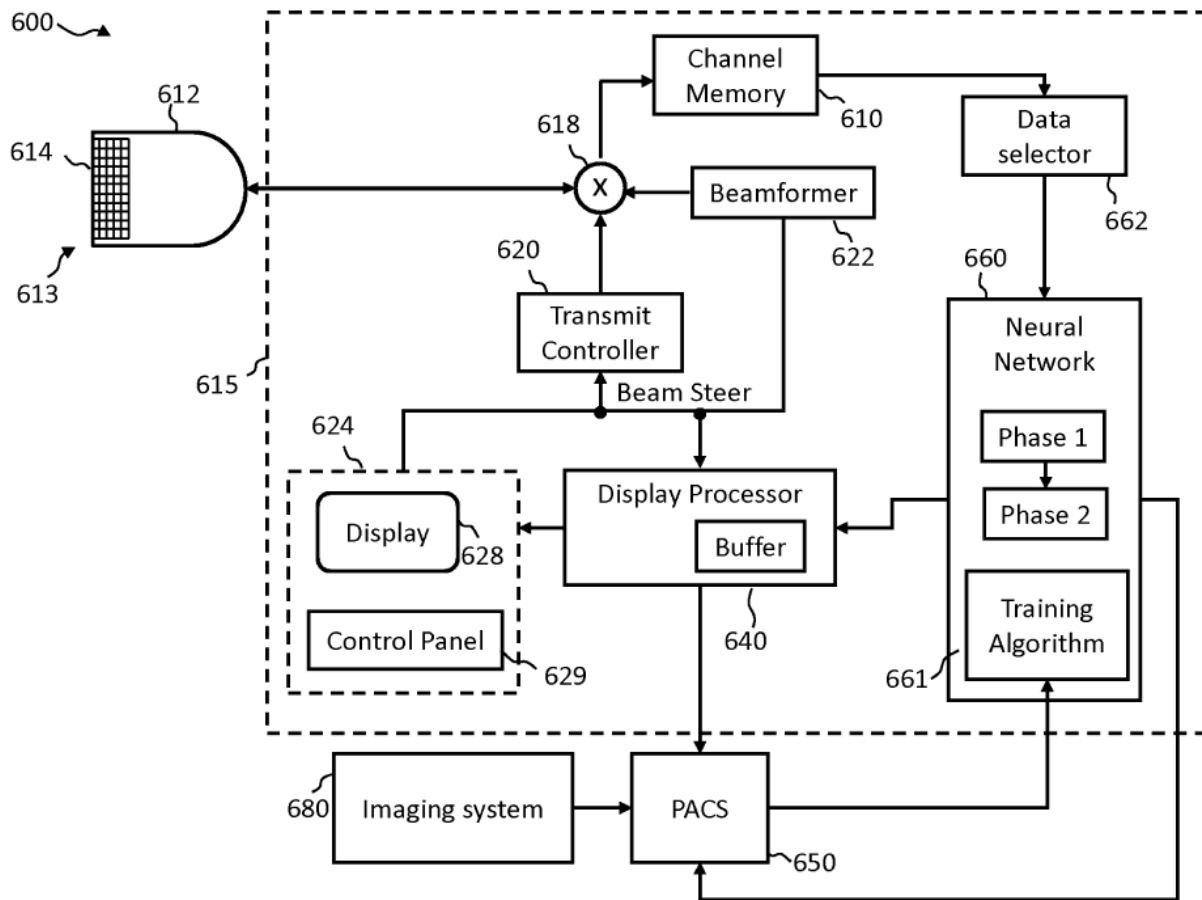


FIG. 6

Id., Fig. 6.

2. **1.1: a transducer configured to output a single static set of raw ultrasound [RF] data forming a single frame of a tissue area**

84. In my opinion, this describes a normal ultrasound transducer. Most ultrasound transducers are, or can be, configured to output single static sets of RF data. Typically, a normal ultrasound transducer would acquire raw RF data in discrete sets, and such discrete data sets represent a single static frame of data. Thus,

those single frames of data are discrete sets representing a single frame of a tissue area. This is analogous to how a camera works; many cameras are capable of outputting pictures, which are single frames of data, or videos, which are sets of data which are formed by multiple single frames.

85. Hope-Simpson discloses the output of “acquired echo signals.” *Id.*, ¶[002]. These “acquired echo signals” are nothing more than raw RF data and are acquired via a transducer. *Id.*, ¶[026] (“[A]cquired echo signals (**raw RF signals**)”), ¶[029] (“[E]cho signals (**also referred to as raw RF signals or simply RF signals, or per-channel data**).”). Therefore, output of “a single static set of raw ultrasound data forming a single frame of a tissue area” would be standard transducer output when imaging tissue using ultrasound.

86. Further, Hope-Simpson discloses a transducer that 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....” *Id.*, ¶[005]. 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.” It is clear to me, therefore, that the transducer of Hope-Simpson is configured to output a single static set of raw ultrasound RF data forming a single frame of a tissue area. *See id.*, ¶¶[005]-[006].

3. 1.2: a memory containing machine readable medium comprising machine executable code having stored thereon instructions

87. The element “a memory...having stored thereon instructions” is a standard computer with application memory. Hope-Simpson discloses a “memory containing machine readable medium comprising machine executable code having stored thereon instructions.” Any machine-readable medium would inherently contain memory if it is to have instructions stored thereon. Therefore, Hope-Simpson discloses a computer-readable medium (or a machine-readable medium) that inherently contains memory which has instructions stored thereon. Those instructions cause the processor to perform a machine-trained algorithm, meaning that said instructions are “machine executable code.”

88. Hope-Simpson also discloses “wherein the neural network is implemented, at least in part, in 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 subsets of the acquired echo signals, the beamformed signals, or both.” *See id.*, Claim 12; *see also id.*, ¶[027] (“[A] software-based neural network may be implemented using a processor...configured to execute **instructions, which may be stored in computer-readable medium**...”), ¶[027] (“[A] processor...configured to execute instructions,

which may be stored in computer-readable medium, and which when executed cause the processor to perform a machine-trained algorithm for producing ultrasound images and/or outputting tissue information from one or more of the above identified inputs.”).

4. 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 the cause the one or more processors to...

89. Hope-Simpson discloses 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.

90. Hope-Simpson discloses a neural network that may be implemented using a processor (or processing unit), which may be multiple processors arranged in parallel. *Id.*, ¶[027] (stating that the “processor” may be a single or multi-core CPU, a single GPU or GPU cluster, or **multiple processors arranged for parallel processing**). 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.* Therefore, Hope-Simpson discloses a signal processing unit comprising one or more processors that are configured to execute the machine executable code.

91. Hope-Simpson also discloses processors (or a processing unit) coupled to the memory. For example, Hope-Simpson’s 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]; *see also id.*, ¶[027] (“[A] processor...configured to execute instructions, which may be stored in computer-readable medium, and which when executed cause the processor to perform a machine-trained algorithm for producing ultrasound images and/or outputting tissue information from one or more of the above identified inputs.”).

5. 1.4: receive the single static set of raw ultrasound RF data

92. The combination of Figures 1 and 2 of Hope-Simpson demonstrate that the ultrasound system of Hope-Simpson will produce, and process localized, static data sets comprised of raw ultrasound RF data. 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.

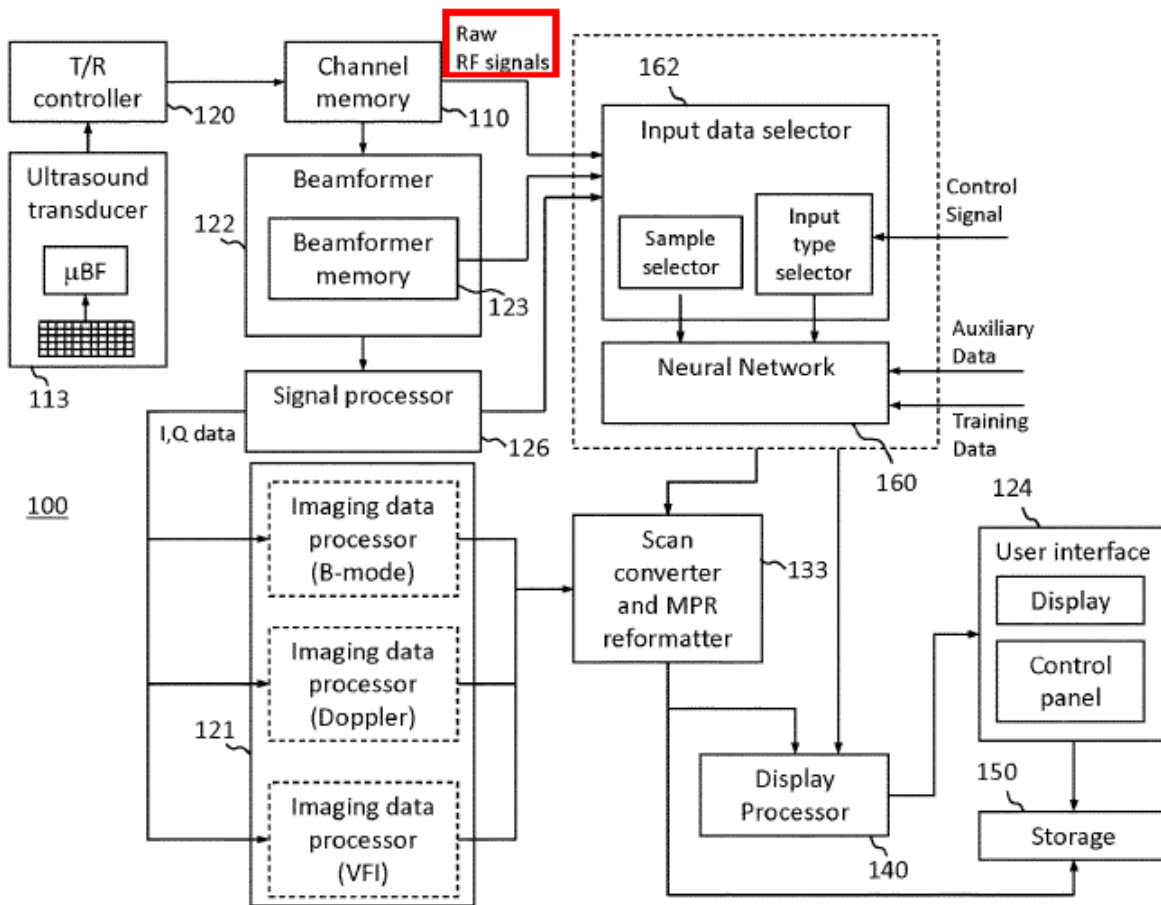


FIG. 1

93. Indeed, the signals that are fed from the transducer to the channel memory and, ultimately, into the signal processing unit, are raw RF signals. “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]. “The channel memory 110 may couple the RF signals to a neural network 160....” *Id.*, ¶[030].

94. Figure 2 of Hope-Simpson describes an example method for selecting a subset of a frame (*e.g.*, an ROI and/or a window of data) for processing based on a depth of interest. This is common in standard ultrasound imaging and conventional ultrasound tissue characterization.

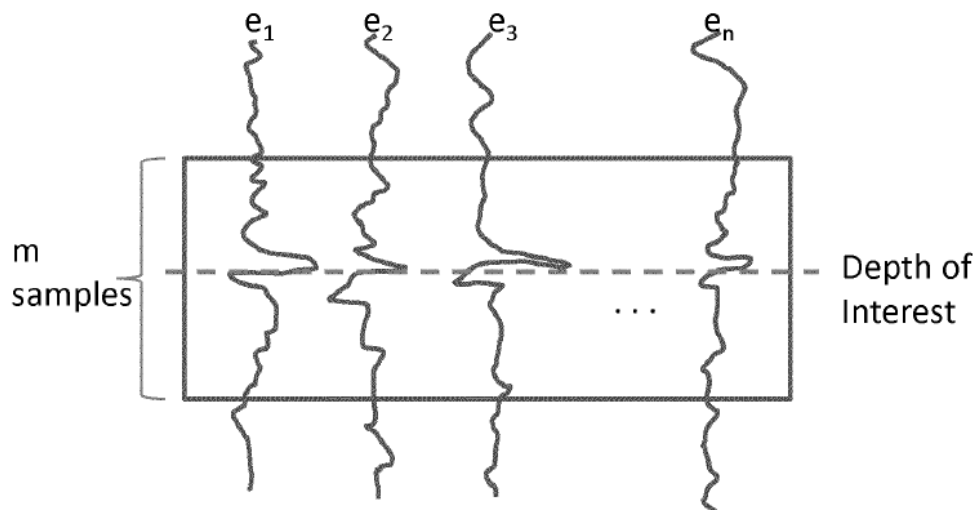


FIG. 2

Id., Fig. 2.

