IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CAPTION HEALTH, INC.
Petitioner

v.

UNIVERISTY OF BRITISH COLUMBIA
Patent Owner

U.S. PATENT NO. 11,129,591

Inter Partes Review No.: IPR2025-

DECLARATION OF DR. RAHUL CHANDRAKANT DEO

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I. INTRODUCTION

1. I have been retained by GE HealthCare Technologies Inc. ("GEHC") and its wholly owned subsidiary, Caption Health, Inc. ("Caption Health"), to provide a declaration in support of Caption Health's Petition for *Inter Partes* Review of U.S. Patent No. 11,129,591 ("the Patent") (Ex1001). The opinions presented here are my own and are based on my own personal knowledge.

2. The Patent contains claims that recite systems and methods for
for facilitating echocardiographic image analysis, as well as training a neural network to facilitate such analysis.

3. I have been asked to prepare this declaration explaining the reasons and bases for my opinions that claims 1-20 of the Patent are unpatentable. As discussed below, I have concluded that these claims would have been obvious to the person of ordinary skill in the art at the time of the alleged invention in light of prior art patent publications including U.S. Patent Application Publication No. 2005/0251013 ("Krishnan") (Ex1005), U.S. Patent Application Publication No. 2016/0247034 ("Lee") (Ex1006), U.S. Patent Application Publication No. 20107/0262985 ("Pagoulatos") (Ex1007) (Ex1008)(Ex1009), and a scientific journal article by Chen ("Chen") (Ex1010).

4. In reaching my opinions, I relied on the documents cited herein and on my decades of knowledge and experience in the field of medical image analysis

(outlined in **Section II**).

5. This report is based on information currently available to me. I reserve the right to supplement my opinions in response to arguments raised by the Patent Owner, University of British Columbia ("UBC" or "Patent Owner"), or in response to any additional information that becomes available to me.

II. QUALIFICATIONS AND EXPERIENCE

6. My qualifications for forming the opinions set forth in this declaration are summarized in the following paragraphs and listed in more detail in my curriculum vitae ("CV"), which is included with Petitioner's filing as Exhibit 1003.

7. I am currently Chief Product Officer and Chief Medical Officer at Atman Health, Inc. Atman Health, Inc. is a health technology company focused on building software for chronic disease management.

8. I received a B.S. in Chemistry from the University of Ottawa (Ottawa, Ontario, Canada) in 1995; a Ph.D. in Molecular Biophysics from the Rockefeller University (New York, NY) in 2001; and an M.D. from the Weill Cornell University Medical College (New York, NY) in 2003. I trained in internal medicine at Brigham and Women's Hospital and in cardiology at the Massachusetts General Hospital. I underwent postdoctoral training in machine learning at Harvard Medical.

9. Prior to my current position at Atman Health, Inc., I was Chief Data

Scientist at One Brave Idea, which comprises a group of multi-disciplinary scientists working to better understand how coronary heart disease is detected, prevented, and treated. My research at One Brave Idea included integrating experimental and computational approaches to address problems of heterogeneity in cardiovascular disease.

10. I am currently a Part-Time Lecturer at the Harvard Medical School. I was previously an Associate Professor in Medicine at Harvard Medical School. Prior to my time at Harvard Medical School, I served as an Associate Professor at the University of California San Francisco School of Medicine, and an Adjunct Associate Professor at the Northwestern University Feinberg School of Medicine.

11. I have engaged in several grant-funded research projects related to cardiology, and image recognition. Examples of some projects include: *Computer Vision Approaches to Detect Cardiotoxicity* (2017-2018); *Algorithms for Detection of Mitral Valvular Disease* (2019-2020); *Machine Learning for Automated Identification and Tracking of Rare Myocardial Diseases* (2018-2024). These projects involved training neural networks to analyze electrocardiogram and echocardiogram data to detect specific cardiac diseases. A standard part of echocardiogram image analysis involved classification of videos according to standardized views and assessment of video quality, and my team trained multiple neural networks towards this goal.

12. I have authored or contributed to over 60 publications in the field. Examples include: *Artificial intelligence-enabled fully automated detection of cardiac amyloidosis using electrocardiograms and echocardiograms*, NATURE COMMUNICATIONS (2021), *Fully Automated Echocardiogram Interpretation in Clinical Practice*, 138 CIRCULATION 16 (2018); *Automated and Interpretable Patient ECG Profiles for Disease Detection, Tracking, and Discovery*, 12 CIRC. CARDIOVASC. QUAL. OUTCOMES (2019). Other authored or co-authored papers include *Machine Learning in Medicine*, PMC5831252 (2015); and *Learning About Machine Learning: The Promise and Pitfalls of Big Data and the Electronic Health Record*, 9 CIRC. CARDIOVASC. QUAL. OUTCOMES 6, 618-20 (2016); and *Multinational Federated Learning Approach to Train ECG and Echocardiogram Models for Hypertrophic Cardiomyopathy Detection*, CIRCULATION, 146:755–769 (2022).

13. I have given numerous presentations and seminars in the field. Examples of some presentations include: *Application of Machine Learning to Cardia Imaging* (2019; Massachusetts Institute of Technology); *A Primer on Unsupervised Learning* (2016; American Heart Association Scientific Sessions); *Machine Learning: Personalized Diagnosis and Therapy* (2019; European Commission's HUMAINT).

14. I have served on the editorial boards of several publications. For

example, I served on the Editorial Board of *Trends in Cardiovascular Medicine* (2014-present), *Circulation: Cardiovascular Genetics* (2016-2017), and *Circulation: Cardiovascular Quality and Outcomes* (2016-present). I was an Associate Editor on *Circulation: Genomic and Precision Medicine* (2017-2022).

15. My professional *curriculum vitae* details my education, experience, and publications, as briefly summarized above, as well as an overview of some of my experience that is relevant to the matters set forth in this declaration.

III. COMPENSATION AND PRIOR TESTIMONY

16. With respect to this matter, I am working as an independent consultant. I am being compensated at an hourly rate of $500 USD, plus expenses, for the time I spend working on this matter. I have never been adverse to the University of British Columbia in any proceeding. I own no stock in GEHC or Caption Health and am aware of no other financial interest I have relating to GEHC or Caption Health. My compensation is not contingent upon the outcome of this matter.

17. I have not testified in any other matters in the last five years.

IV. LEGAL STANDARDS

18. Although I am not an attorney and do not expect to offer any opinions regarding the law, I have been informed of certain legal principles that I relied on in forming the opinions set forth in this report.

A. Priority Date

19. I have been asked to assume that the priority date of the Patent is April 21, 2016.

B. Claim Construction

20. I understand that in an *inter partes* review proceeding the claims of a patent are construed using the same claim construction standard that would be used to construe the claims in a civil action. I understand that under this standard the words of a claim are generally given their ordinary and customary meaning. I understand the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. I understand the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but also in the context of the entire patent, including the specification. I have not been asked to offer an affirmative opinion on claim construction. As set forth below, it is my opinion, that the identified prior art references cited and discussed below disclose or teach the elements of claims 1-20 of the Patent.

C. Obviousness

21. I understand that a patent claim is invalid if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of

ordinary skill in the pertinent art.

22. I understand that a person of ordinary skill in the art provides a reference point from which the prior art and claimed invention should be viewed. This reference point prevents one from using his or her own insight or hindsight in deciding whether a claim is obvious.

23. I also understand that an obviousness determination includes the consideration of various factors such as (1) the scope and content of the prior art, (2) the differences between the prior art and the asserted claims, (3) the level of ordinary skill in the pertinent art, and (4) the existence of secondary considerations of obviousness or non-obviousness.

24. I understand that an obviousness determination can be based on a single prior art reference, a combination of multiple prior art references, or a combination of prior art references and the patentee's admissions regarding the scope and content of the prior art.

25. I understand that the prior art itself may provide a suggestion, motivation, or reason to combine or modify the teachings of the prior art, or that such a reason may come from other sources, such as the knowledge of a person having ordinary skill in the art, common sense, and market forces. I understand that the following rationales may support a finding of obviousness:

- Combining prior art elements according to known methods to yield predictable results;

- Simple substitution of one known element for another to obtain predictable results;

- Use of a known technique to improve similar devices, methods, or products in the same way;

- Applying a known technique to a known device, method, or product ready for improvement to yield predictable results;

- "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

26. I understand that a patentee's admissions, for example in the specification of the patent, are permissible evidence for establishing the background knowledge possessed by a person of ordinary skill in the art and provide a factual foundation as to what a skilled artisan would have known at the time of invention.

27. I understand that a patentee's admissions regarding the scope and content of the prior art can be used to: (1) supply missing claim limitations that were generally known in the art prior to the effective filing date of the claimed invention; (2) support a motivation to combine particular disclosures; or (3) demonstrate the knowledge of an ordinarily skilled artisan at the time of the effective filing date of the claimed invention.

28. I understand that an obviousness determination when combining or modifying prior art elements requires a reasonable expectation of success in achieving the claimed invention.

29. I understand that secondary considerations of non-obviousness may include: (1) a long felt but unmet need in the prior art that was satisfied by the invention of the patent; (2) commercial success or lack of commercial success of processes covered by the patent; (3) unexpected results achieved by the invention; (4) praise of the invention by others skilled in the art; (5) the taking of licenses under the patent by others; (6) deliberate copying of the invention; (7) teaching away; and, *contra*, (8) the simultaneous invention of the claimed subject matter. I understand that contemporaneous and independent invention by others is a secondary consideration supporting an obviousness determination.

30. I understand that any secondary consideration must bear a nexus to the claimed invention. Where the offered secondary consideration actually results

from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention. For example, when commercial success is due to marketing rather than the patented features of a product, the commercial success is not an indication of non-obviousness. I further understand that the patentee bears the burden of demonstrating that the relevant commercial success is attributable to the claimed invention, as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter.

D. Person of Ordinary Skill in the Art ("POSITA")

31. I have been informed that a person of ordinary skill in the art is a hypothetical person who is presumed to have known all the relevant art at the time of the invention. I have been informed that the person of ordinary skill in the art may possess the education, skills, and experience of multiple actual people who would work together as a team to solve a problem in the field. I have been informed that factors that may be considered in determining the level of ordinary skill in the art may include: (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the educational level of active workers in the field.

32. Based on my consideration of these factors and my experience in the field of medical image analysis, I have been asked to opine as to the level of skill

of the hypothetical person of ordinary skill in the art ("POSITA") to which the Patent is directed. In my opinion, the hypothetical person of ordinary skill in the art would include a person who, at the time of the invention, had an advanced degree in Computer Engineering, Computer Science, Physics, or other field related to computer imaging, and at least 1 year of research experience training machine learning models to analyze ultrasound data.

33. I have undertaken to consider the knowledge the POSITA would have had as of April 21, 2016, which is the date I have been asked to assume is the priority filing date for the Patent. When I refer to the POSITA in this declaration in my discussion of the Patent, I am referring to a person of ordinary skill in the art as of that date.