95. Hope-Simpson also 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 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 (box 702) after being output by the transducer.

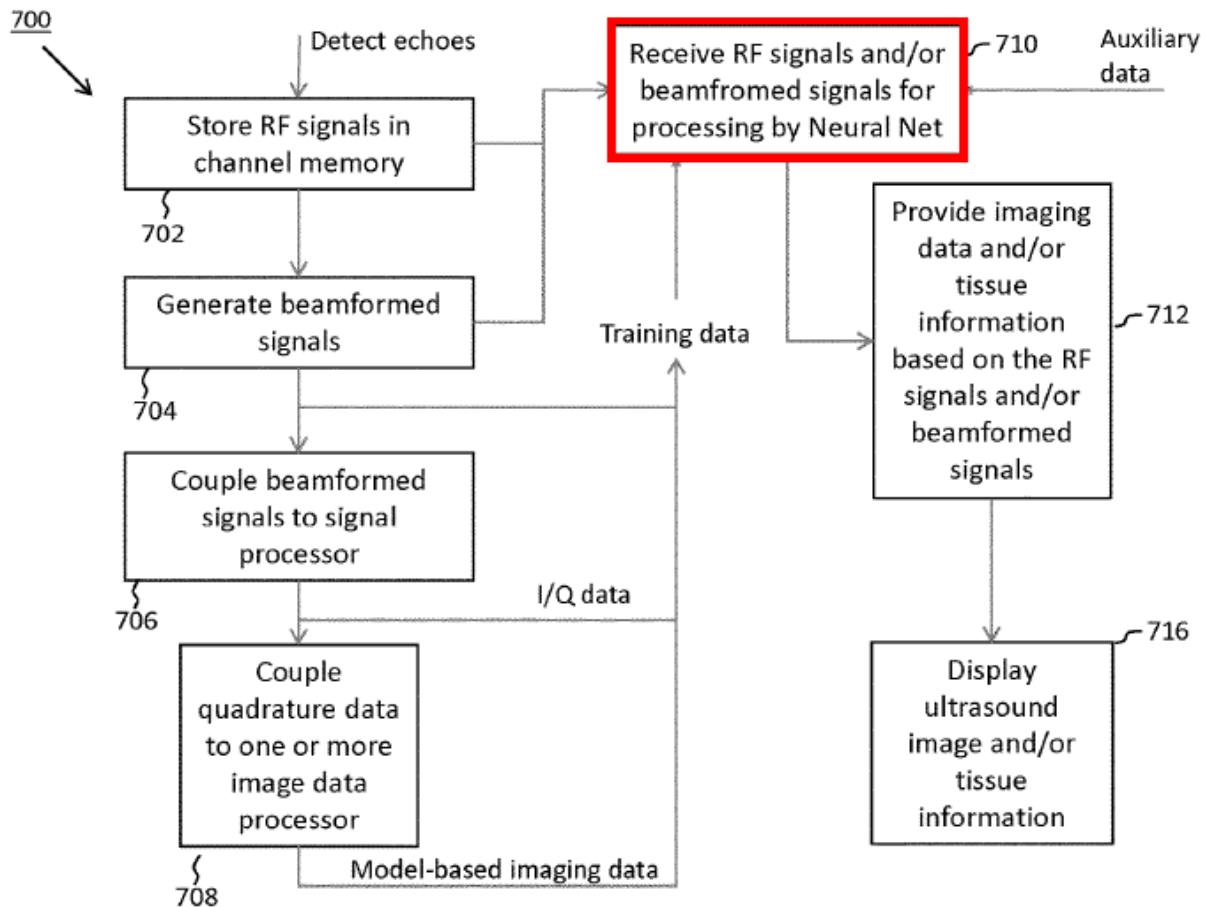


FIG. 7

Id., Fig. 7 (annotated).

96. Box 710 of Figure 7 states “Receive RF signals and/or beamformed [sic] signals for processing by the Neural Net.” *Id.* This indicates that the processors of Hope-Simpson that are responsible for processing raw RF data with a machine learning model (in this case, a neural net) are also configured to receive the static set

of raw ultrasound RF data. Therefore, the processors that I understand to be inherent in box 710 of Figure 7, outlined in red above, are configured to receive the static set of raw ultrasound RF data.

6. 1.5: process the single static set of raw RF ultrasound data with a machine learning model

97. Hope-Simpson discloses processing the single static set of raw RF ultrasound data with a machine learning model. Figure 7, for example, shows that “the process 700 may begin by storing the acquired echo signals or RF signals in channel memory, as shown in block 702. The RF signals stored in channel memory correspond to the echoes detected from the tissue being image response to ultrasound transmitted by a transducer (e.g., transducer 113) operatively coupled to an ultrasound system (e.g., system 100).” EX1005, ¶[066].

98. The data that is stored in the channel memory “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 imaging data and/or tissue information directly from the raw RF signals... as shown in block 712.” *Id.* Hope-Simpson describes that “tissue information” includes “a variety of tissue characterization or diagnostic information.” *Id.*, ¶[026].

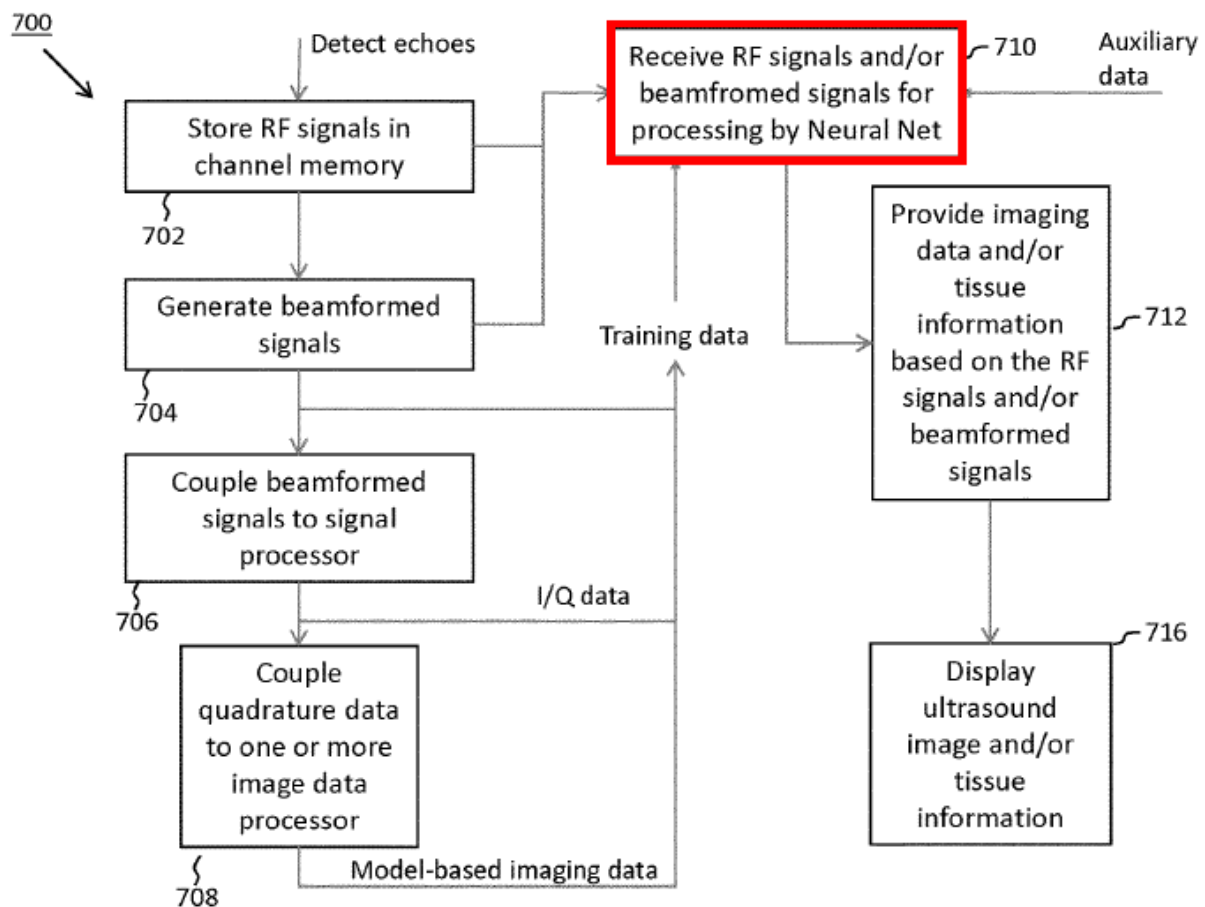


FIG. 7

Id., Fig. 7.

99. Neural networks are machine learning models, as disclosed in Hope-Simpson. “For example, a software-based neural network may be implemented using a processor...which when executed cause the processor to perform a **machine-trained algorithm** for producing ultrasound images and/or outputting tissue information from one or more of the above identified inputs.” *Id.*, ¶[027]. “Machine-trained algorithm” is a synonym for a machine learning model in this context.

100. Because Hope-Simpson discloses processing raw RF signals with a neural network, and because a neural network is a machine learning model, I understand that Hope-Simpson discloses processing the single static set of raw RF data with a machine learning model.

7. 1.6: output classification of the raw RF ultrasound data from an output of the machine learning model

101. Hope-Simpson discloses outputting a variety of tissue characterization or diagnostic information, collectively referred to as tissue information, from raw RF signals. *See, e.g., id.*, ¶[026] (“In yet further examples, the 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.”).

102. The 330 Patent uses the term “classification,” while Hope-Simpson uses the more conventional terminology of “tissue characterization.” I understand both terms to be synonymous in this context. The process of determining tissue characteristics is a classifying process. Hope-Simpson also frequently uses the term “tissue information” to refer to “tissue characterization or diagnostic information.” *Id.*, ¶[026] (“In yet further examples, the 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.”). As an illustrative example, when Hope-Simpson discloses the use of its ultrasound system to characterize fat content and plaque within tissue (*Id.*, ¶[069]), it is specifying that its characterization process *classifies* tissue as fat, plaque, etc.

103. Hope-Simpson, therefore, uses the term “tissue information” to refer to “tissue characterization or diagnostic information.” *Id.*, ¶[026]; *see also 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** produce imaging data and/or **tissue information directly from the raw RF signals** or beamformed RF signals, as shown in block 712.”), ¶[027] (“For example, a software-based neural network may be implemented using a processor... configured to execute instructions, which may be stored in computer-readable medium, and which when executed cause the processor to **perform a machine-trained algorithm** for producing ultrasound images and/or **outputting tissue information** from one or more of the above identified inputs.”).

B. Dependent Claims 2, 4, and 5

104. Dependent claims 2-5 each depend on claim 1. These claims recite minor features or variations, most of which are also found in Hope-Simpson. In my opinion, claims 2, 4, and 5 are also anticipated by Hope-Simpson and claim 3 is obvious in view of Hope-Simpson and Nair.

105. **Dependent claim 2** recites “[t]he 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).” Claim 1 is anticipated by Hope-Simpson, as discussed above. In my opinion, Hope-Simpson contains all of the elements of claim 2 and thus anticipates claim 2 as well.

106. As an initial matter, claim 2 lists several types of machine learning models as alternatives to use in the system of the 330 Patent. Thus, I understand that the use of any one of these models would be sufficient to show anticipation of claim 2. Hope-Simpson discloses the use of a deep neural network (DNN), a convolutional neural network (CNN), or a combination thereof. EX1005, ¶[008]. 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 characterization) of an image for display from raw channel data.

107. **Dependent claim 4** recites “[t]he ultrasound system of claim 1, wherein the machine learning model is an unsupervised model.” Claim 1 is anticipated by Hope-Simpson, as discussed above. In my opinion, Hope-Simpson contains all of

the elements of claim 4 and thus anticipates claim 4 as well.

108. 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]. The term “unsupervised” is not explicitly used to describe Hope-Simpson’s model above, but an algorithm that does not rely on direct input of data relationships from a user inherently describes an unsupervised model. Hope-Simpson also incorporates all “currently known” machine learning techniques, which includes unsupervised models that were widely known and used in the art well before the 330 Patent. Exhibit 1008, for example, discusses the use of unsupervised machine learning algorithms at least as early as 1992.⁴

109. ***Dependent claim 5*** recites “[t]he 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.” Claim 1 is anticipated by Hope-Simpson, as discussed above. In my opinion, Hope-Simpson contains all of the elements of claim 5 and thus anticipates claim 5 as well.

110. The use of a display to visualize tissue classification is intuitive to me.

⁴ I cite to EX1008 to reinforce my assertion that unsupervised models were known in the art, which is derived from my knowledge as a POSA.

In fact, the use of a display to visualize tissue classification is *necessary*, and does not represent any surprising or novel activity. I have seen this sort of visualization in the form of full frame parametric frames or regions overlayed onto conventional ultrasound images. Frequently, the parametric image that is displayed has various colors, each color being associated with a value in a corresponding scale. Each color, therefore, is a unique identifier corresponding to a particular property of the tissue.

111. Such use of a unique identifier based on the output of the machine learning model is disclosed by Hope-Simpson. Hope-Simpson describes several embodiments that perform a classification process and display an output image containing tissue characterization 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]. The color coding that Hope-Simpson discloses is, as discussed, a set of unique identifiers corresponding to particular properties. 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.

C. Independent Claim 11

112. As discussed in more detail below, I have compared claim 11 to Hope-Simpson. In my opinion, Hope-Simpson discloses all the elements of claim 11 of the

330 Patent and therefore anticipates claim 11.

1. 11.P: Preamble - A method

113. To the extent that the preamble is limiting, Hope-Simpson discloses a method. For example, “the present disclosure pertains to ultrasound systems and methods.” *Id.*, ¶[001].

2. 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

114. As discussed with respect to claim 1 above, the combination of Figures 1 and 2 of Hope-Simpson demonstrate that the ultrasound system of Hope-Simpson will produce and process localized, static data sets comprised of raw ultrasound RF data. 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.

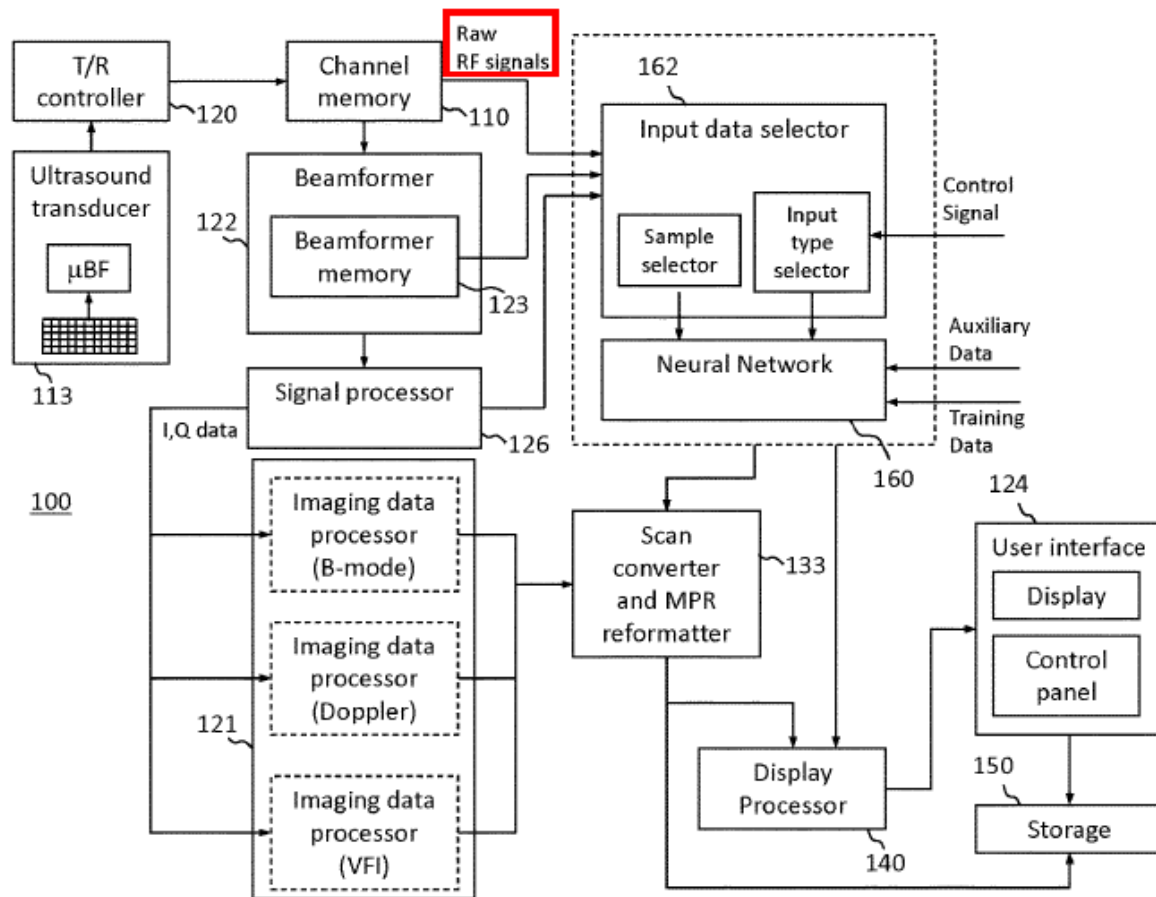


FIG. 1

EX1005, Fig. 1.

115. Indeed, the signals that are fed from the transducer to the channel memory and, ultimately, into the signal processing unit, are raw RF signals. “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).” *Id.*, ¶[029]. “The channel

memory 110 may couple the RF signals to a neural network 160....” *Id.*, ¶[030].

116. Figure 2 of Hope-Simpson describes an example method for selecting a subset of a frame for processing based on a depth of interest. This is common in standard ultrasound imaging and conventional ultrasound tissue characterization.

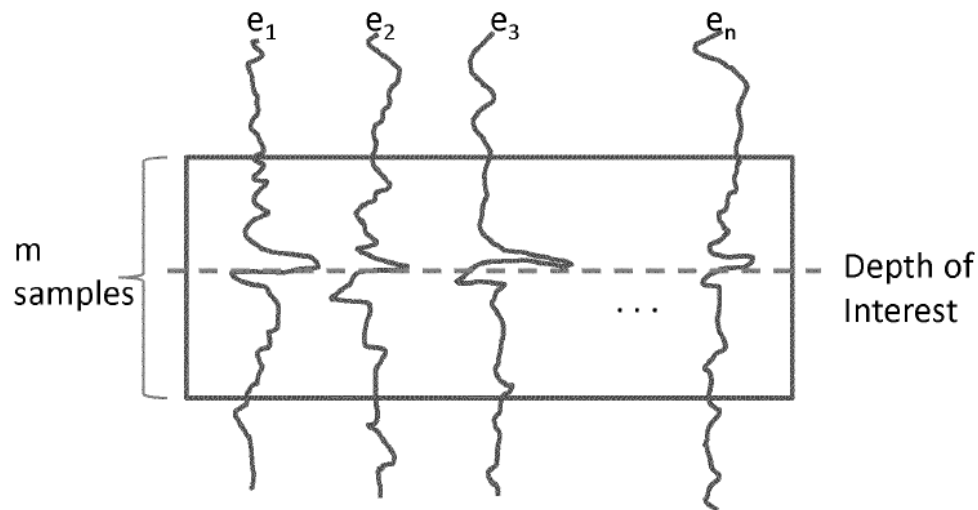


FIG. 2

Id., Fig. 2.

117. Hope-Simpson also 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 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 (box 702) after being output by the transducer.

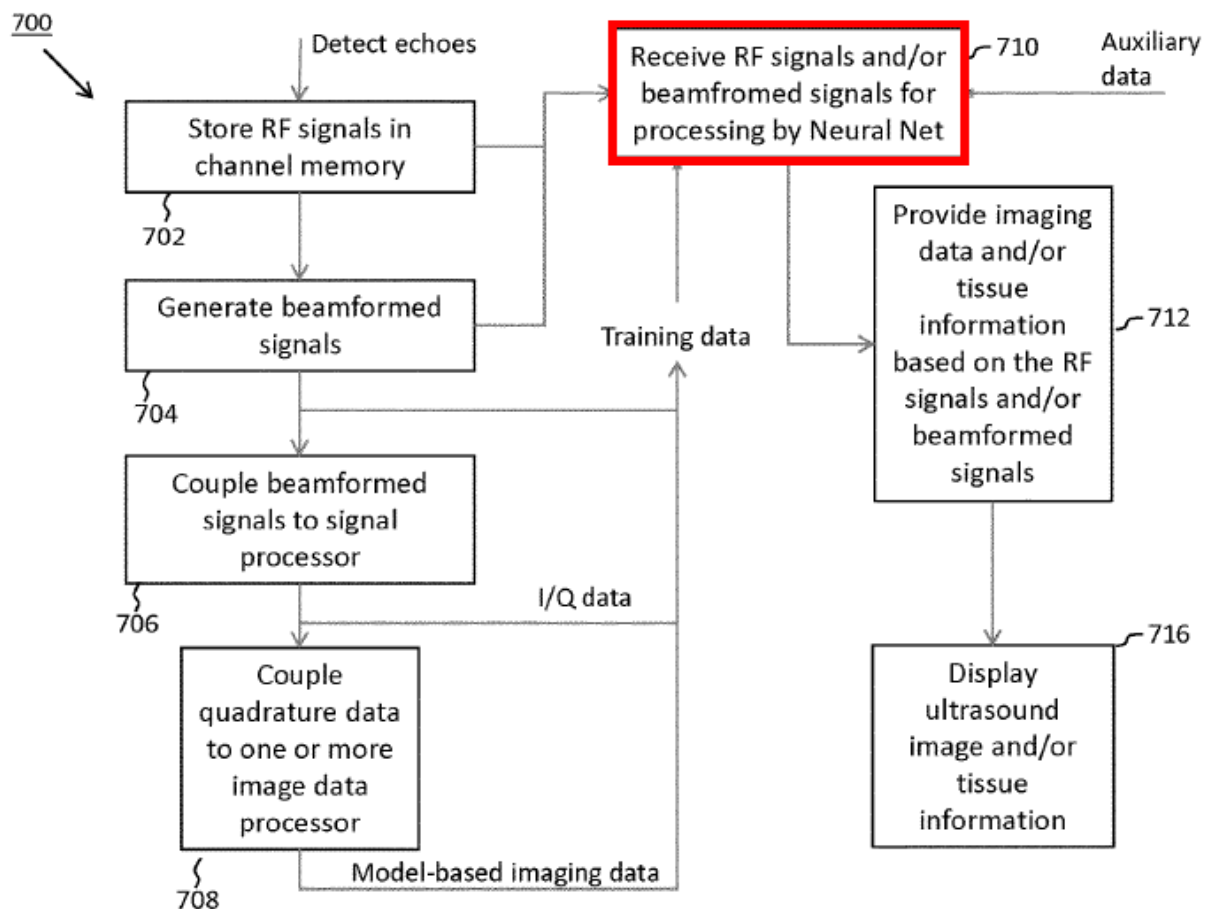


FIG. 7

EX1005, Fig. 7 (annotated).

118. Box 710 of Figure 7 states “Receive RF signals and/or beamformed [sic] signals for processing by the Neural Net.” *Id.* This indicates that the processors of Hope-Simpson that are responsible for processing raw RF data with a machine learning model (in this case, a neural net) are also configured to receive the static set of raw ultrasound RF data. Therefore, the processors that I understand to be inherent in box 710 of Figure 7, outlined in red above, are configured to receive the static set

of raw ultrasound RF data.

119. Hope-Simpson also discloses the output of “acquired echo signals.” *Id.*, ¶[002]. These “acquired echo signals” are nothing more than raw RF data, and I understand them to be acquired via a transducer. Therefore, output of “a single static set of raw ultrasound data forming a single frame of a tissue area” would be standard transducer output when imaging tissue using ultrasound.

120. Further, Hope-Simpson discloses a transducer that 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....” *Id.*, ¶[005]. It is clear to me, therefore, that the transducer of Hope-Simpson is configured to output a single static set of raw ultrasound RF data forming a single frame of a tissue area. *See id.*, ¶¶[005]-[006].

3. 11.2: processing the single static set of ultrasound RF data as an input to a machine learning model

121. 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 of Hope-Simpson includes the step “[r]eceive RF signals...for processing by Neural Net. EX1005, Fig. 7. Potential inputs to that step include raw ultrasound RF data. Indeed, Hope-Simpson describes that “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.”).