V. TECHNOLOGICAL BACKGROUND

34. I have been asked to provide a brief background discussion relating to the technologies and terminology at issue. Except where otherwise noted, this background is based on my personal knowledge and experience in the relevant fields as described above.

A. Medical Imaging Modalities

35. Medical imaging is a non-invasive technology for visualizing and quantifying the structure inside the human body—as well as its function—thus aiding clinicians in the diagnosis and treatment of various medical conditions and

diseases. Over the last century, the science of medical imaging has developed into a robust and diverse field, encompassing a wide range of techniques and technologies designed to address the myriad organs and tissues in the body, as well as the many different disease or disorder states.

1. Ultrasound Imaging

36. Ultrasound is a commonly used medical imaging modality and is employed to capture an anatomic representation of diverse organ systems, including the abdomen, the thyroid, skeletal muscle and the heart. Ultrasound uses a probe to emit ultrasound waves which are then reflected by tissue, captured by a transducer, and reconstructed to typically provide a two-dimensional view of the tissue of interest. The image observed depends on the location of the probe on the body space, its angle in space, as well as the amount of pressure placed on it. The potential number of possible images is infinite, which makes clinical interpretation challenging.

37. To overcome this limitation, radiologists have adopted a series of standardized two-dimensional planes or "views" which highlight critical structures of interest. By way of example, for cardiac ultrasound imaging, the American Society of Echocardiography (ASE) recommends using standard ultrasound views in B-mode to obtain sufficient cardiac image data—the apical two-chamber view (A2C), the apical four-chamber view (A4C), the apical long axis view (ALAX),

the parasternal long axis view (PLAX), and the paternal short axis view (PSAX). *See* Ex1005, [0019]; Ex1020 (Lang). These standard views are used to derive specific measurements such as the area or thickness of cardiac chambers. Image quality assessment in ultrasound imaging is typically view-specific and includes the ability to visualize key structures, which differ by view. *See* Ex1021 (Salomon).

38. Still, acquisition of these "standard" views can be challenging for non-experts. It has thus been a longstanding area of interest to use artificial intelligence methods to assist users in capturing and confirming standardized views.

2. Artificial Intelligence

39. Artificial Intelligence (AI) is a broad concept that generally refers to any technique that enables computers to mimic human intelligence. Applications for AI in the field of medical imaging are numerous and include complex tasks such as object identification in images.

40. There are several objectives in the field of artificial intelligence. One objective is the study of how computers can improve perception, thinking, or actions based on data and experience. Another objective, often referred to as computer vision, involves training machines to accomplish tasks carried out by the human visual system, specifically interpretation of images or videos. Computer

vision generally involves classification (i.e., where the machine determines whether an image or video contains a specific object or representation of a specific action) and/or segmentation (i.e., where the machine locates the boundaries of an object within the image).

41. Computer vision algorithms date back at least to the 1960's and more general machine learning algorithms date back even further.

42. Machine learning is a subset of AI that focuses on the development of algorithms that allow computers to learn from, and make predictions based on, data. Instead of being explicitly programmed to perform a task, machine learning algorithms are trained on large datasets and use statistical techniques to identify patterns and make decisions based on predictions.

43. Deep learning is a specialized subset of machine learning that uses artificial neural networks with many layers (hence "deep") to analyze and iteratively learn from data such as images.

3. Neural Networks

44. An artificial neural network is a computational model inspired by the highly interconnected structure of neurons in the human brain. It consists of interconnected nodes (like neurons) organized in layers. Each connection between neurons in adjacent layers has an associated weight, and the selected weight for each connection of the cumulative network determines the ability of the network to

accurately predict outcomes (*e.g.*, whether an image contains the number "8").

45. Artificial neural networks often use supervised learning, meaning that the model is trained with labeled data (*e.g.*, labeled pictures of cats and dogs) to make a prediction about how new data should be labeled (*e.g.*, cat or dog). Specifically, the process of supervised training adjusts the weights between each interconnected node of the network to minimize the error in predicted outputs.

46. Neural networks are a type of machine learning algorithm that attempts to mimic the human visual system by stacking a series of layers of "neurons," each of which represent a transformation of the prior layer of numerical data. Non-linear transformations used between layers in neural networks introduce more flexibility. The transformed data can then be used for some of the tasks described above, such as classifying an image. For instance, as early as 1990, neural networks were used in recognizing handwritten digits. Ex1022 (LeCun).

47. Neural networks trained for image recognition were known in the art well before 2016. And, as of April 2016, it was recognized that neural networks could be implemented in a wide variety of applications, including medical imaging. For example, Hao Chen et al., *Standard Plane Localization in Fetal Ultrasound via Domain Transferred Deep Neural Networks*, (Sept. 2015) (Ex1010) (Chen) used convolutional neural networks to analyze fetal ultrasound images. *See also* Ex1023 (Bouzerdoom). Methods of training such networks were also well

documented in the art. Ex1011, p.450 ("For a network to be trained … a 'training' data set of example inputs and their corresponding desired outputs is required…. During learning the example inputs are presented to the network and the resultant and desired outputs are compared.")

48. Trained neural networks had been applied to cardiac imaging. As early as 1999, U.S. Patent No. 5,906,578 to Rajan described using a trained neural network to analyze cardiac ultrasound image data and provide real-time guidance to an ultrasound technician during data collection. Ex1013. Later publications provided even more examples of pairing trained neural networks with cardiac ultrasound imaging systems. U.S. Patent Application Publication No. 2009/0074280 ("Lu") (Ex1014) published in 2009, described collecting three-dimensional echocardiographic data and processing such data with neural network classifiers to determine whether desired views of the heart were being collected. Ex1014. A 2007 patent publication, U.S. Patent Application Publication No. 2007/0055153 ("Simopoulos"), described using convolutional neural networks to facilitate image recognition of cardiac ultrasound images. Ex1015. Krishnan similarly describes using neural network classifiers to perform real-time analysis of cardiac images and provide users with guidance on adjusting an ultrasound probe. Ex1005. As yet another example, a 2014 article, Beatriz González et al., *Echocardiogram Image Recognition Using Neural Networks in Recent Advances*

on Hybrid Approaches for Designing Intelligent Systems, 427-35 (2014) ("González"), described training a neural network with cardiac images, 427-29. Ex1016. Once trained, the neural network demonstrated good results in cardiac view recognition.

4. Neural Network Architecture

49. Neural networks can be adapted to a wide variety of tasks by varying the network architecture which consists of the arrangement of layers and the connections between them. In 2014, Donahue et al. described a neural network architecture to process videos (temporal sequences of images). Donahue et al.'s contemplated neural network consisted of one or more convolutional neural network (CNN) layers. Ex1017.

50. At a high level, CNNs are constructed of convolutional layers of nodes that apply filters to the input image, looking for hierarchical patterns (*e.g.*, edges, curves, circles), and creating feature maps that depict detected patterns. Eventually, fully connected layers of the CNN evaluate the features extracted by the convolutional layers to make final predictions including, for example, whether a particular pixel of an image is part of a particular organ that the neural network has been trained to look for. In this way, artificial neural networks can segment organs or bones in a medical image by accurately predicting which pixels in the image correspond to a particular organ or bone.

51. The CNN described in Donahue et al. applied a convolution or linear transformation to individual pixels within the image in order to extract useful features (e.g., edges), followed by one or more recurrent neural network (RNN) layers which integrated information from the preceding or following image in a temporal sequence. Ex1017. The type of RNN they proposed to use is called long-short term memory (LSTM). *See* Ex1026. Donahue et al. showed that neural networks with this architecture could be trained to perform a variety of complex computer vision tasks such as classifying the video in terms of the various categories of action that it contains. Medical applications of this same architecture were seen as early as 2015 in Chen, where an LSTM was used to classify the view plane of fetal ultrasound images. Ex1010, p.509 ("Fig. 2 (left) shows the architecture of the proposed T-RNN, which is a hybrid model integrating deep convolutional neural networks (CNN) and recurrent neural networks (LSTM model).")

5. Multi-Task Learning

52. Although neural networks can be trained to perform complex tasks, they typically require a large amount of labeled training data. For example, training a neural network to classify the view of ultrasound images typically requires thousands of images representing a diversity of views, each with an expert assigned label.

53. Often a user needs neural networks for multiple distinct yet related tasks, none of which have adequate numbers of training examples on their own. Caruana showed in 1993 that multi-task learning (MTL) is far more efficient than training individual neural networks for each task. *See* Ex1018. The architecture of such a network consists of multiple shared hidden layers, which typically are responsible for feature extraction from the raw inputs, followed by multiple distinct task-specific layers, which use these extracted features as inputs. The parameters of the shared layers are learned using all the training examples, while the parameters of the individual task-specific layers are learned only using the labeled examples appropriate for that task. Unsurprisingly, this technique was used broadly across computer vision applications including in medical imaging. For example, Chen used MTL to train neural networks to recognize individual view planes from fetal ultrasound image. Ex1010, p.510 ("Previous studies have indicated that the knowledge learned from one domain or task via CNN could benefit the training for another domain or task with limited annotated data [6]. Inspired by these studies, it is reasonable to speculate that leveraging the transferred knowledge across similar US detection tasks can mitigate the challenge of insufficient training data for a specific task as well as improve the generalization performance of the learning. To the end, we propose a joint learning model with CNN across multiple detection tasks of US standard planes, as illustrated in

[Figure 2].")