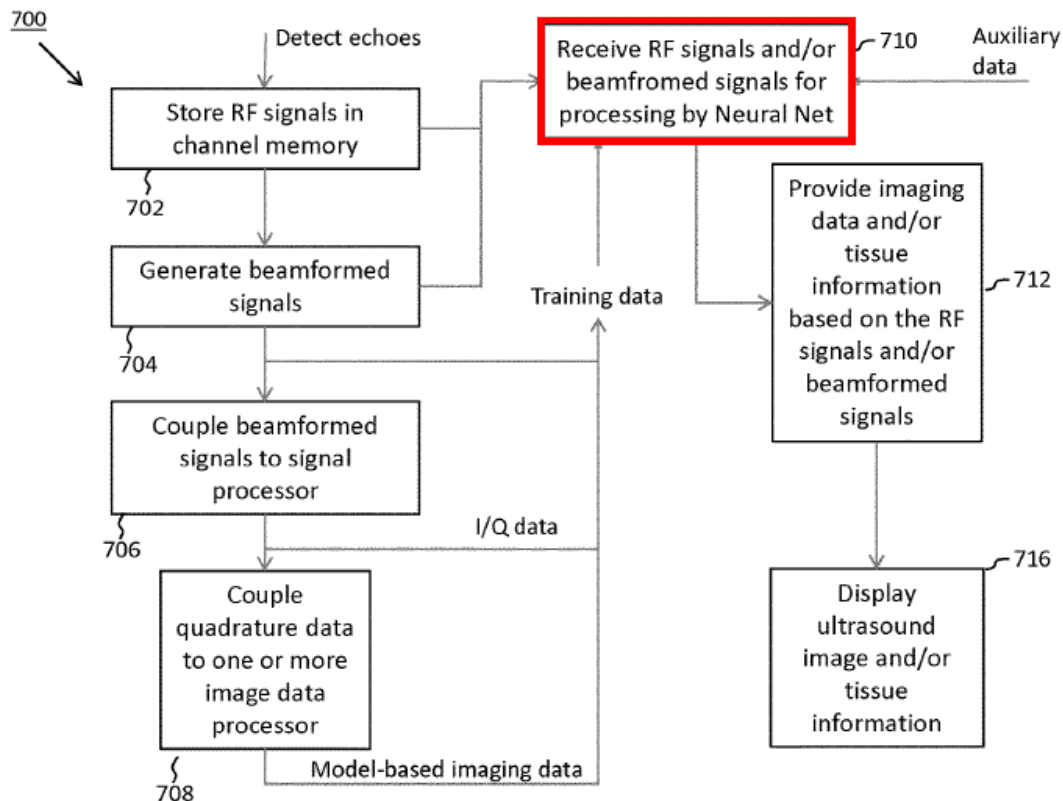


FIG. 7

Id., Fig. 7.

4. 11.3: outputting a classification of the tissue area from the machine learning model

122. As discussed with respect to claim 1, Hope-Simpson discloses outputting a classification of the tissue area, collectively referred to as tissue information, from RF signals. *Id.*, ¶[026]. Figure 7 details the process of performing tissue characterization using machine learning algorithms processing 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.*

D. Dependent Claims 14 and 16

123. **Dependent claim 14** recites “[t]he 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). Hope-Simpson anticipates claim 11, as discussed above. It is my opinion that Hope-Simpson discloses every element of claim 14 and thus anticipates claim 14.

124. As discussed with respect to claim 2 above, Hope-Simpson discloses the use of a deep neural network (DNN), a convolutional neural network (CNN), or a combination thereof. *Id.*, ¶[008]. Hope-Simpson also discloses that the DNN and CNN may be trained using any of a 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 characterization) of an image for display from raw channel data. *Id.*

125. **Dependent claim 16** recites “[t]he method of claim 11, wherein the machine learning model is an unsupervised model.” Hope-Simpson anticipates claim 11, as discussed above. It is my opinion that Hope-Simpson discloses every element of claim 16 and thus anticipates claim 16.

126. As discussed with respect to claim 4 above, Hope-Simpson discloses 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]. Hope-Simpson’s use of an algorithm that does not rely on “an explicit model of the input/output relationship” describes, and thus discloses, the use of an unsupervised model.

127. I also recognize that Hope-Simpson incorporates all “currently known” or “later developed” machine learning techniques. *Id.*, ¶[025]. I understand this to encompass unsupervised machine learning techniques, because those techniques were widely known and used in the art well before the 330 Patent. For example, Exhibit 1008 discusses the use of unsupervised machine learning algorithms at least as early as 1992. EX1008, pp. 796-801. This reinforces my knowledge as a person of skill in the art that unsupervised machine learning models were not new at the time of filing of the 330 Patent.

**X. GROUND 2: HOPE-SIMPSON IN VIEW OF THE KNOWLEDGE OF A POSA
RENDERS OBVIOUS CLAIMS 1, 2, 4, 5, 11, 14, AND 16 OF THE 330 PATENT**

128. In view of the knowledge within the art at the time of the 330 Patent’s effective priority date, which I understand to be December 12, 2017, I understand that the 330 Patent would be obvious in view of Hope-Simpson at least because any

differences between the disclosure of Hope-Simpson and the alleged invention of the 330 Patent amount to nothing more than well-understood, routine, and conventional activity for one of skill in the art.

129. For example, the 330 Patent itself discloses the use of various machine learning models in analogous arts such as MRI, CT, and X-ray analysis, and further states that the field of ultrasound “is relatively behind other areas of quantitative image analysis” in that “many of the quantitative analysis techniques process the data from B-mode, after the ultrasound has already been converted into two dimensional images and much additional RF data has been removed.” EX1001, 1:34-40. The assertion that the use of machine learning to process and interpret raw ultrasound RF data is somehow novel is misguided. As demonstrated by Hope-Simpson, the use of a machine learning algorithm to interpret raw ultrasound RF data was known at least as early as Hope-Simpson’s effective priority date of January 5, 2017 (stemming from Provisional Application No. 62/442,691), which predates the earliest priority date of the 330 Patent.

130. Having established that the use of machine learning models to process raw ultrasound RF data is not new or surprising to one of skill in the art, the only points of novelty that the 330 Patent purports to add with claims 1, 2, 4, 5, 11, 14, and 16, none of which I would consider novel in view of the state of the art at the time, are summarized as follows.

131. Claims 1 and 11 describe a conventional ultrasound system (claim 1) and a method of its operation (claim 11) which include: (1) receiving raw RF data, (2) processing that data with a machine learning model, and (3) classifying the tissue that was scanned.

132. Hope-Simpson discloses processors within its system receiving RF data. For example, as discussed under Ground 1 above, the combination of Figures 1 and 2 demonstrate that the ultrasound system of Hope-Simpson will produce and process localized, static data sets comprised of raw ultrasound RF data. Figure 1 of Hope-Simpson expressly discloses a transducer 113 that is coupled to channel memory 110, and the channel memory 110 is then coupled to an input data selector 162 which is tied to a neural network 160. Between the channel memory 110 and the input data selector 162 on the flowchart of Figure 1, it is expressly stated that the type of data being transmitted is “raw RF signals,” highlighted in red below.

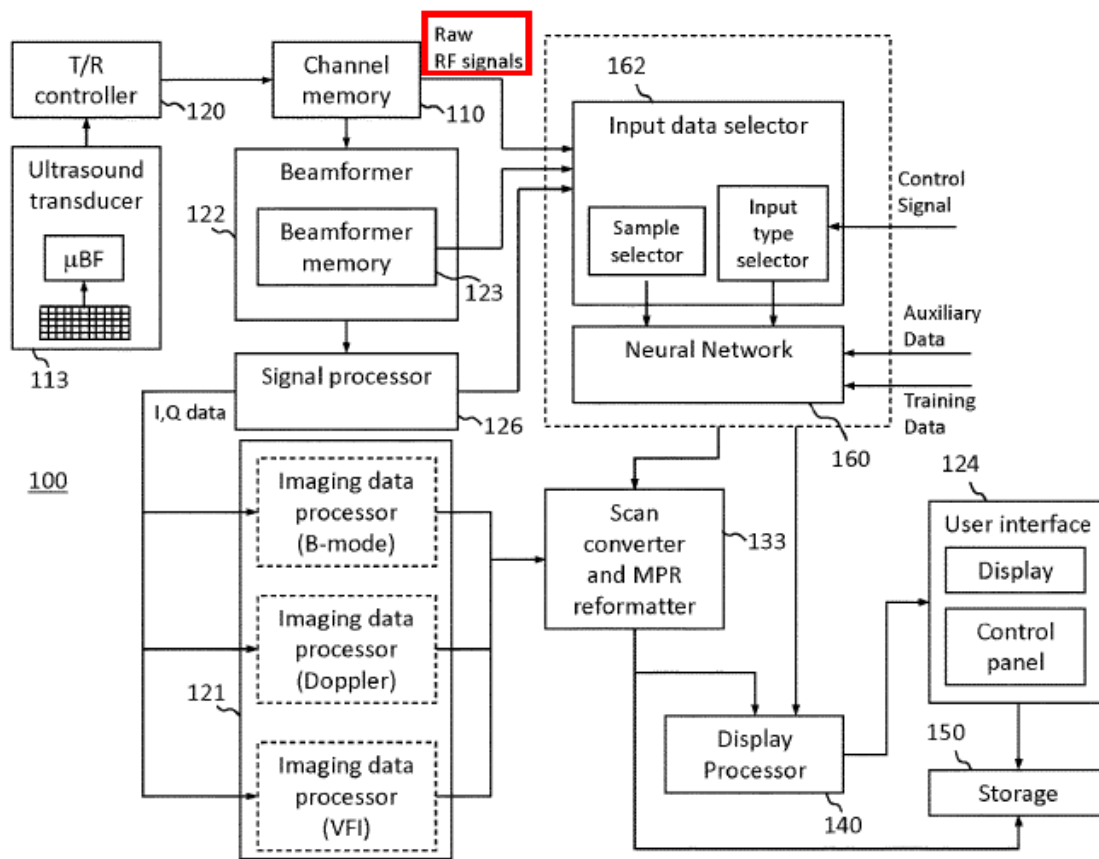


FIG. 1

EX1005, Fig. 1.

133. As shown, it is not new for a machine learning model to receive raw RF signals from an ultrasound transducer, and such a system would be (if not fully anticipated by Hope-Simpson), wholly obvious to me in view of Hope-Simpson. Processing the raw RF data with the machine learning model (here, Neural Network 160), is also obvious to me in view of Hope-Simpson. As seen below in Figure 7, Hope-Simpson's Neural Net receives the RF signals (which may be raw RF signals, as seen in Figure 1) and processes them. I would intuitively understand that box 710

of Figure 7, highlighted in red below, renders obvious the processing of RF signals with a machine learning model.

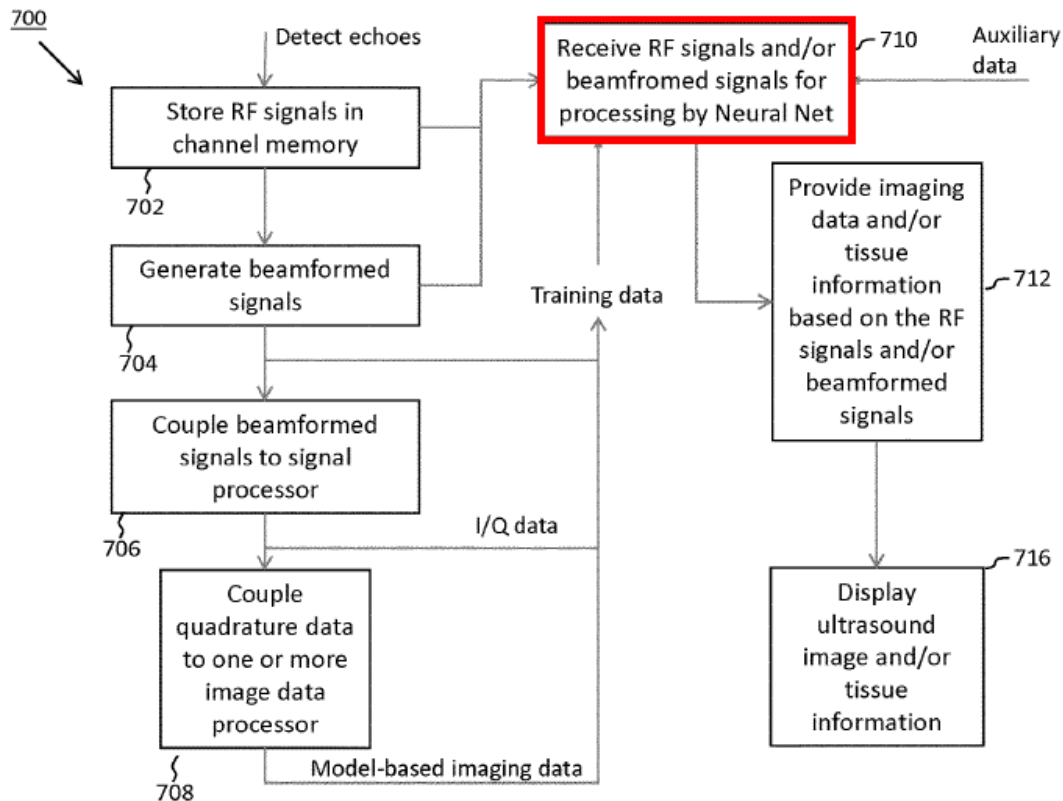


FIG. 7

Id., Fig. 7.

134. Finally, I find it patently obvious for an output of the machine learning model to be “classification of the raw RF ultrasound data.” Hope-Simpson discloses the output of “tissue characterization” and “tissue information.” EX1005, ¶[026]. As discussed above, I believe that these terms are synonymous with “tissue classification” in this context. To the extent that they are not synonymous, any minor

differences between the terms would be a simple matter of choice when configuring the outputs of the machine learning model.

135. Claims 2 and 14 are further obvious in view of Hope-Simpson because all they disclose is the use of various machine learning algorithm types with the system and method of claims 1 and 11, respectively. Models such as K-means models, Convolutional Neural Networks, Restricted Boltzmann Machines, Long Short Term Memory models, and Capsure Networks, are widely known in the art. Thus, the use of any one or a combination of these models with the obvious system of claims 1 and/or 11 would be obvious. Indeed, the 330 Patent implies that these sorts of models are already being used within other imaging and tissue classification areas.

136. Claims 4 and 16 are further obvious in view of Hope-Simpson because they simply disclose the use of an unsupervised machine learning model. Unsupervised machine learning models are common within the art, and because claims 1 and 11 are obvious, the obvious use of an *unsupervised* machine learning model within those systems is nothing more than a conventional permutation of those systems.

137. Claim 5 is obvious in view of Hope-Simpson because it simply discloses the use of a display to visualize the outputs from the machine learning model. Specifically, claim 5 indicates the use of a unique identifier on the display to

indicate an output parameter of the machine learning model. This is not new. The use of something such as color coding, as disclosed in Hope-Simpson, is common in the art and renders these limitations obvious.

XI. GROUND 3: HOPE-SIMPSON AND NAIR RENDER OBVIOUS CLAIMS 3, 6-9, 12, 13, 15, AND 17-20 OF THE 330 PATENT

138. In my opinion, Hope-Simpson in view of Nair renders obvious at least claims 3, 6-9, 12, 13, 15, and 17-20 of the 330 Patent for at least the reasons described herein. Hope-Simpson and Nair are analogous art because they both relate to systems for characterizing tissue status using reflected signals from the tissue of interest.

A. Dependent Claim 3

139. *Dependent claim 3* recites “[t]he ultrasound system of claim 1, wherein the machine learning model is trained using ultrasound images labeled by a radiologist.” Claim 1 is anticipated by Hope-Simpson, as discussed above. In my opinion, the combination of Hope-Simpson and Nair renders claim 3 obvious.

140. The process of preparing and labeling training data for machine learning algorithms has a high impact on the success of a classifying system. 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 include known properties of the imaged tissue.”

EX1005, ¶[010], Claim 5. I would understand that the labeling that Hope-Simpson discloses would typically be done by a radiologist. Nair also discloses such a situation, where a clinician identifies and characterizes the tissue type(s) when preparing a tissue specimen for slide review. EX1006, ¶[0064]. “The identified tissue type(s) and/or characterization conclusions are provided to the characterization application 250 as characterization data.” *Id.*, [0066]. A POSA would understand Nair’s “clinician” that identifies and characterizes tissue types, or labels the ultrasound images, to include a radiologist.

141. Therefore, I understand a radiologist to be an obvious choice to label such data sets.

B. Independent Claim 6

142. As discussed in more detail below, I have compared claim 6 to Hope-Simpson and Nair. Hope-Simpson expressly includes each and every claim element of claim 6 except for processing the single static set of raw ultrasound RF data set of windows to determine a power spectrum. Nair discloses this step, and for the reasons set forth below, a POSA at the time of the invention would have been motivated to combine Nair with Hope-Simpson. In my opinion, claim 6 would have been obvious to a POSA in view of Hope-Simpson and Nair for the reasons I discuss below.

1. 6.P: Preamble - A method

143. To the extent that the preamble is limiting, Hope-Simpson discloses a method. *See, e.g.*, EX1005, ¶[001] (“The present disclosure pertains to ultrasound systems and **methods**....”). Nair also discloses a method. *See, e.g.*, EX1006, ¶[0210] (“The systems and **methods** described herein....”).

2. 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

144. As discussed with respect to claims 1 and 11 above, the combination of Figures 1 and 2 of Hope-Simpson demonstrate that the ultrasound system of Hope-Simpson will produce and process localized, static data sets comprised of raw ultrasound RF data. 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.

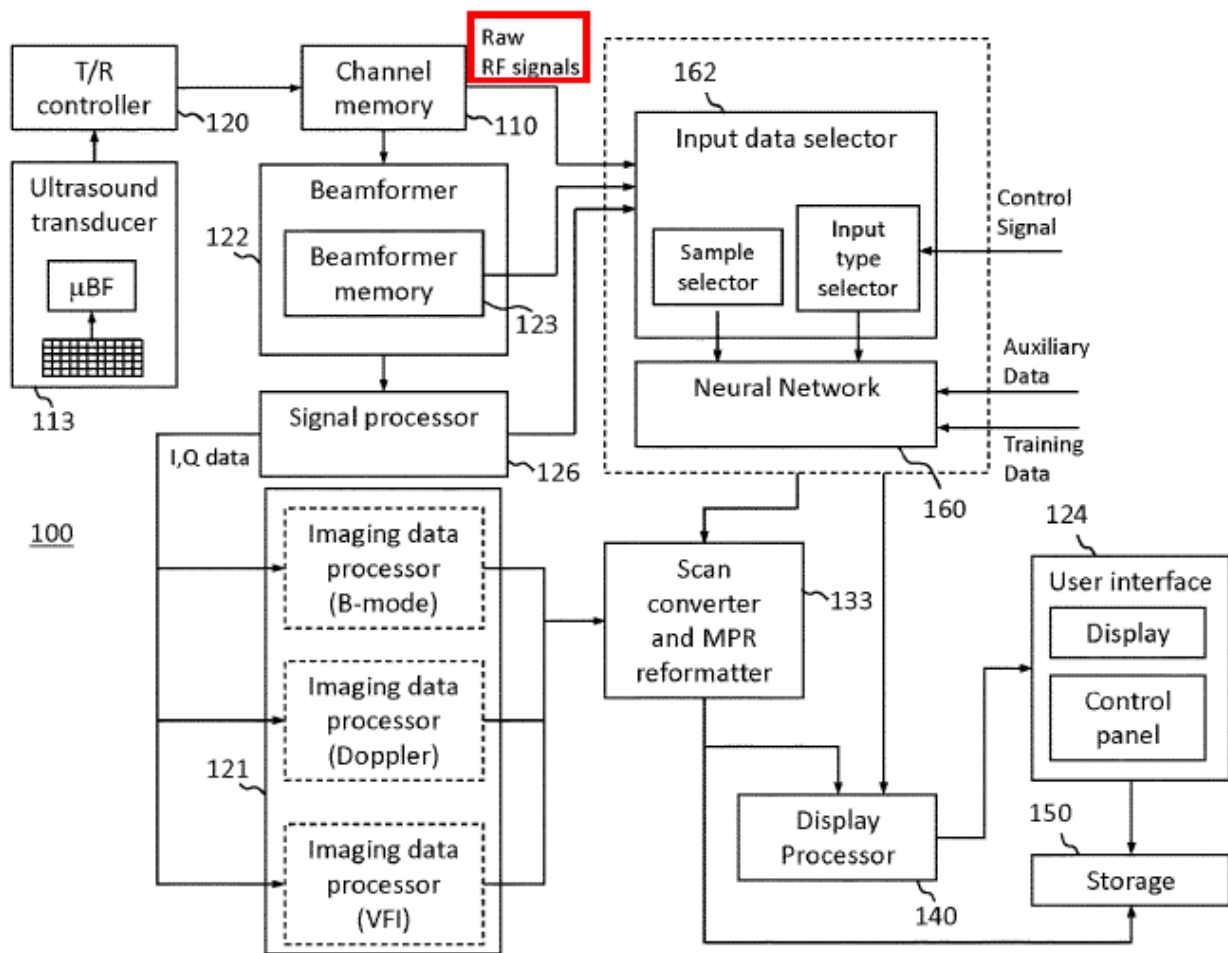


FIG. 1

EX1005, Fig. 1.

145. Indeed, the signals that are fed from the transducer to the channel memory and, ultimately, into the signal processing unit, are raw RF signals. “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] (emphasis added). “The channel memory 110 may couple the RF signals to a neural network 160...” *Id.*, ¶[030] (emphasis added).

146. Figure 2 of Hope-Simpson describes an example method for selecting a subset of a frame for processing based on a depth of interest. This is common in standard ultrasound imaging and conventional ultrasound tissue characterization.

147. 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 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 (box 702) after being output by the transducer.

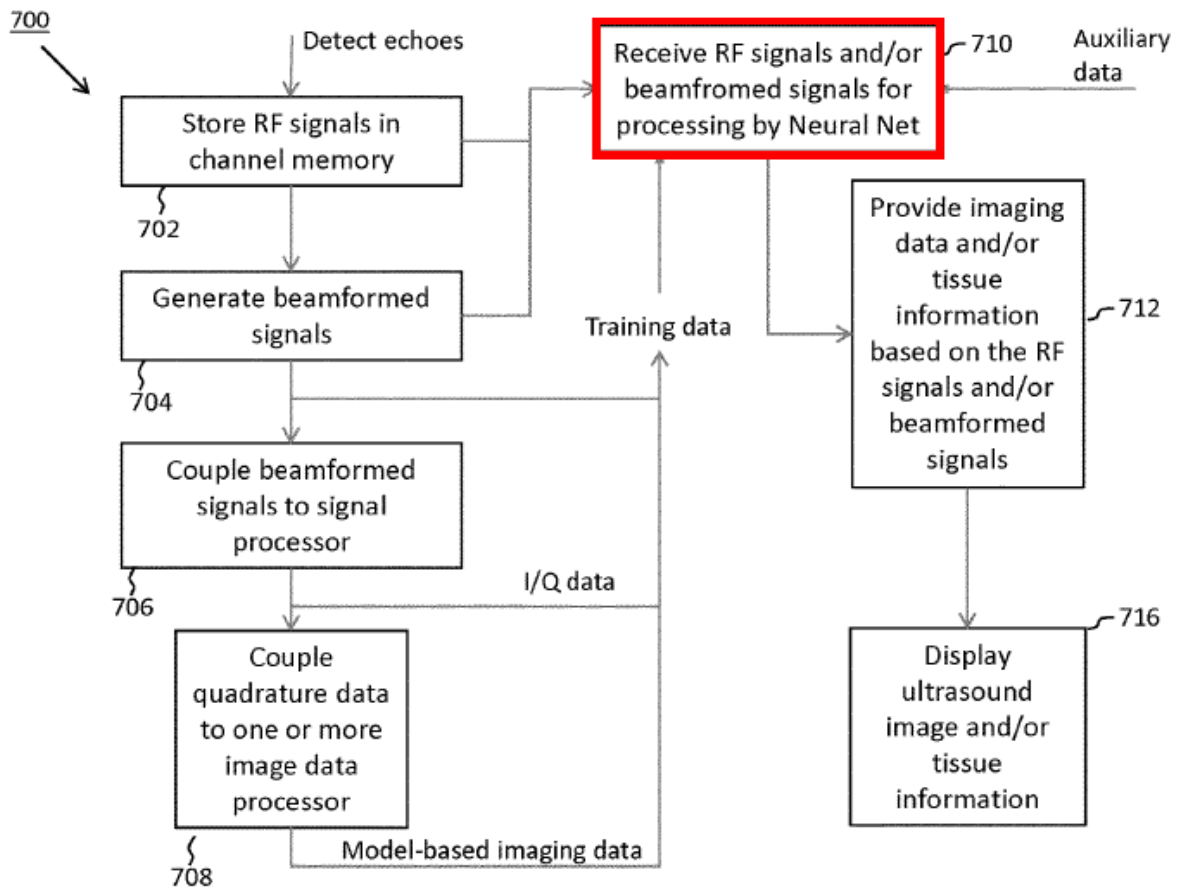


FIG. 7

Id., Fig. 7.

148. Box 710 of Figure 7 states “Receive RF signals and/or beamformed [sic] signals for processing by the Neural Net.” *Id.* This indicates that the processors of Hope-Simpson that are responsible for processing raw RF data with a machine learning model (in this case, a neural net) are also configured to receive the static set of raw ultrasound RF data. Therefore, the processors that I understand to be inherent in box 710 of Figure 7, outlined in red above, are configured to receive the static set

of raw ultrasound RF data.

149. Hope-Simpson also discloses the output of “acquired echo signals.” *Id.*, ¶[002]. These “acquired echo signals” are nothing more than raw RF data, and I understand them to be acquired via a transducer. Therefore, output of “a single static set of raw ultrasound data forming a single frame of a tissue area” would be standard transducer output when imaging tissue using ultrasound.