VI. THE '591 PATENT AND PROSECUTION HISTORY

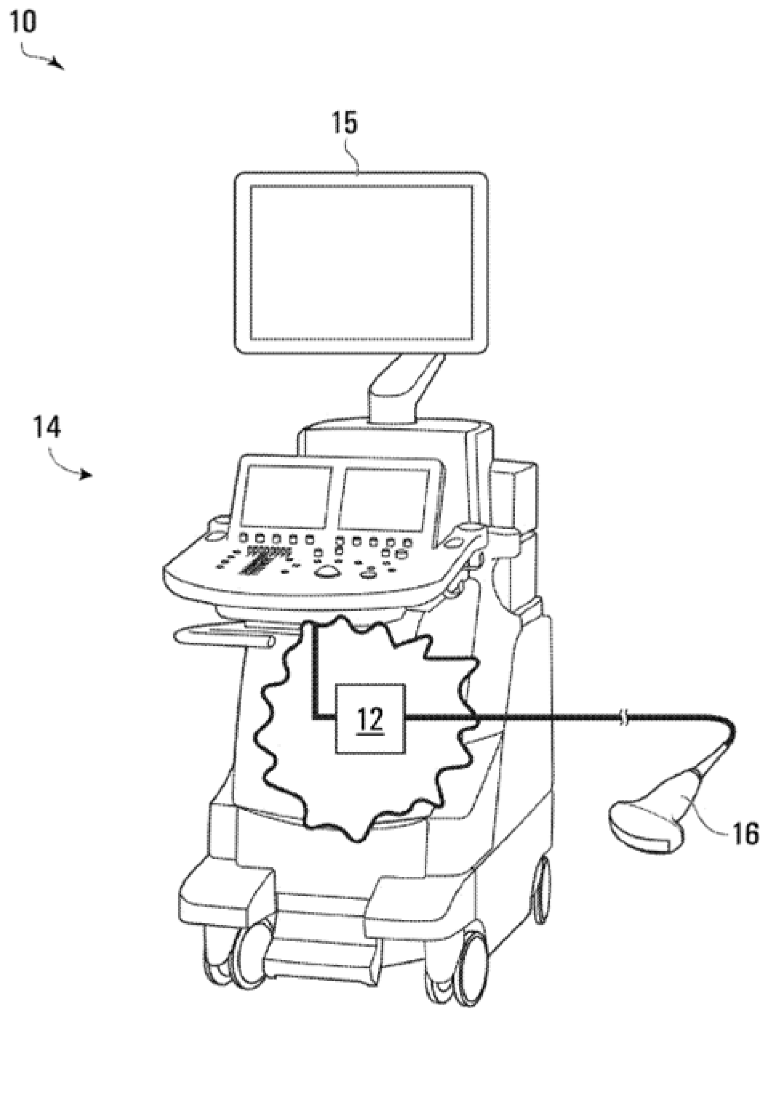
54. The Patent, entitled "ECHOCARDIOGRAPHIC IMAGE ANALYSIS," was filed as a PCT application on October 22, 2018 and issued on September 28, 2021. Ex1001, cover. I have been instructed by counsel to conservatively treat April 21, 2016 as the priority date of the Patent, which is the filing date of priority Provisional Application No. 62/325,779.

55. The Patent explains that "cardiac ultrasound, better known as echocardiography (echo), is the standard method for screening, detection, and monitoring of cardiovascular disease. This noninvasive imaging modality is widely available, cost-effective, and may be used for clinical measurement of anatomical features which may then be used for evaluation of cardiac structure and/or function." Ex1001, 1:23-29.

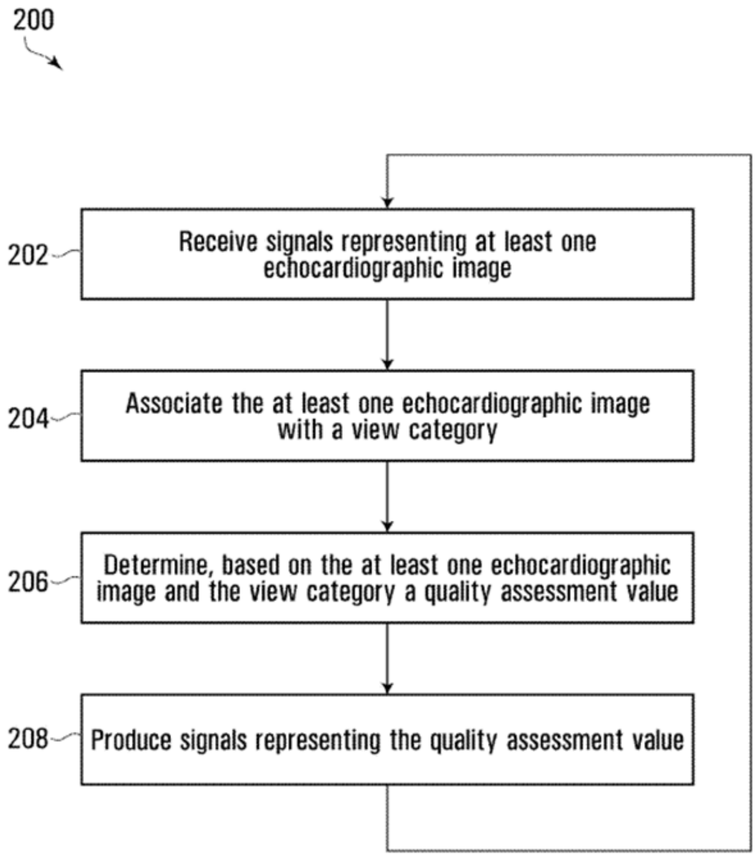
56. According to the Patent, "existing echocardiographic systems may be configured to provide feedback regarding general properties of captured images. However, this feedback may not assist echocardiographers in capturing high quality echocardiographic images for use in subsequent quantified clinical measurement of anatomical features." Ex1001, 1:30-34. The Patent purports to identify an invention relating to "echocardiographic image analysis and more particularly to echocardiographic image analysis for image quality assessment."

Id., 1:15-17.

57. The Patent identifies Figure 1, below, as "a schematic view of a system for facilitating echocardiographic image analysis in accordance with various embodiments of the invention." Ex1001, 3:60-63, Fig. 1.



58. The Patent discloses and claims an echocardiographic image analysis workflow shown in Figure 3 below:



Ex1001, 7:53-8:65, Fig. 3. Figure 3 is "a flowchart depicting blocks of code for directing the analyzer [(12)] of the system of [Figure 1] [(shown above)] to perform image analysis function in accordance with various embodiments of the invention." *Id.,* 4:1-4. At block 206, the workflow utilizes multiple neural networks to generate quality assessment values for images from various view categories. Ex1001, 11:27-51. Specifically, to provide a quality assessment for each image that is tailored to the view category of the image, the Patent uses "a plurality of sets of parameters, each set defining a neural network," where "each of the sets of parameters may be associated with a view category to indicate that the set of parameters defines a neural network that is to be applied to echocardiographic images which are associated with that view category." *Id*., 11:52-59. Thus, "each of the image view categories AP2, AP3, AP4, $PSAX_A$, and PSAXPM may be associated with a view category specific neural network…." *Id*., 13:48-52.

59. Figure 8, below, depicts an "exemplary image quality assessment neural network that may be used" (Ex1001, 4:15-17), which the Patent characterizes as a "multi-stream network" (*id*., 12:31-35) that "includes 5 image quality assessment neural networks" (*id*., 12:10-18). Each of the five-image quality assessment neural networks (370, 372, 374, 376, 378) share some common neural network layers with comment assessment parameters but also include view-specific neural network layers with view-specific assessment paraments. *Id*., 12:7-21, 12:31-35, 13:5-11, Figs. 9-10.

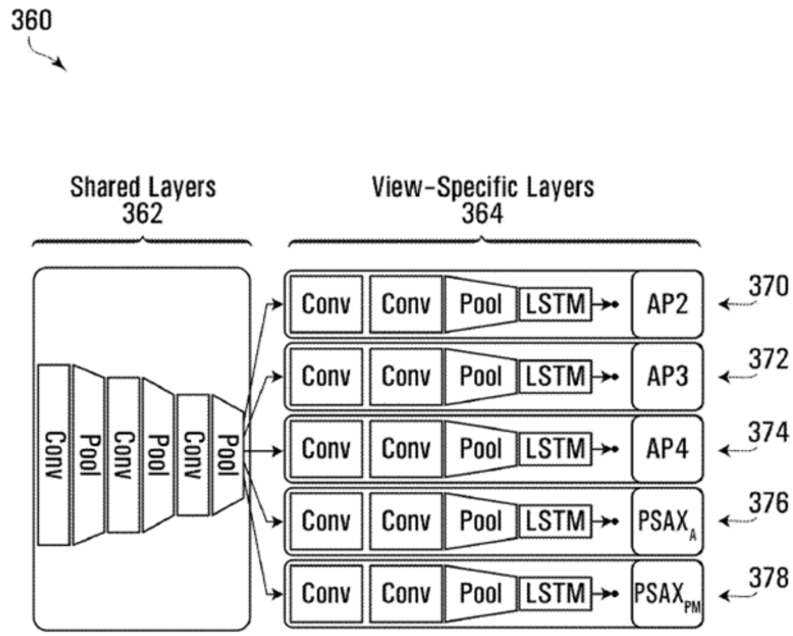


FIG. 8

60. Figure 12, below, depicts "a representation of an exemplary quality assessment record that may be used in the system shown in [Figure 1]." Ex1001, 4:27-29.

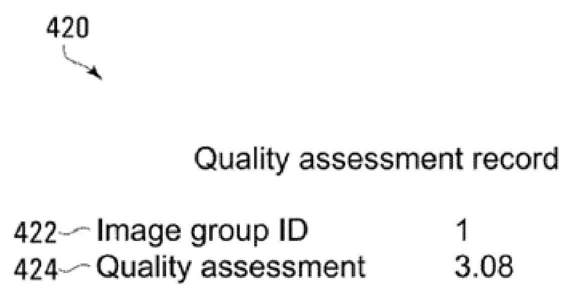


FIG. 12

61. The Patent states that "splitting the neural network 360 into a common portion and view category specific portions may facilitate more efficient training of the neural networks" and "may require fewer learning parameters than would be required if using fully separate neural networks." Ex1001, 13:53-61.

62. The Patent describes "training" neural networks for its workflow by using a "plurality of echocardiographic training images" and "associated expert quality assessment values to determine sets of neural network parameters defining the neural networks." Ex1001, 2:2-11, Figs. 14, 16. More specifically, as shown below in Figure 14, the Patent contemplates a "neural network trainer" (502, below) that is "configured to retrieve and/or receive the echocardiographic images, which may act as echocardiographic training images, from the training image source 504." *Id.,* 18:1-4. "In some embodiments, the neural network trainer 502 may, after receiving the training images, produce signals representing the echocardiographic training images and associated view categories to cause the user interface system 506 to present the echocardiographic images and the view categories to one or more experts, such as, echocardiographers or physicians trained in echocardiography." *Id.,* 18:5-11.

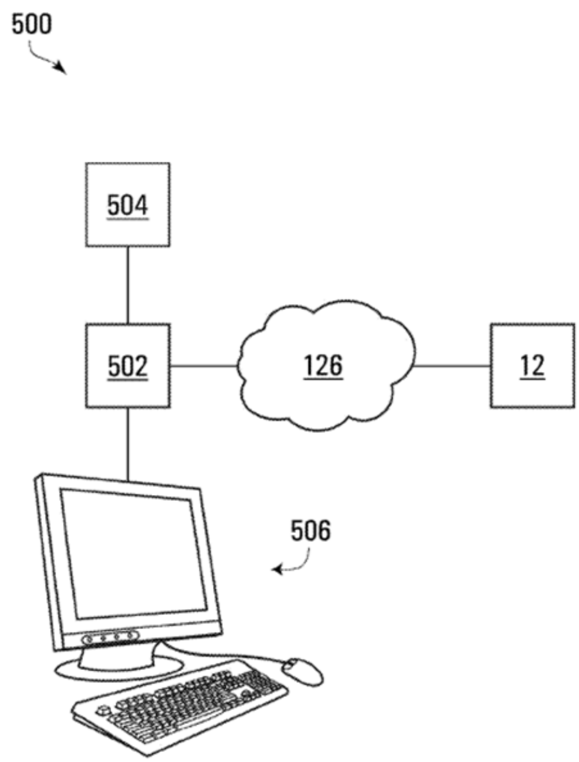


FIG. 14

63. According to the Patent, "after quality assessment values have been received and associated with each set of echocardiographic training images, the neural network trainer 502 may train neural networks using the echocardiographic training images as inputs and the associated expert quality assessment values as desired outputs to determine sets of neural network parameters defining the neural networks, wherein at least a portion of each of the neural networks is associated with one of the image view categories." Ex1001, 18:27-35.