150. Further, Hope-Simpson discloses a transducer that 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....” *Id.*, ¶[005]. It is clear to me, therefore, that the transducer of Hope-Simpson is configured to output a single static set of raw ultrasound RF data forming a single frame of a tissue area. *See id.*, ¶¶[005]-[006].

**3. 6.2: processing the single static set of raw ultrasound
RF data set of windows to determine a power
spectrum**

151. Conventional approaches to interpreting ultrasound data using machine learning often use a two-step method of (1) partitioning the raw RF data into “windows” and (2) determining a power spectrum for each window. Indeed, this is a standard image processing approach in conventional ultrasound tissue characterization algorithms and is well known in the art. Therefore, anyone of

ordinary skill in my field would know how to do this. In this way, pre-processing the data into windows and a power spectrum for each window, as conventionally known, would put the data in a format that can be predictably and easily analyzed by a neural network.

152. The 330 Patent admits that processing the single static set of raw ultrasound RF data into windows and then determining the power spectrum for each window is prior art.

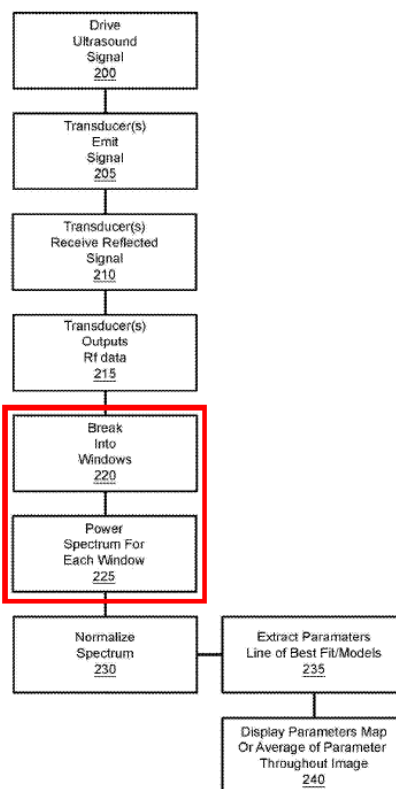


FIG. 2
(PRIOR ART)

EX1001, Fig. 2 (annotated).

153. Figure 2 from the 330 Patent, reproduced above, is described as “a flowchart showing a **prior art** method of tissue classification.” EX1001, 3:1-2 (emphasis added). Figure 2 depicts step 220 and 225, in red above, as “**break into windows**” (220) and “**power spectrum for each window**” (225). More specifically, the 330 Patent describes that “in **previously described systems** [e.g., prior art systems], the raw ultrasound data is typically **broken up into various windows** 220. Then, the **power spectral for each window** 225 may be determined.” *Id.*, 6:36-39 (emphasis added).

154. These windows are also shown in figure 7 of Nair.

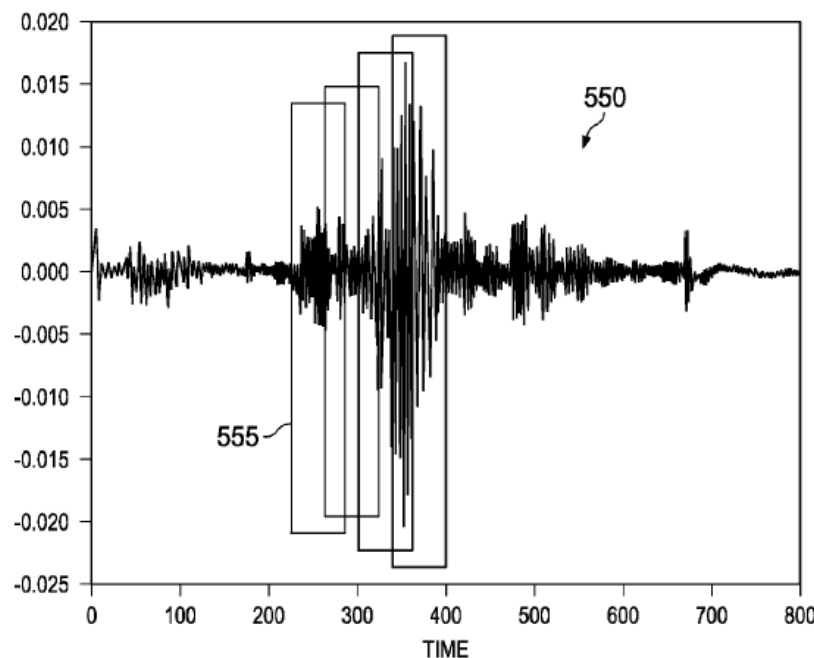


Fig. 7

EX1006, Fig. 7.

155. According to the disclosure of Nair, the scan line is analyzed in

segments represented by the **windows** illustrated in the figure, such as window 555. EX1006, ¶[0088] (emphasis added). The data within the window 555 is then transformed to a power spectrum density plot, which is shown in Figure 8 of Nair. Figure 8 of Nair is an illustration of a **power spectrum plot** generated from the data of Figure 7. *Id.*, ¶[0023] (emphasis added).

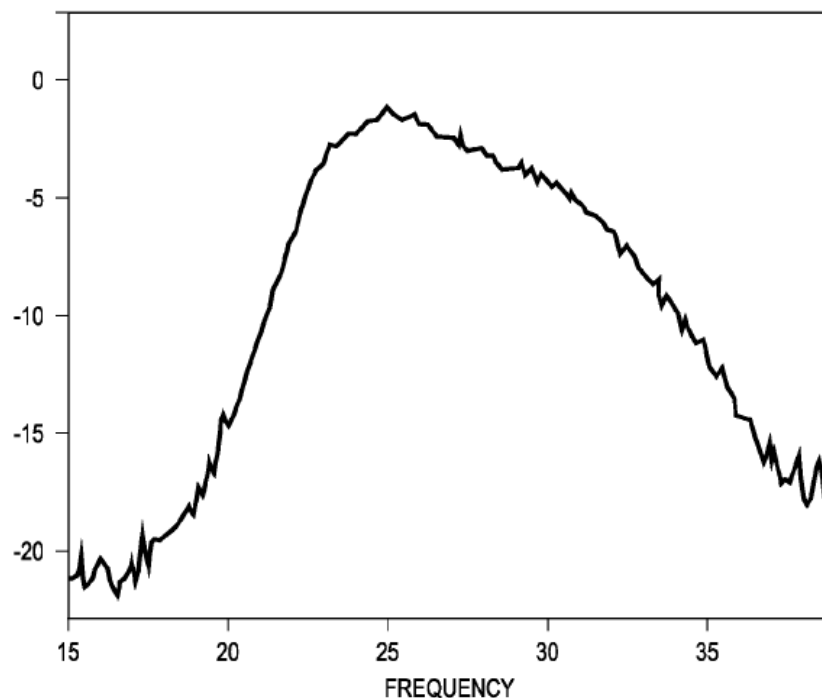


Fig. 8

Id., Fig. 8.

4. 6.3: processing the determined power spectrum as an input into a machine learning model

156. Hope-Simpson demonstrates that ultrasound tissue classification can be performed on complete data sets without the need for pre-processing signal properties. EX1005, ¶[030]. Using this method on heavily processed ultrasound

signals such as power spectra, whose properties are well demonstrated tissue classifiers, would yield similar results.

157. Hope-Simpson also discloses processing raw RF data before inputting it to the machine learning model. *Id.*, ¶[067]. It would be intuitive, therefore to process the power spectra (which is in turn processed RF data) as input into the machine learning model because this would provide a predictable and easily analyzed data format for a neural network, such as the one disclosed by Hope-Simpson, to analyze. Indeed, Hope-Simpson discloses that “the neural network may be operatively associated with a training algorithm configured to receive an array of training inputs and known outputs, wherein the training inputs include echo signals, beamformed signals, or combinations thereof associated with a region of imaged tissue and the known outputs include known properties of the imaged tissue.” *Id.*, ¶[010].

5. 6.4: outputting a classification of the tissue area from the machine learning model

158. As discussed with respect to claim 1 and 11, Hope-Simpson discloses outputting a classification of the tissue area, collectively referred to as tissue information, from RF signals. *Id.*, ¶[026]. Figure 7 details the process of performing tissue characterization using machine learning algorithms processing 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.*

159. Nair also discloses the step of outputting a classification of the tissue area from the machine learning model. For example, “the image data obtained can be used by the characterization application 250 to **output tissue characterization**... in real time.” EX1006, ¶[0204] (emphasis added). “[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**.” *Id.*, Claim 7 (emphasis added).

C. Dependent Claims 7-9, 12, 13, 15, 17, and 18

160. ***Dependent claim 7*** recites “[t]he method of claim 6, wherein the classification is a cancer status of the tissue.” Claim 6 is obvious in view of Hope-Simpson and Nair, as discussed above. It is my opinion that Hope-Simpson and Nair also render claim 7 obvious.

161. I understand “cancer status” to refer to the presence or state of cancerous tissue within a given sample. Determining the “cancer status” of tissue was a well-known and common application of ultrasound tissue classification. Thus, it would have\ been obvious to a POSA to characterize a cancer status of the tissue as claimed.

162. Indeed, the use of an ultrasound system to classify the cancer status of tissue was not new in the art. For example, an article from January of 2017 in the European Scientific Journal by Al-shamasneh and Obaidellah, titled “Artificial Intelligence Techniques for Cancer Detection and Classification: Review Study,” that “[t]his paper presents a review of the detection methods for lung, breast, and brain cancers. These methods used for 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.” EX1009, Abstract (emphasis added). In any event, a common, and therefore obvious, use of tissue classification or characterization is to classify tissue as “cancerous” or “non-cancerous” to aid in cancer diagnosis.

163. Moreover, Hope-Simpson discloses tissue characterization, as discussed above. *See, e.g.*, EX1005, ¶[025] (“[T]he neural network of an ultrasound system according to the present disclosure can be trained to produce images and/or tissue characterization.”). Nair also discloses tissue characterization. For example, “[t]he 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.” EX1006, ¶[0048]. In my opinion, Nair’s discussion of characterization information such as “type of tissue” or “different cell components

within the tissue” would include the cancer status of the tissue.

164. **Dependent claim 8** recites “[t]he method of claim 6, wherein the method further comprises processing the power spectrum to determine a normalized power spectrum.” Claim 6 is obvious in view of Hope-Simpson and Nair, as discussed above. It is my opinion that Hope-Simpson and Nair also render claim 8 obvious.

165. As discussed with respect to portions of claim 6 above, Figure 2 of the 330 Patent admits “a flowchart showing a **prior art** method of tissue classification.” EX1001, 3:1-2 (emphasis added). The steps of breaking the RF data into windows and determining a power spectrum from each window are represented in steps 220 and 225 of Figure 2. The following step, step 230, is “normalize spectrum.” *Id.*, Fig. 2. More specifically, the 330 Patent states “[t]hen, the power spectral for each window 225 may be determined, **and the spectrum normalized** 230.” *Id.*, 6:38-40 (emphasis added).

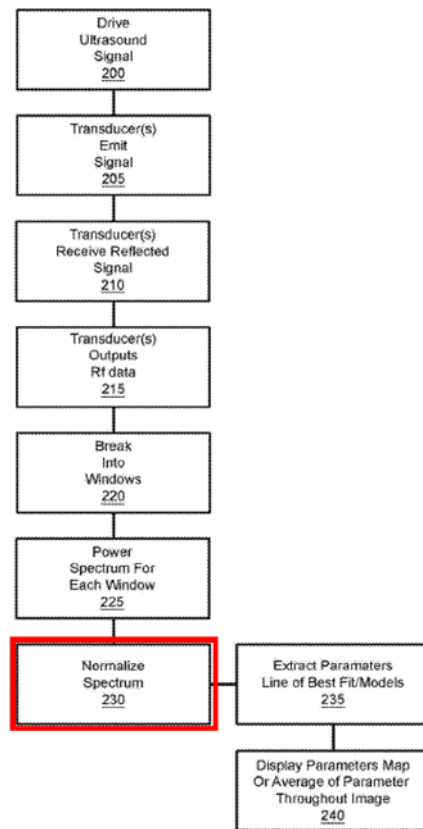


FIG. 2
(PRIOR ART)

EX1001, Fig. 2 (annotated).

166. Indeed, it is often necessary to normalize the power spectrum as a calibration mechanism. This is common in ultrasound tissue characterization applications. As discussed in the 330 Patent, the power spectrum would be normalized “to calibrate for certain hardware and parameters settings (to be independent to system and acquisition parameters properties).” *Id.*, 6:40-42.

167. **Dependent claim 9** recites “[t]he method of claim 6, wherein the power spectrum is taken using a continuous Fast Fourier Transform (FFT).” Claim 6 is

obvious in view of Hope-Simpson and Nair, as discussed above. It is my opinion that Hope-Simpson and Nair also render claim 9 obvious.