64. I have reviewed the prosecution file history of the Patent, Ex1004, which is available digitally from the United States Patent and Trademark Office website, www.uspto.gov.

65. The Patent issued from U.S. Patent Application No. 16/095,601 ("the Application"), which was filed on October 22, 2018.

66. In a first Office Action, dated May 5, 2021, the Examiner rejected all claims (1-24) under 35 U.S.C. § 102(a)(1) as being anticipated by Krishnan (Ex1005). Ex1004, p. 207-252.

67. In response to the May 2021 Office Action, the Patent Owner amended every independent claim to allegedly distinguish Krishnan. Ex1004, pp. 254-273. The Patent Owner argued that, as amended, "[t]he claims include determining that a set of assessment parameters is associated with a respective view category and, in response, inputting a corresponding echocardiographic image into a respective neural network to determine the respective quality assessment value of each image." Ex1004, p. 266. Since "the first and second images are associated with respective first and second view categories … it is determined that respective first and second sets of assessment parameters are associated with those view categories." Ex1004, p. 267. Then, "[t]o obtain quality assessment values, the first and second images are input into neural networks defined by the first and second sets of assessment parameters, respectively." *Id.*

According to the Patent Owner, "Krishnan fails to teach or suggest determining a quality assessment value of an image using a neural network <u>defined by a set of assessment parameters associated with a view category associated with that image</u>." Ex1004, p. 268 (emphasis added).

68. On August 18, 2021, the Examiner issued a Notice of Allowance stating that the closest prior art, including Krishnan (Ex1005), does not teach or suggest the below functionality, as claimed in each independent claim:

> wherein the at least one processor is configured to determine the [first/second] quality assessment value by: determining that a [first/second] set of assessment parameters of the sets of assessment parameters is associated with the [first/second] view category; and in response to determining that the [first/second] set of assessment parameters is associated with the [first/second] view category, inputting the [first/second] at least one echocardiographic image into the neural network defined by the [first/second] set of assessment parameters;

Ex1004, pp. 274-298.

69. I address below claims 1-20 of the Patent in the context of the identified prior art. I have reviewed claims 1-20 for purposes of this analysis and include herewith as **Attachment A**, an appendix of Claims 1-20.

VII. OPINIONS REGARDING CLAIM CONSTRUCTION

70. Unless otherwise stated herein, I interpret the terms of the Patent's

claims as having their ordinary and customary meaning.[1] After having reviewed the Patent specification and its prosecution history, for the specific purpose of understanding the teachings of the prior art as against the Patent claims, I do not see any need to deviate from the plain and ordinary meaning of the claim language based on, for example, disclaimer, disavowal, or unique lexicography.

VIII. SUMMARY OF THE PRIOR ART

A. US2005/0251013 ("Krishnan")

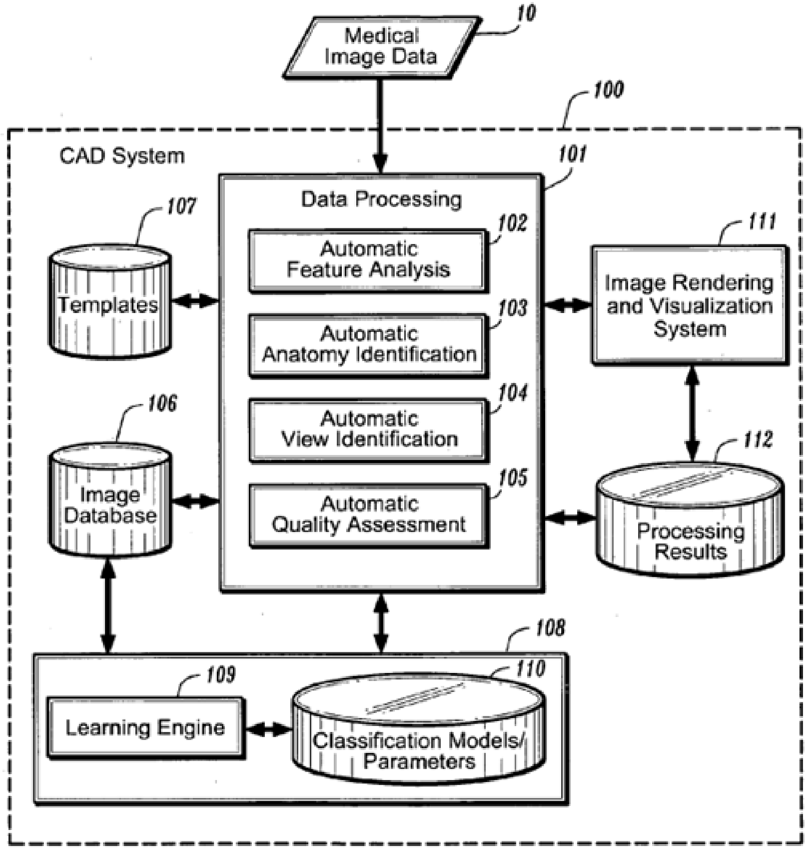
71. Krishnan is a U.S. patent application published on November 10, 2005. Ex1005, cover. I understand, therefore, that Krishnan is prior art to the Patent, even if I assume that the Patent is entitled to a priority date of April 21, 2016.

72. Krishnan is directed to "systems and methods for processing a medical image to automatically identify the anatomy and view (or pose) from the medical image and automatically assess the diagnostic quality of the medical image." Ex1005, [0002]. In the primary embodiment, the medical image is an

[1] I reserve the right, in the district court litigation brought by Patent Owner against Petitioner, to identify other claim terms and phrases that might require construction. Such additional terms – not addressed here – might be material to the determination of infringement of the accused instrumentalities, even if they are not relevant based on the features of the prior art cited in this Petition.

ultrasound image of the heart, and the identified view can be one of the standard views recognized by the American Society of Echocardiography such as, for example, the apical two-chamber view (A2C) or the apical four-chamber view (A4C). Ex1005, [0009], [0019]. "[T]he results of image quality assessment are presented to a user in real-time during image acquisition" so that "the sonographer can determine whether the acquired images are of sufficient diagnostic quality, thereby allowing for changes in image acquisition, if necessary." Ex1005, [0009].

73. Referring to Figure 1, below, Krishnan discloses a computer-implemented system 100 that includes an image feature extraction module 102, an anatomy identification module 103, a view identification module 104, an image quality assessment module 105, a database 106 of previously diagnosed/labeled medical images, and a classification module 108 with a learning engine 109 and a "bank of classifiers" 110 that are used by the various modules 102-105 to perform their respective functions. Ex1005, [0016], [0021], [0023], [0043].



Medical Image Data
10
100
CAD System
Data Processing
101
107
Templates
102
Automatic Feature Analysis
103
Automatic Anatomy Identification
104
Automatic View Identification
105
Automatic Quality Assessment
106
Image Database
111
Image Rendering and Visualization System
112
Processing Results
108
109
Learning Engine
110
Classification Models/ Parameters

FIG. 1

74. The system 100 performs the method depicted in Figure 2, below, including the steps of: (i) obtaining an image dataset including "one or more medical images" (Ex1005, [0033]); (ii) extracting relevant feature data from the image data set using "known segmentation and/or filtering methods" (Ex1005, [0034]); (iii) using the extracted features to automatically identify the anatomy, view and/or quality of the image(s) (Ex1005, [0035]; and (iv) labeling the image(s) according to the anatomy, view, and quality assessment results (Ex1005, [0036]).

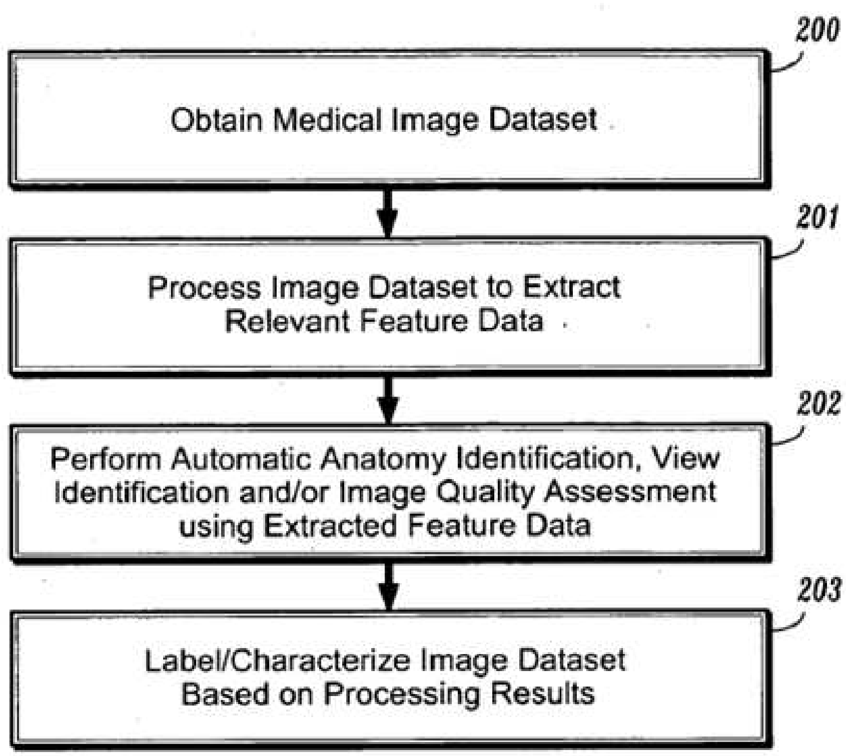


FIG. 2

75. The image feature extraction module 102 "implements methods for automatically extracting one or more types of features/parameters from input medical image data and combining the extracted features/parameters in a manner

that is suitable for processing by [the other modules (e.g., view identification module 104)].” Ex1005, [0017]. “These features could include any kind of characteristic that could be extracted from the image, such as a particular shape or texture.” Ex1005, [0034]. Additionally, “feature data can be obtained across images, such as motion of a particular point, or the change in a particular feature across images.” *Id*.

76. The anatomy identification module 103 and view identification module 104 use the extracted “features/parameters” to automatically identify anatomical objects and the view of the acquired image, respectively. Ex1005, [0018]-[0019]. Likewise, the quality assessment module 105 also “us[es] the extracted features/paraments to assess a level of diagnostic quality of an acquired image data set.” *Id.*, [0020]. Additionally, Krishnan states that “the results of anatomy and/or view identification may be used for quality assessment.” *Id.*, [0020], [0029] (“The results of anatomy identification and/or view identification can be used to perform automatic image quality assessment…”), Claim 11 (“wherein determining a diagnostic quality of the image data further comprises using results of automatic view identification”).

77. According to an exemplary embodiment, the various modules 103-105 perform their respective functions using machine learning. Ex1005, [0023]. For example, the various modules 103-105 may be implemented using one

or more trained classifiers that have been built by the learning engine 109 using training data such as previously diagnosed/labeled images from the database 106. *Id*. As explained by Krishnan, "a classifier design can include a multiplicity of classifiers" and can be "built using neural networks." Ex1005, [0044]. "These classifiers would use the set of [extracted] features as an input, and classify the image as belonging to a particular anatomy, view, or level of quality." *Id.*, [0043].

B. US2016/0247034 ("Lee")

78. Lee is a U.S. patent application filed on February 22, 2016, and published on August 25, 2016. Ex1006, cover. I understand, therefore, that Lee is prior art to the Patent, even if I assume that the Patent is entitled to a priority date of April 21, 2016.

79. Lee is directed to an electronic device, such as a "an ultrasound machine" (Ex1006, [0038]), that determines the quality of images from various image categories using image-category-specific classifiers (Ex1006, [0009]). The device includes a memory that stores a plurality of classifiers, and a processor configured to "analyze a category of an image of which an image quality evaluation is requested, and determine a classifier corresponding to the category of the image from among the plurality of classifiers." Ex1006, [0009]. This process is schematically depicted in Figure 6, which is reproduced below.

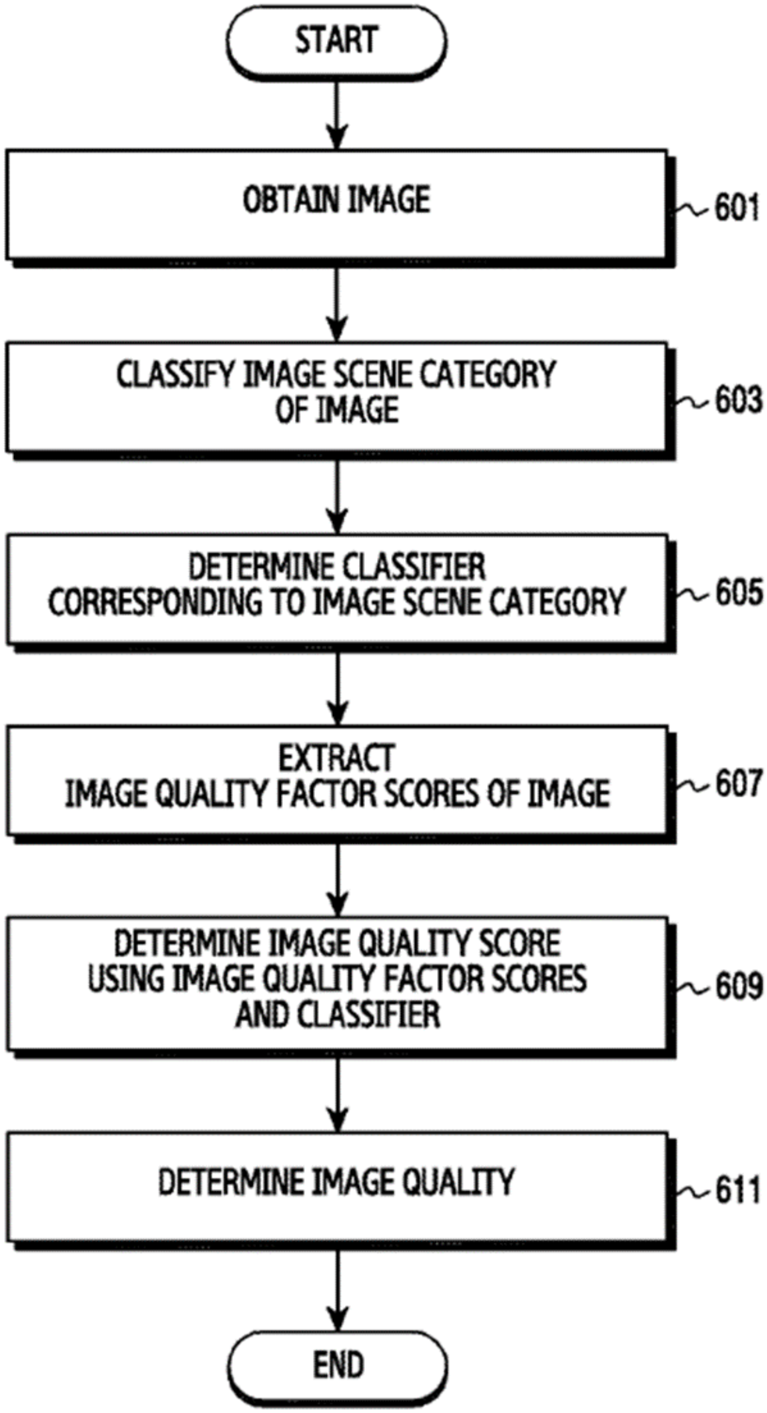

START
OBTAIN IMAGE
601
CLASSIFY IMAGE SCENE CATEGORY OF IMAGE
603
DETERMINE CLASSIFIER CORRESPONDING TO IMAGE SCENE CATEGORY
605
EXTRACT IMAGE QUALITY FACTOR SCORES OF IMAGE
607
DETERMINE IMAGE QUALITY SCORE USING IMAGE QUALITY FACTOR SCORES AND CLASSIFIER
609
DETERMINE IMAGE QUALITY
611
END

FIG.6

80. With reference to Figure 5, Lee describes a quality measuring module 485 that includes a category classifying module 520, a classifier selecting module 530, and an image quality evaluating module 550. Ex1006, [0149].

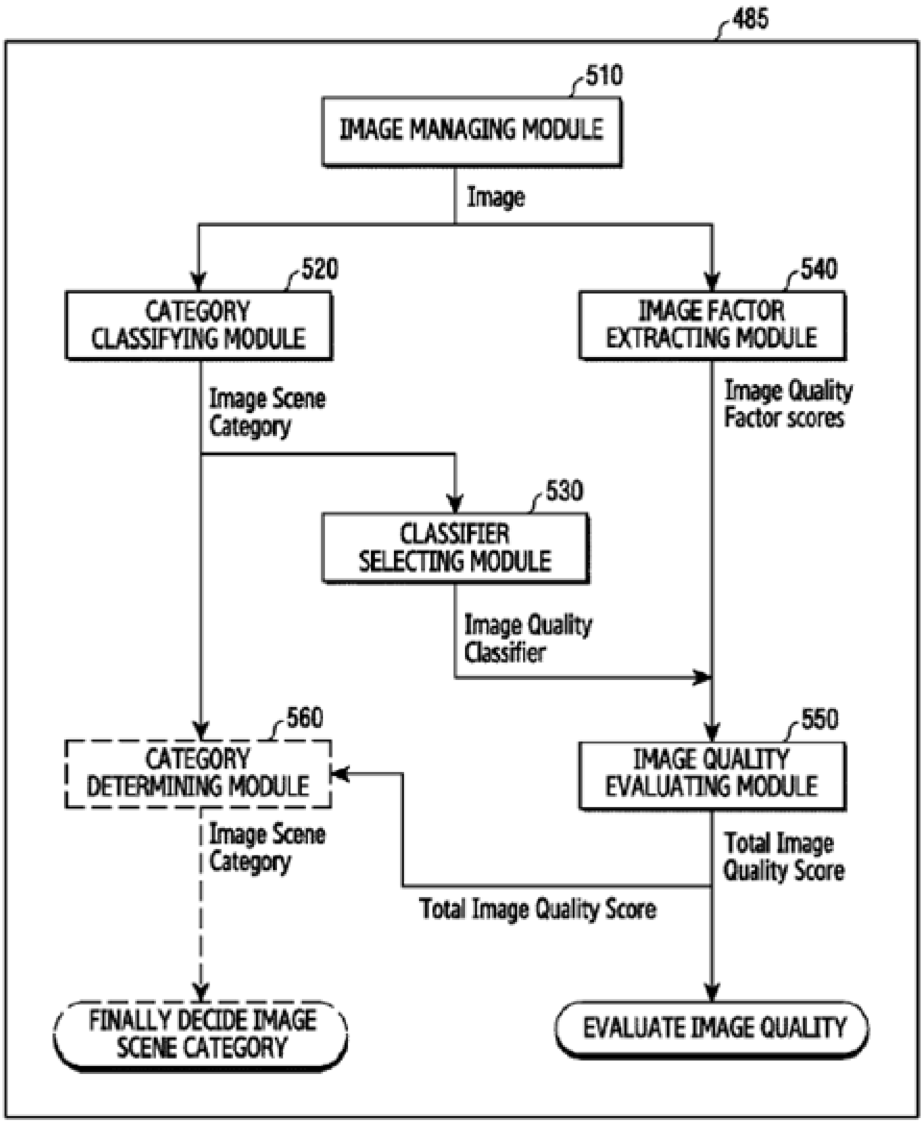


FIG.5

81. The category classifying module 520 may use "deep learning" to

determine a "category or a class" of an image. Ex1006, [0151]. Then, "[t]he classifier selecting module 530 may select (determine) a classifier (e.g., an image quality classifier) corresponding to the image scene category that is transferred from the category classifying module 520." Ex1006, [0152].

82. Lee explains that "when the quality of an image is measured, the quality may be measured from a different perspective view based on an image scene category." Ex1006, [0153]. Therefore, the selected "classifier may indicate a reference value that is used for <u>differentially measuring quality based on an image scene category</u> of a corresponding image when the classifier measures the quality of the image." Ex1006, [0152] (emphasis added).

C. US2017/0262982 ("Pagoulatos")

83. Pagoulatos is a published U.S. patent application with a priority filing date of March 9, 2016. Ex1007, cover; *see also* Ex1008, Ex1009. I understand, therefore, that Pagoulatos is prior art to the Patent, even if I assume that the Patent is entitled to a priority date of April 21, 2016.

84. Pagoulatos is generally directed to an ultrasound imaging system that uses artificial intelligence, including, for example, trained artificial neural networks, to determine "whether acquired ultrasound images represent a clinically desirable view of one or more organs" (e.g., the heart). Ex1007, [0002], [0035]; *see also* Ex1008, p. 2, 6-7 (1:4-7, 5:23-6:5); Ex1009, p.15, 17, 20 (1:8-10, 3:8-15, 6:4-

21).

85. The system includes an ultrasound image recognition module 120, which can implement view-category-specific assessment parameters through a neural network 300 like the one depicted in Figure 3 below. Ex1007, [0016], [0042]-[0044], [0054]; *see also* Ex1008, Fig. 3 p. 4, 9, 12-13, 38 (3:6-8, 8:6-26, 11:24-12:19); Ex1009, p. 17, 24, 27, 33 , 42 (3:23-25, 10:17-26, 19:3-14 13:9-24, Fig. 4).