168. The use of an FFT is a standard method for computing power spectrum data for ultrasound tissue characterization applications. Nair discloses the use of a Fourier Transformation to produce a power spectrum plot, among other methods. EX1006, ¶[0090] (“Various transformation algorithms include a **Fourier transformation**, Welch periodograms, and auto-regressive modeling.”) (emphasis added). Claim 9 recites a *fast* Fourier transform, which simply means that the Fourier transform is efficient (*e.g.*, fast). The use of fast Fourier transforms was routine and common in the art at the time of the invention. Indeed, a POSA would have understood Nair’s description of the use of Fourier transformation to include the use of a fast Fourier transform. Therefore, it would have been a natural choice at the time of the invention for 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. Likewise, a POSA would have had a reasonable expectation of success in implementing a FFT to compute a power spectrum as claimed.

169. ***Dependent claim 12*** recites “[t]he 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 11 is anticipated by Hope-Simpson, as discussed above. It is my opinion that Hope-Simpson and Nair render claim 12 obvious.

170. As discussed above with respect to a portion of claim 6, the 330 Patent itself admits that the steps of (1) partitioning the raw RF data into windows and (2) determining a power spectrum for each window, are a standard approach to image processing in algorithms, which are well known in the art. Again, Figure 2 is “a flowchart showing a **prior art** method of tissue classification.” EX1001, 3:1-2 (emphasis added). Steps 220 and 225, which are below in red, are described as follows: “[I]n **previously described systems**, the raw ultrasound data is typically **broken up into various windows** 220. Then, the **power spectral for each window** 225 may be determined.” *Id.*, 5:36-38 (emphasis added).

171. Figures 7 and 8 of Nair also illustrate this process. In Figure 7, the scan line is analyzed in segments represented by the windows illustrated in the figure, such as window 555. EX1006, ¶[0088].

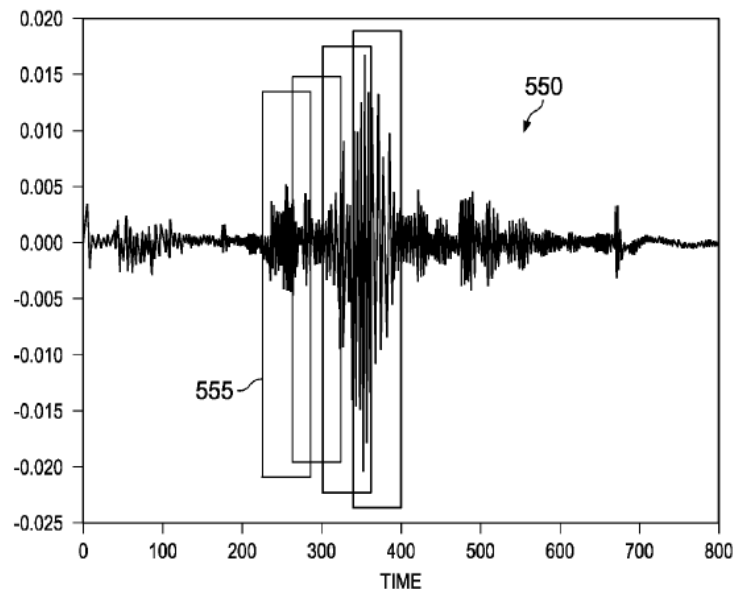


Fig. 7

Id., Fig. 7.

172. The data within the window 555 is then transformed to a power spectrum density plot, which is shown in Figure 8 of Nair. Figure 8 of Nair is an illustration of a **power spectrum plot** generated from the data of Figure 7. *Id.*, ¶[0023] (emphasis added).

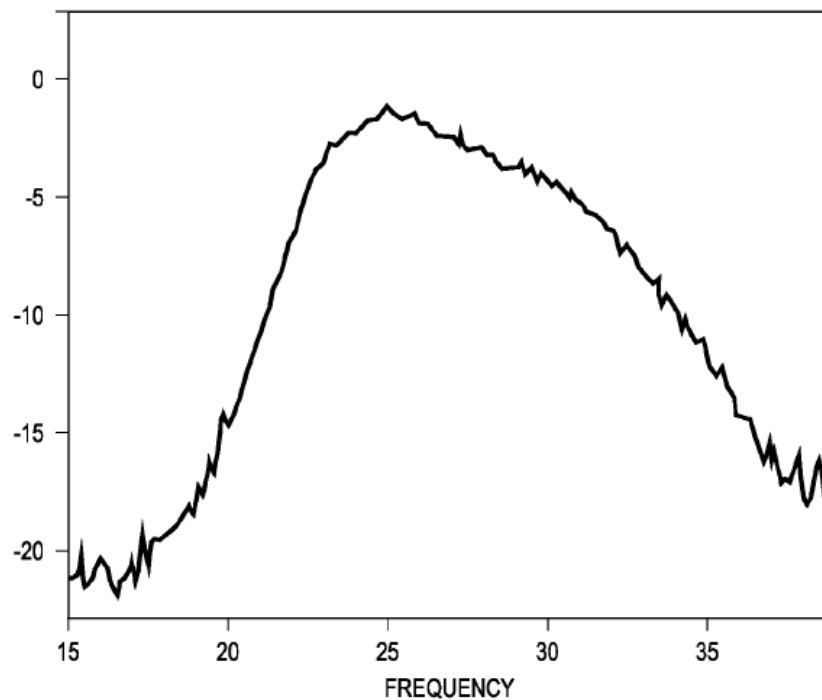


Fig. 8

Id., Fig. 8.

173. **Dependent claim 13** recites “[t]he 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.” This claim ultimately depends from claim 11, as claim 12 depends on claim 11. As discussed above, claim 11 is anticipated by Hope-Simpson and claim 12 is obvious in view of Hope-Simpson and Nair. It is also my opinion that Hope-Simpson and Nair render claim 13 obvious.

174. I interpret this claim as describing the processing step which computes frequency information for individual “windows,” or segments of original RF signals. The method involves taking segments of a signal (windows) and analyzing them

using a technique that looks at both the time and frequency aspects of the signal.

175. It is common in signal processing to take segments of a signal, which in this case would be the windows recited in the claim, and analyze them using a technique that looks at both the time and frequency aspects of the signal (e.g., a “time-frequency domain processing technique”). Hope-Simpson describes a system which uses neural networks to perform traditional physics-based models to derive imaging data. *See, e.g.*, EX1005, ¶[065]. It also describes the same method being used to perform tissue classification. *Id.* These traditional physics-based models would include a system which computes windowed power spectrum data from raw RF data and derives imaging data. A time frequency domain processing technique would be an obvious system to use for a task such as computing windowed power spectrum data from raw RF data. 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.

176. ***Dependent claim 15*** recites “[t]he method of claim 11, wherein the machine learning model is trained using ultrasound images labeled by a radiologist.” Claim 11 is anticipated by Hope-Simpson, as discussed above. In my opinion, the combination of Hope-Simpson and Nair renders claim 15 obvious.

177. As discussed with respect to claim 3, the process of preparing and labeling training data for machine learning algorithms has a high impact on the success of a classifying system, such as a system that uses a supervised 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 include known properties of the imaged tissue.” *Id.*, ¶[010]. I would understand that the labeling that Hope-Simpson discloses would often be done by a radiologist. Nair also discloses such a situation, where a clinician identifies and characterizes the tissue type(s) when preparing a tissue specimen for slide review. EX1006, ¶[0064]. “The identified tissue type(s) and/or characterization conclusions are provided to the characterization application 240 as characterization data.” *Id.*, ¶[0066]. A POSA would understand Nair’s “clinician” that identifies and characterizes tissue types, or labels the ultrasound images, to include a radiologist. Therefore, I understand a radiologist to be an obvious choice to label such data sets.

178. **Dependent claim 17** recites “[t]he method of claim 11, wherein the classification is a cancer status of the tissue.” Claim 11 is anticipated by Hope-Simpson, as discussed above. It is my opinion that Hope-Simpson and Nair render claim 17 obvious.

179. As discussed above with respect to claim 7, I understand “cancer status”

to refer to the presence or state of cancerous tissue within a given sample. Hope-Simpson discloses tissue characterization, as discussed above. *See, e.g.*, EX1005, ¶[025] (“[T]he neural network of an ultrasound system according to the present disclosure can be trained to produce images and/or **tissue characterization.**”) (emphasis added). Nair also discloses tissue characterization. For example, “[t]he 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.” EX1006, ¶[0048] (emphasis added). In my opinion, Nair’s discussion of characterization information such as “type of tissue” or “different cell components within the tissue” would include the cancer status of the tissue.

180. The use of an ultrasound system to classify the cancer status of tissue was not new in the art. For example, an article from January of 2017 in the European Scientific Journal by Al-shamasneh and Obaidellah, titled “Artificial Intelligence Techniques for Cancer Detection and Classification: Review Study,” states in its abstract that “[t]his paper presents a review of the detection methods for lung, breast, and brain **cancers**. These **methods used for 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.” EX1009, Abstract (emphasis added).

181. **Dependent claim 18** recites “[t]he method of claim 11, further comprising outputting a specific multi-parametric biomarker from the machine learning model.” Claim 11 is anticipated by Hope-Simpson, as discussed above. It is my opinion that Hope-Simpson and Nair render claim 18 obvious.

182. 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. Indeed, the use of multi-parametric tissue classification is well-documented in my field. *See, e.g.*, EX1010, 1:30-53 (discussing the use of multiple parameters such as effective scatterer diameter and effective acoustic concentration in tissue classification).

183. All three of the systems described above use multiple parameters. It is obvious to me that tissue classification applications would necessarily output biomarkers, and any biomarkers output from the above systems would be based on multiple parameters and thus be “multi-parametric biomarkers.”

D. Independent Claim 19

184. As discussed in more detail below, I have compared claim 19 to Hope-Simpson and Nair. In my opinion, Hope-Simpson and Nair render claim 19 of the 330 Patent obvious.

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

185. Hope-Simpson discloses an ultrasound system. There are many ultrasound system descriptions within the Hope-Simpson patent. Figures 1, 4, 5, and 6 are all exemplary ultrasound systems. For example, Hope-Simpson is titled **“Ultrasound Imaging System** with a Neural Network for Image Formation and Tissue Characterization.” EX1005, Title (emphasis added); *see also* Section IX(A)(1).

186. Figure 1 of Hope-Simpson depicts an ultrasound system. EX1005, ¶[016].

187. Figures 4, 5, and 6 also depict ultrasound systems. *Id.*, ¶¶[019]-[021] (“FIG. 4 is block diagram of **an ultrasound system**... FIG. 5 is block diagram of **another ultrasound system**... FIG. 6 is block diagram of **yet another ultrasound system**...” (emphasis added).

2. 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

188. In my opinion, this describes a normal ultrasound transducer. Many ultrasound transducers are, or can be, configured to output single static sets of RF data. Typically, a normal ultrasound transducer would acquire raw RF data in discrete sets, and it would be a routine matter to configure such a “discrete set” to equal a single frame of a tissue area.

189. Hope-Simpson discloses the output of “acquired echo signals.” *Id.*, ¶[002]. These “acquired echo signals” are nothing more than raw RF data, and I understand them to be acquired via a transducer. Therefore, output of “a single static set of raw ultrasound data forming a single frame of a tissue area” would be standard transducer output when imaging tissue using ultrasound.

190. Further, Hope-Simpson discloses a transducer that 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...” *Id.*, ¶[005]. It is clear to me, therefore, that the transducer of Hope-Simpson is configured to output a single static set of raw ultrasound RF data forming a single frame of a tissue area. *See id.*, ¶¶[005]-[006].

3. 19.2: a signal processing unit operable to:

191. Hope-Simpson discloses a neural network that may be implemented using a processor. *Id.*, ¶[027]. The “signal processing unit” here is described as a unit that may include one or more processors. EX1001, 1:56-57. Likewise, the “processor” of Hope-Simpson can be one or more processors. EX1005, ¶[027]. Because Hope-Simpson describes a processor which “may be multiple processors arranged in parallel,” this is synonymous with the signal processing unit of the 330 Patent.

4. 19.3: receive the single static set of raw ultrasound RF data;

192. The combination of Figures 1 and 2 of Hope-Simpson demonstrate that the ultrasound system of Hope-Simpson will produce, and process localized, static data sets comprised of raw ultrasound RF data. 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.