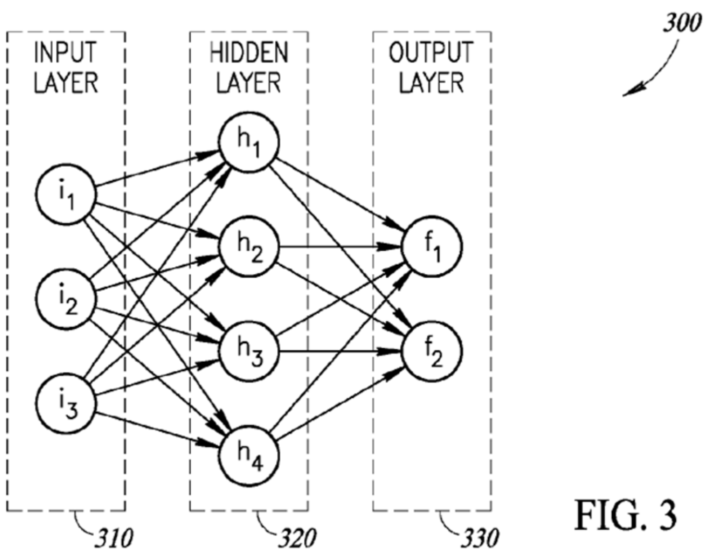


FIG. 3

86. As depicted in Figure 2, below, Pagoulatos is also directed to methods and systems for training such neural networks using training images. Ex1007, [0037]-[0038], [0046]-[0047]; *see also* Ex1008, p. 7-8, 10, 37 (6:12-7:12, 9:9-27, Fig. 2); Ex1009, p. 22-23, 28-29, 41 (8:20-9:24, 14:6-15:2, Fig. 3).

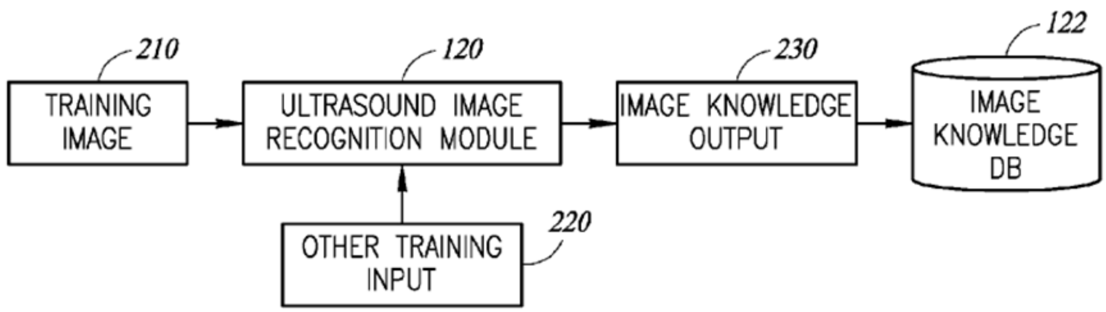


FIG. 2

87. With reference to Figures 2 and 3, above, Pagoulatos explains: "The neural network 300 may be trained by providing training images 210 to the input layer 310" where "<u>the training images may include</u> ultrasound image <u>information</u> having a wide variety <u>of known characteristics</u>, <u>including</u>, for example, <u>various organ views, various image qualities</u> or characteristics, various imaging angles, and so on." Ex1007, [0046] (emphasis added); Ex1008, p.10 (9:9-19); Ex1009, p. 28 (14:6-19). Additionally, Pagoulatos explains that "through training, the neural network 300 may generate and/or modify the hidden layer 320, which represents weighted connections mapping the training images 210 provided at the input layer 310 to known output information at the output layer 330." *Id*. The "[r]elationships between neurons of the input layer 310, hidden layer 320 and output layer 330, formed through the training process and which may include weight connection relationships" constitute "ultrasound image knowledge 230," which is stored in an "ultrasound image knowledge database 122." Ex1007, [0046], [0042]; Ex1008,

p.10, 9 (9:9-19, 8:6-14); Ex1009, p. 28, 24 (14:6-19, 10:17-26).

88. Once the neural network 300 has been sufficiently trained, as discussed above, it can receive non-training images at the input layer 310 and use view-category-specific ultrasound image knowledge stored in database 122 to make determinations about the received images at the output layer 330. Ex1007, [0047]; Ex1008, p. 10 (9:20-27); Ex1009 p. 28-29 (14:20-15:2). For example, Pagoulatos states that "a user may select … a desired view of an organ that is to be imaged" (e.g., a subcostal view of a heart), and the selected view may be communicated to the image recognition module 120 so that "the ultrasound image recognition module 120 may access the appropriate ultrasound image knowledge (e.g., knowledge, rules or regulations associated with a subcostal view of the heart) in the image knowledge database 122 such that received ultrasound images may be compared with, or processed by, knowledge corresponding to the selected view." Ex1007, [0054]; Ex1008, p. 12-13 (11:24-12:19); Ex1009, p. 33 (19:3-14).

D. Automatic Fetal Ultrasound Standard Plan Detection ("Chen")

89. Chen is a conference paper from the 18th International Conference on Medical Image Computing and Computer-Assisted Intervention held in Munich, Germany, on October 5-9, 2015. It was published by Springer International Publishing on November 18, 2015, in Medical Image Computing and Computer-Assisted Intervention, MICCAI 2015, Volume 9349, pp.507-514.

Ex1010. In my opinion, an interested member of the public could have reasonably located this reference by searching the Open Access collection of Springerlink.com, the National Library of Medicine's PubMed® database, or the article's DOI reference (*e.g.*, at crossref.org). I understand, therefore, that Chen is prior art to the Patent, even if I assume that the Patent is entitled to a priority date of April 21, 2016.

90. Chen describes methods for automatically detecting when an acquired image corresponds to a standard fetal ultrasound plane (*i.e.*, view) using trained neural networks. Ex1010, p.507. Specifically, Chen explores the feasibility of accurately identifying ultrasound images that correspond to the fetal abdominal standard plane (FASP), fetal face axial standard plane (FFASP), and fetal four-chamber view standard plane (FFVSP) of the heart. *Id*. Chen also suggests, however, that the general framework of its teachings "can be easily extended to other US [ultrasound] standard plane or anatomical structure detection problems" such as detection of standard echocardiographic views. Ex1010, p.509.

91. Chen teaches the advantages of using convolutional neural network ("CNN") classifiers trained by "joint learning with knowledge transfer" across multiple domains or tasks. Whereas conventional training of a CNN to perform a task (*e.g.*, identify a particular ultrasound standard plane) requires large datasets of labeled (*i.e.*, annotated) images, Chen explains that "[p]revious studies have

indicated that the knowledge learned from one domain or task via CNN could benefit the training for another domain or task with limited annotated data." Ex1010, p.510. Accordingly, Chen proposes "a joint learning model with CNN across multiple detection tasks of US standard planes, as illustrated in Figure 2 (right)," which is reproduced below.

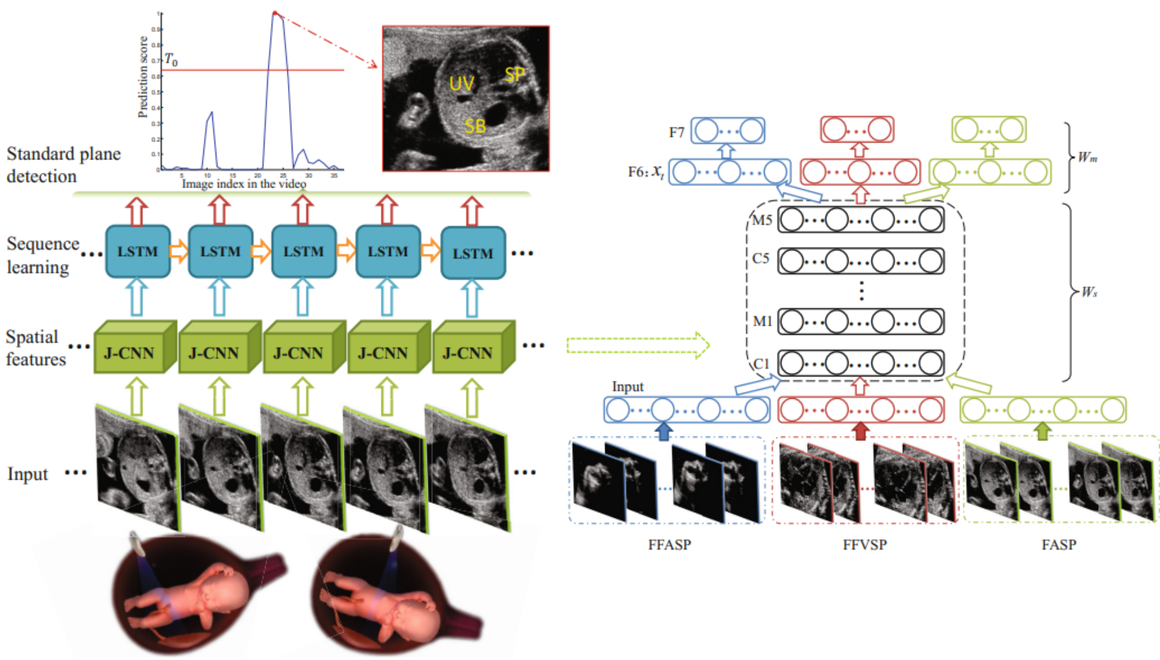


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

92. Referring to the right side of Figure 2 above, Chen states: "In the figure, the matrix W_s denoting the parameters of layers from C1 to M5 is trained from all training samples of the three detection tasks [(i.e., FFASP, FFVSP,

FASP)] and shared among these tasks." Ex1010, p.510 (emphasis added). By contrast, "[t]he W_m (m = 1, 2, 3 represents the task of FFASP, FFVSP and FASP, respectively) denotes the parameters of F6 and F7 layers and is trained individually on each task for the discrimination of different standard planes." *Id*. (emphasis added). Thus, Chen discloses a multi-classification CNN that contains shared layers with common assessment parameters and view/plane/task specific layers that were individually trained and contain unique, view/plane/task-specific assessment parameters.

IX. DETAILED OPINIONS REGARDING INVALIDITY

93. As detailed below, in my opinion, claims 1-20 of the Patent are unpatentable as obvious in view of the prior art. I rely principally on two combinations of references: (1) Krishnan (Ex1005) in view of Lee (Ex1006) ("Krishnan-Lee"), and (2) Krishan-Lee in view of Pagoulatos (Ex1007) ("Krishnan-Lee-Pagoulatos"). For claims 6, 10, 14, and 40 of the Patent, I rely on these principal combinations, with the addition of Chen (Ex1010).

94. Each of the presented combinations teach or at least suggest the combination of every limitation of the independent claims of the Patent, and most of the further limitations of the remaining claims.

95. The following table sets forth the combination of prior art that renders obvious each of claims 1-20:

Ground	Prior Art	Basis	Claims Challenged
A	Krishnan in view of Lee ("Krishnan-Lee")	Obviousness	1-5, 15-19
B	Krishnan-Lee in further view of Pagoulatos ("Krishnan-Lee-Pagoulatos")	Obviousness	7-9, 11-13
C	Krishnan-Lee in further view of Chen	Obviousness	6, 20
D	Krishnan-Lee-Pagoulatos in further view of Chen	Obviousness	10, 14

A. Ground A: Krishnan-Lee

1. Claim 1:

a) [1(pre)]: "A computer-implemented system for facilitating echocardiographic image analysis, the system comprising at least one processor configured to:"

96. I understand that the preamble of a claim is typically just a statement of intended use, but may, in some circumstances, include limitations on the scope of the claim. For the purposes of providing a thorough analysis, I will assume that the preamble of claim 1 is limiting and I will address it like any other claim limitation. As I explain further below, it is my opinion that Krishnan discloses "[a] computer-implemented system for facilitating echocardiographic image analysis."

97. Krishnan discloses "systems and methods" for "processing a medical image to automatically identify the anatomy and view (or pose) from the medical image and automatically assess the diagnostic quality of the medical image." Ex1005, Abstract. The "systems and methods" disclosed by Krishnan "may be implemented in various forms of hardware, software, firmware, special purpose

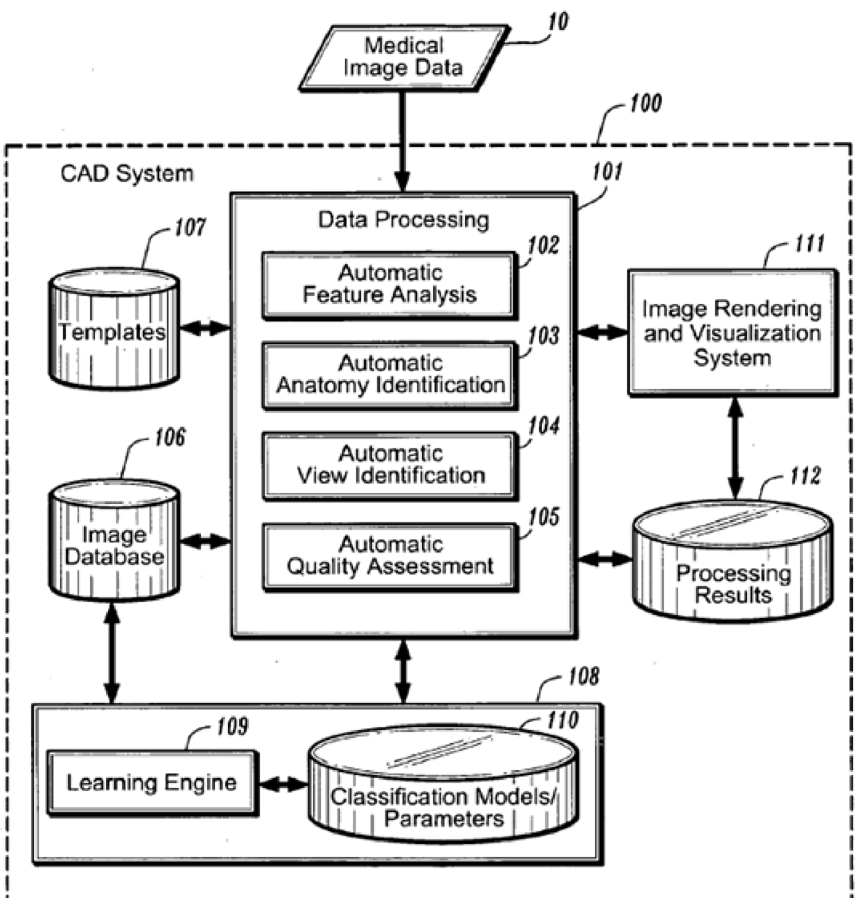
processors, or a combination thereof." Ex1005, [0045]; *see also* Ex1005, [0005], [0009], Fig. 1.

98. Accordingly, it is my opinion that Krishnan discloses all the limitations of the preamble of claim 1.

b) [1(a)/(e)]: "receive signals representing a [first/second] at least one echocardiographic image;"

99. Below I analyze claim elements 1(a) and 1(e) together. Claim elements 1(a) and (e) disclose the same "receiving" functionality for a "first" and "second" echocardiographic image. Krishnan's system contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. As explained in Krishnan, "it is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at <u>multiple views</u>." Ex1005, [0032] (emphasis added). Accordingly, Krishnan states that the acquired image dataset may be "one or more medical images." Ex1005, [0033]. For example, during a "stress-echo" examination, "[i]t is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at multiple views" including "up to four (and sometimes more) <u>loops of data for each view</u>, where each loop represents a heart cycle." *Id.*, [0032] (emphasis added). By providing a quality check, the sonographer can be assured (in real time) "that <u>images</u> are being acquired of diagnostic quality." *Id.* (emphasis added).

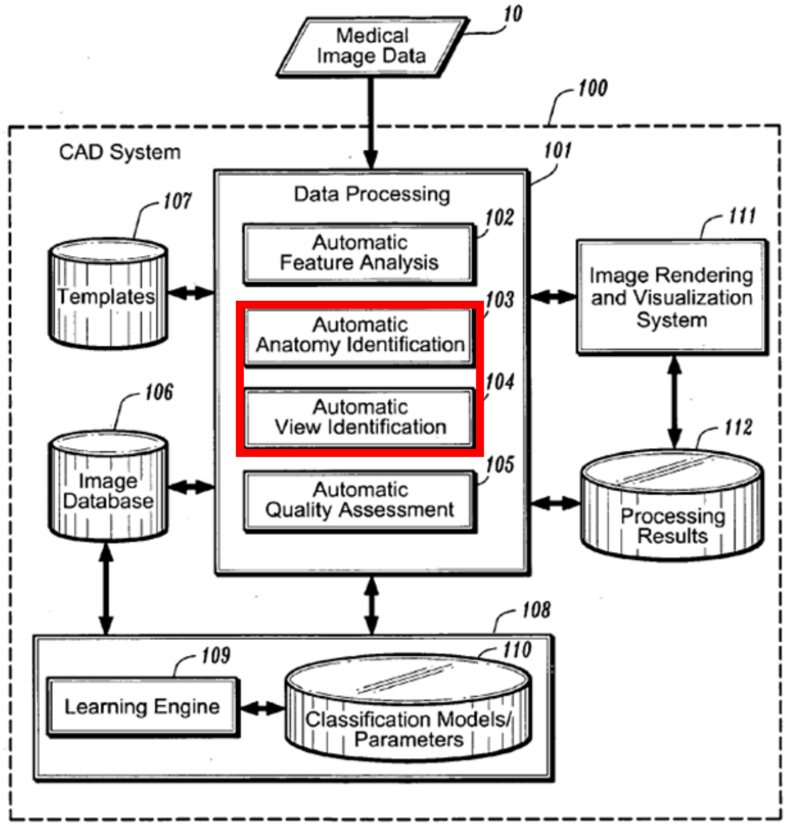
100. It is my opinion that Krishan discloses limitations 1(a) and 1(e). As discussed above, Figure 1 of Krishnan discloses a diagnostic system 100 "for providing automated decision support for medical imaging." Ex1005, [0016]. The system 100 "comprises a data processing module (101) that implements various methods for analyzing medical image data (10) in one or more imaging modalities (e.g., ultrasound image data, MRI data, nuclear medicine data, etc.) to automatically extract and process relevant information from the medical image." *Id.*; *see also* Ex1005, Figs. 1-2, [0009], [0016], [0017], [0032], [0033].



c) [1(b)/(f)]: “associate the [first/second] at least one echocardiographic image with a [first/second] view category of a plurality of predetermined echocardiographic image view categories, [said second view category being different from the first view category];”

101. Below I analyze claim elements 1(a) and 1(e) together. Claim elements 1(b) and (f) disclose the same functionality for a “first” and “second” echocardiographic image, with the requirement that the “first” and “second” images have their own associated “view categories.” Krishnan’s system contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. *See* Section IX.A.1.b.

102. It is my opinion that Krishan discloses limitations 1(b) and 1(f). The anatomy identification module 103 and view identification module 104 in Krishnan’s system, highlighted below in Figure 1, below, use the extracted “features/parameters” to automatically identify anatomical objects and the view of the acquired image, respectively. Ex1005, [0018]-[0019].



103. At the "automatic view identification" step, "the view identification module (103) [sic] implements methods for using the extracted features/parameters to automatically identify the view of an acquired image. In other words, the view identification module (104) [sic] implements methods for pose estimation and label a medical image with respect to what view of the anatomy the medical image contains." Ex1005*,* [0019].

104. The identified "view" may correspond to certain, standard ultrasound views. Krishan explains that "the American Society of Echocardiography (ASE) recommends using standard ultrasound views in B-mode to obtain sufficient cardiac image data—the apical two-chamber view (A2C), the apical four-chamber

view (A4C), the apical long axis view (ALAX), the parasternal long axis view (PLAX), the parasternal short axis view (PSAX).” *Id.* Consistent with ASE recommendations, Krishnan discloses that “the view identification module (103) [sic]” implements methods for identifying an unknown cardiac image as one of several different ASE standard views. Ex1005, [0019].

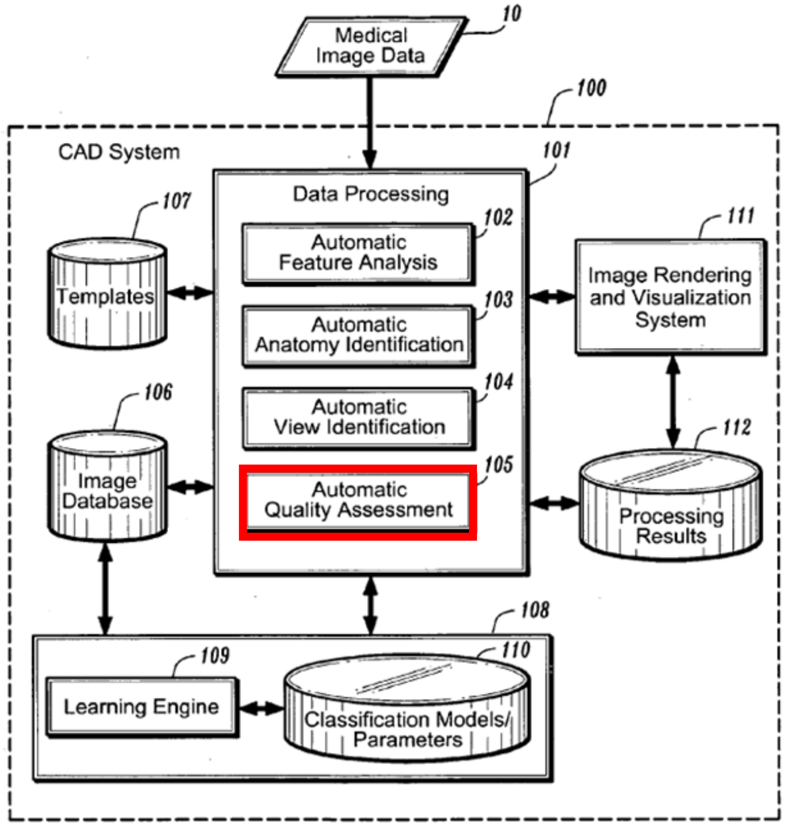
d) [1(c)/(g)]: “determine, based on the [first/second] at least one echocardiographic image and the [first/second] view category, a [first/second] quality assessment value representing a view category specific quality assessment of the [first/second] at least one echocardiographic image;”

105. Below I analyze claim elements 1(c) and 1(g) together. Claim elements 1(c) and (g) disclose the same functionality for a “first” and “second” echocardiographic image, with the requirement that the “first” and “second” images have their own associated “view categories” and “quality assessment values representing a view category specific quality assessment.” Krishnan’s system contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. *See* Section IX.A.1.b.