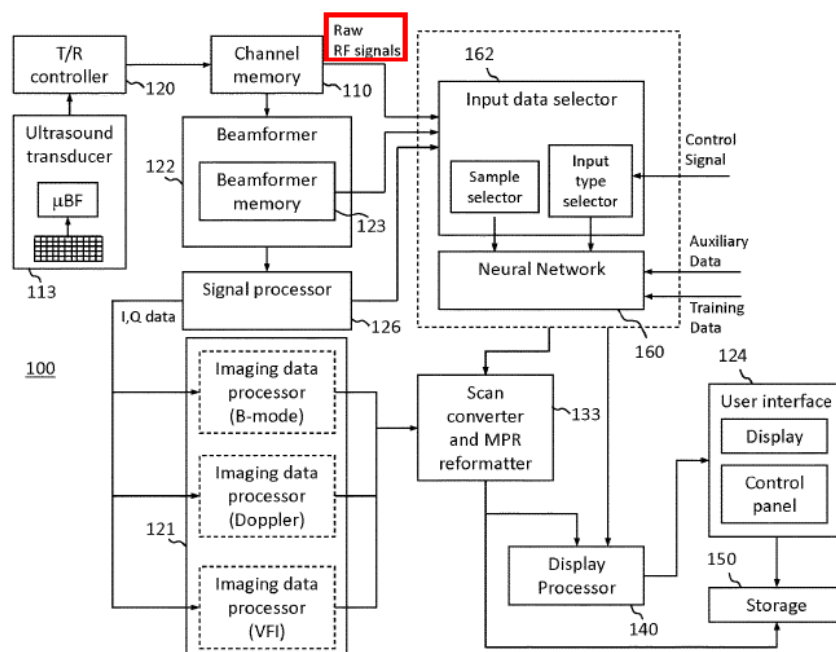


FIG. 1

EX1005, Fig. 1.

193. Indeed, the signals that are fed from the transducer to the channel memory and, ultimately, into the signal processing unit, are raw RF signals. “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] (emphasis added). “**The channel memory 110 may couple the RF signals to a neural network 160...**” *Id.*, ¶[030] (emphasis added).

194. Figure 2 of Hope-Simpson describes an example method for selecting a subset of a frame for processing based on a depth of interest. This is common in standard ultrasound imaging and conventional ultrasound tissue characterization.

195. Hope-Simpson also 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 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 (box 702) after being output by the transducer.

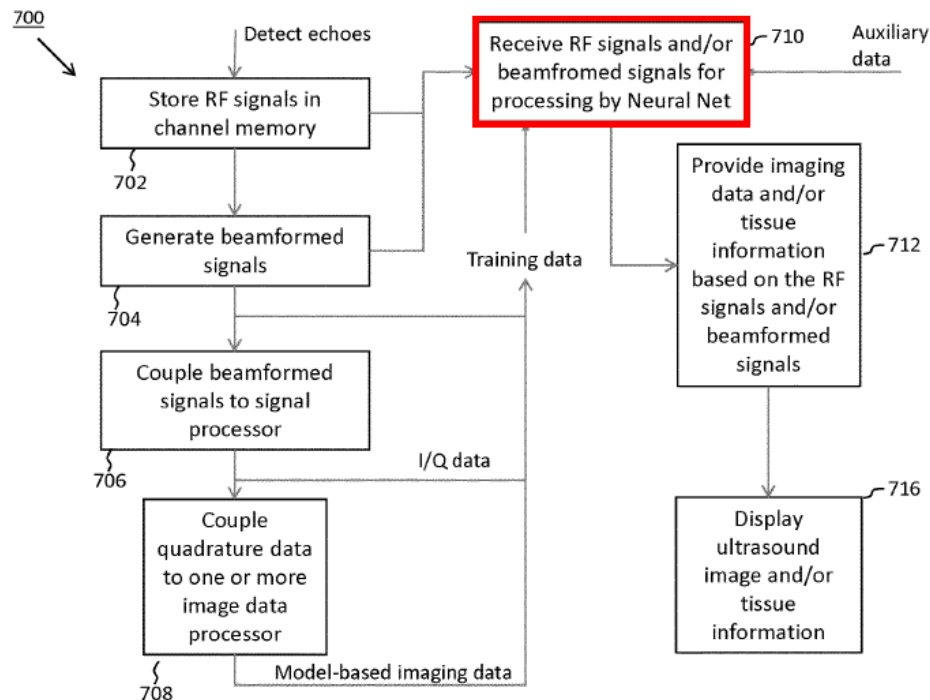


FIG. 7

Id., Fig. 7 (Annotated).

196. Box 710 of Figure 7 states “Receive RF signals and/or beamformed [sic] signals for processing by the Neural Net.” *Id.* This indicates that the processors of Hope-Simpson that are responsible for processing raw RF data with a machine learning model (in this case, a neural network) are also configured to receive the static set of raw ultrasound RF data. Therefore, the processors that I understand to be inherent in box 710 of Figure 7, outlined in red above, are configured to receive the static set of raw ultrasound RF data.

5. 19.4: process the set of single static set of raw ultrasound RF data to determine a raw power spectrum.

197. Calculating a power spectrum from ultrasound RF data is a common processing step in conventional ultrasound tissue characterization. Nair discloses transforming RF data to a power spectrum density plot as shown in Figure 8. EX1006, ¶[0088].

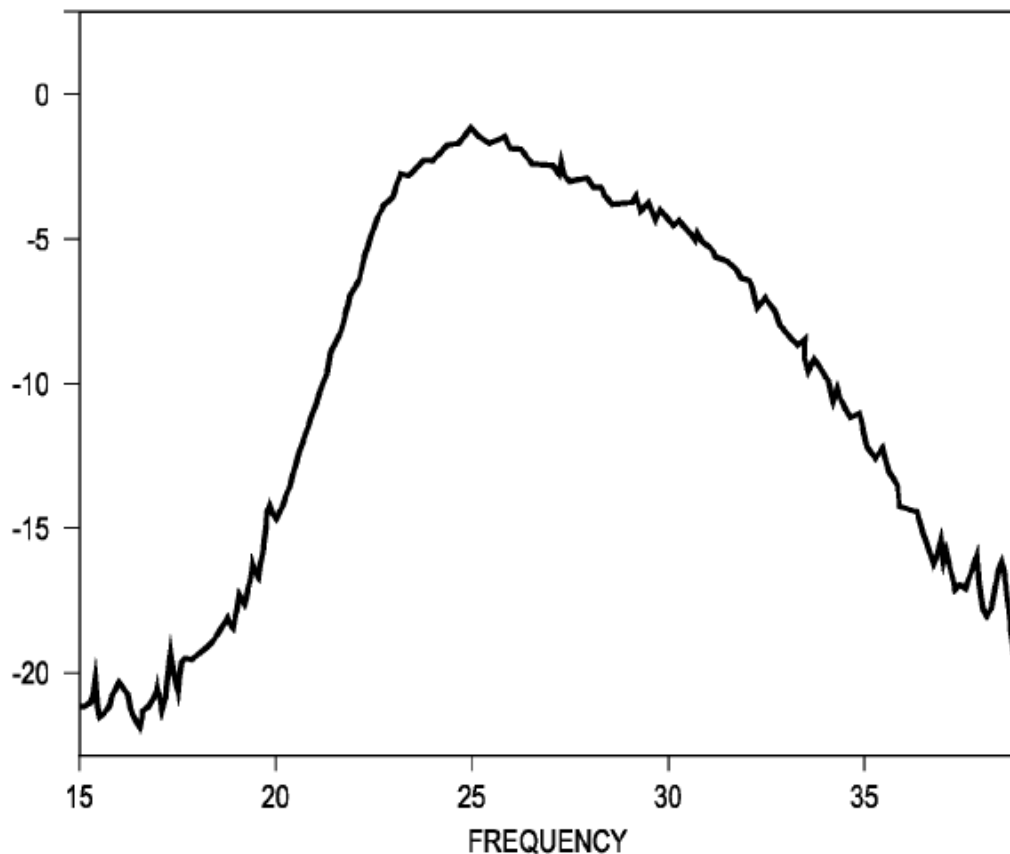


Fig. 8

EX1006, Fig. 8.

6. 19.5: process the raw power spectrum as an input to a machine learning model; and

198. Hope-Simpson demonstrates that ultrasound tissue classification can be performed on complete data sets without the need for pre-processing signal properties. EX1005, ¶[031]. This means that tissue classification can be performed on **raw RF data**. Notably, the “raw power spectrum” of this claim would be the same thing as the “determined power spectrum” (*e.g.* measured power spectrum) in claim 6, given that the power spectrum in this context is “determined” from the raw RF signal data. I also understand that using this method on heavily processed signals, such as power spectra, would yield a similar result. Indeed, it was well-known in the art that power spectra determined from ultrasound RF data could be used, and were often used, to characterize tissue.

7. 19.6: “output a classification of the raw power from an output of the machine learning model.

199. Claim 19’s reference to “classification of the raw power” is synonymous with claim 6’s “classification of the tissue area,” because the raw power spectrum in this case is completely dependent on the characteristics of the tissue area. As such, classification of the raw power spectrum is necessarily also a classification of the tissue area. Hope-Simpson discloses several 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.” *Id.*, ¶[025]. As another example, Hope-Simpson discloses that its system “may process the received signals in accordance with conventional physics-based pre-programmed models to derive the imaging data for producing ultrasound images.” *Id.*, ¶[065].

200. Nair also discloses the step of outputting a classification of the tissue area from the machine learning model. [T]he image data obtained can be used by the characterization application 250 to output tissue characterization... in real time.” EX1006, ¶[0204]. “[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.” *Id.*, Claim 7.

E. Dependent Claim 20

201. ***Dependent claim 20*** recites “[t]he 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 19 is obvious in view of Hope-Simpson and Nair, as discussed above. In my opinion, Hope-Simpson and Nair also render claim 20 obvious.

202. As discussed with respect to claim 5, the use of a display to visualize tissue classification is intuitive to me and does not represent any surprising or novel

activity. I have seen this sort of visualization most often in the form of full frame parametric frames or regions overlayed onto conventional ultrasound images. Frequently, the parametric image that is displayed has various colors, each color being associated with a value in a corresponding scale. Each color, therefore, is a unique identifier corresponding to a particular property of the power spectra.

203. Such use of a unique identifier based on the output of the machine learning model is disclosed by Hope-Simpson. Hope-Simpson describes several embodiments that perform a classification process and display an output image containing tissue characterization output from the machine learning model. *See, e.g.*, 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]. The color coding that Hope-Simpson discloses is, as discussed, a set of unique identifiers corresponding to particular properties. 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.

**XII. GROUND 4: HOPE-SIMPSON IN VIEW OF NAIR IN FURTHER VIEW OF AZIZI
RENDERS OBVIOUS DEPENDENT CLAIM 10 OF THE 330 PATENT**

204. In my opinion, Hope-Simpson in view of Nair and in further view of Azizi renders claim 10 of the 330 Patent obvious for at least the reasons described

herein. Hope-Simpson, Nair, and Azizi are analogous art because they each relate to systems for characterizing tissue status using reflected signals from the tissue of interest.

A. Dependent Claim 10

205. *Dependent claim 10* recites “[t]he method of claim 6, wherein the power spectrum is taken using a discrete FFT.” Claim 6 is obvious in view of Hope-Simpson and Nair, as discussed above. In my opinion, claim 10 is obvious in view of Hope-Simpson, Nair, and Azizi. Nair discloses the use of various transformation algorithms to produce a power spectrum plot, such as a Fourier Transformation. EX1006, ¶[0090]. I understand the “various transformation algorithms” of Nair to include foundational mathematical concepts such as discrete FFTs. Moreover, a POSA would understand that both a discrete FFT and a FFT used in this manner would produce the same output. Thus, the use of a FFT as discussed above with respect to claim 9 would be no different than the use of a discrete FFT as recited in claim 10.

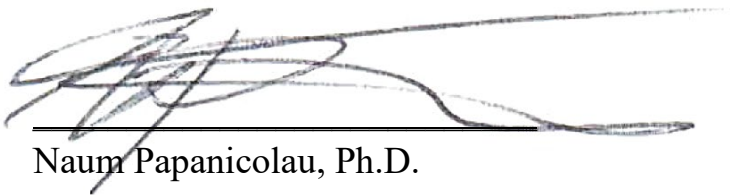
206. In any event, Azizi discusses the detection and grading of cancer tissue by using machine learning techniques to interpret ultrasound data. EX1007, Abstract. Therefore, to the extent that Nair does not disclose the use of a discrete FFT, Azizi discloses an example of an ultrasound tissue classification application which uses a discrete FFT to compute power spectra from raw RF signal data.

EX1007, p. 1296 (“For this purpose, **we take the Discrete Fourier Transforms** (DFT) of all zero-mean US time series corresponding to the RF samples in each ROI, normalized to the frame rate.”) (emphasis added). It would be advantageous to use a DFFT as disclosed by Azizi because it can efficiently process sequences of any size and it is particularly suited for digital signal processing that uses discretely sampled time inputs, such as the static windows in this context.

XIII. CONCLUSION

207. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: November 26, 2024



Naum Papanicolau, Ph.D.