106. It is my opinion that Krishan discloses limitations 1(c) and 1(g). As explained in Krishnan, “the results of anatomy and/or view identification may be used for quality assessment.” Ex1005, [0020], [0029].

107. Figure 1 of Krishnan, below, identifies an “automatic quality

assessment" step (105), highlighted below. Ex1005, Fig. 1.



After "features/parameters" of one or more medical images are extracted (Ex1005, [0017]), at step 105, the "quality assessment module (105) implements methods for using the extracted features/parameters to assess a level of diagnostic quality of an acquired image data set." Ex1005, [0020]. The system may then provide a "quality measure within a predefined range of values to provide an indication as the quality level of the acquired images based on some specified criteria," including "diagnostic quality level." *Id.*

108. Figure 2 of Krishan further details Krishnan's quality assessment

workflow. Ex1005, [0033], Fig. 2.

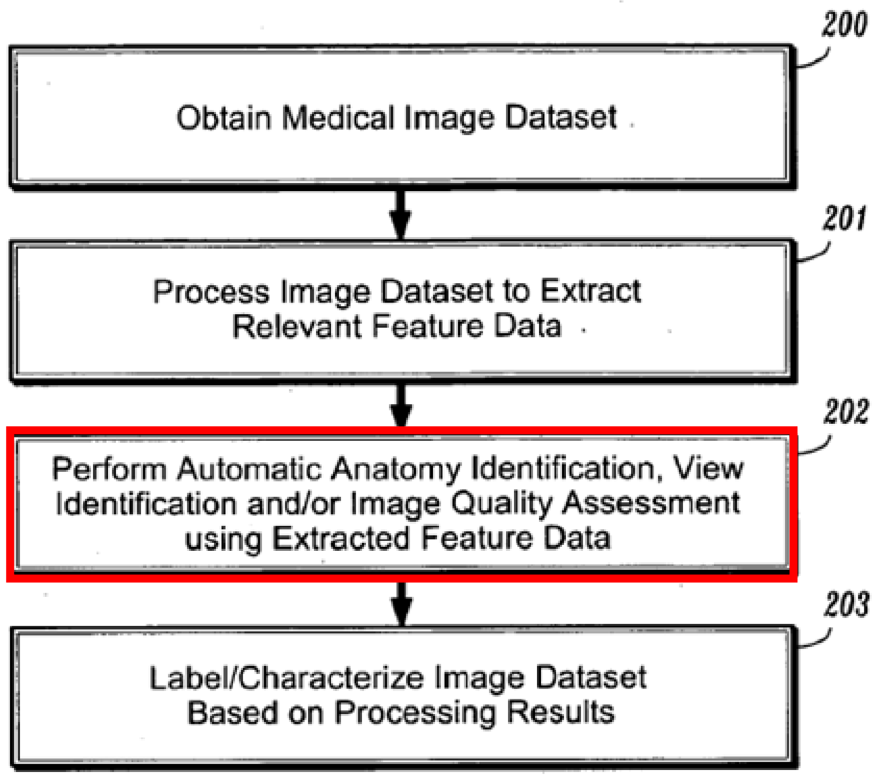


FIG. 2

109. As shown in Figure 2, above, the system uses extracted data from "one or more medical images" to automatically identify the anatomy, view and/or quality of the image(s) (202) (annotated). Ex1005, [0035]. The system then labels the image(s) according to the anatomy, view, and quality assessment results (203). Ex1005, [0036]).

110. Krishnan's explicitly discloses using both the image and the view category of the image to determine a view-category-specific quality assessment value of the image. Krishnan explicitly states that "the results of … view

identification may be used for quality assessment." Ex1005, [0020], [0029]; *see also* Ex1005, [0042], [0043]. For example, Krishnan explains that "templates could be constructed for different cardiac views" and the content of the input images could be compared to the content of the view-specific templates to determine the quality of the acquired images. Ex1005, [0041]. Similarly, Krishnan states that "view identification and[] image quality assessment are performed using <u>associated</u> classifiers." Ex1005, [0006] (emphasis added).

e) [1(d)/(h)]: "produce signals representing the [first/second] quality assessment value for causing the [first/second] quality assessment value to be associated with the [first/second] at least one echocardiographic image;"

111. Below I analyze claim elements 1(d) and 1(h) together. Claim elements 1(d) and (h) disclose the same functionality for a "first" and "second" echocardiographic image, with the requirement that the "first" and "second" images have their own "quality assessment value[s]." Krishnan's system contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. *See* Section IX.A.1.b.

112. It is my opinion that Krishan discloses limitations 1(d) and 1(h). With reference to Figure 2 of Krishnan, after quality assessment is performed using extracted features from an image dataset, the dataset is labeled based on the quality

assessment results. Ex1005, Fig. 2 (203). For example, Krishnan explains that "[t]he image dataset will be labeled … based on the processing results" and "for image quality assessment, the medical images may include a quality score (within a predefined range)." *Id.*, [0036]. Krishnan also contemplated the implantation of methods "for providing real-time feedback during image acquisition regarding the diagnostic quality of the acquired images." *Id.*, [0020], [0032].

f) [1(i)/(l)]: "wherein each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that define a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values, and [wherein the at least one processor is configured to determine the [first/second] quality assessment value] by:"

113. Below I analyze claim elements 1(i) and 1(l) together. Claim elements 1(i) and (l) disclose the same functionality for a "first" and "second" echocardiographic image, with additional requirements for how those images are processed in the contemplated workflow. Krishnan's system contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. *See* Section IX.A.1.b.

114. In my opinion, Krishnan in view of Lee, discloses, teaches, or

suggests limitations 1(i) and 1(l).

115. As previously discussed, Krishnan describes determining echocardiographic image quality assessment values using view-category-specific templates (Ex1005, [0041]) or, alternatively (*id*., [0035]), a "bank of classifiers" (*id*., [0042]-[0043]). "The classifiers can be implemented using machine learning methods, model-based methods, or any combination of machine learning and model-based methods." *Id.*, [0006], [0023]. The "classifiers" may consist of various "types of classifier frameworks," "a multiplicity of classifiers," or may be "'black boxes' that are unable to explain their prediction to a user (which is the case if classifiers are built using neural networks, example." *Id.,* [0042]-[0044].

116. As previously discussed, Lee describes determining image quality assessment values using view-category-specific assessment parameters. After first classifying an image as belonging to a particular category, Lee then determines which of a plurality of stored classifiers corresponds to that category and determines an image quality score using that classifier. Ex1006, Figs. 5-6, and 11, [0009], [0152]-[0153], [0169], [0177]. <u>Each classifier is based on different assessment parameters</u>. *Id*., [0096] ("[T]he image quality may be determined by applying, to the image, a different weight based on the determined image scene classifier."), [0152]-[0153], [0160]-[0161]. Thus, Lee discloses, as claimed, that each of a plurality of image view categories is associated with a respective set of

assessment parameters.

117. It is my opinion that a POSITA would have been motivated, based on the express teachings of Krishnan, to modify Krishnan's systems and methods to determine image quality assessment values using view-category-specific assessment parameters as taught by Lee.

118. Both Krishnan and Lee are directed to the automatic assessment of the quality of images in different categories using machine learning. Ex1005, [0002], [0009]; Ex1006, [0009], [0038], [0168]. And both references contemplate application of their teachings to a variety of medical imaging devices, including ultrasound machines. *See* Ex1006 [0038]; Ex1005, [0016]. The use of neural networks for image quality assessment was well known as early as 2004. *See* Section V.A.3. As deep convolutional networks became the dominant architecture for computer vision, they were proposed for use in quality assessment tasks such as selecting the best quality image in a set for submitting to a facial recognition system. *See* Ex1024 (Vignesh).

119. A POSITA considering both references would understand from their combined disclosures that Krishnan's "bank of classifiers" could be a plurality of view-category specific quality assessment classifiers as taught by Lee. Additionally, these view-category-specific classifiers could each be neural networks instead of view-category-specific templates, as expressly described in

Krishnan. Neural networks would be considered a type of machine learning model that could be used for classification tasks.

120. A POSITA would understand that each of these view-category-specific classifiers would have different assessment parameters for evaluating the quality of images in different view categories "from a different perspective," as taught by Lee. This is common sense; the various standard echocardiographic views depict different anatomical structures from different angles and standard views only include a subset of anatomic structures important for medical diagnosis. The quality of images associated with these respective views should thus be evaluated differently.

121. In my opinion, a POSITA would have had a reasonable expectation of success practicing Krishnan in this manner since Krishnan already contemplates having a "bank of classifiers" and expressly allows for variability of implementation and configuration. Ex1005, [0045].

122. Furthermore, since neural networks, by necessity, include an input layer and an output layer, and since Krishnan's quality assessment classifiers output a "quality score" of an echocardiographic image, Krishnan teaches or suggests the multi-layer neural network framework described in [1(i)/(l)]. Accordingly, in my opinion, the combined disclosures of Krishnan and Lee teach or suggest, as claimed, a plurality of view quality assessment neural networks, each

associated with a respective echocardiographic image view category, each having respective assessment parameters, and each configured to output a view-category-specific quality assessment value of one or more received images.

123. A POSITA would have found it obvious, and been motivated, to implement Krishnan using multiple view-category-specific neural networks based on the express teachings in Lee, as discussed above, because the references suggest as much.

124. As detailed above, Krishnan explains that echocardiographic images are categorized according to standard views and states that the identification of these views can be used to assess the quality of the echocardiographic images. Ex1005, [0019], [0026], [0042]-[0043]. Krishnan already describes template-based embodiments in which the quality of an image is determined by comparing its contents to the contents of view-category-specific templates. Ex1005, [0041]. And more broadly, Krishnan states that the "classifiers" used to assess the quality of images "can be implemented using machine learning methods, model-based methods, or any combination of machine learning and mode-based methods" (Ex1005, [0006]), including "neural networks" (id., [0044]).

125. Lee expressly teaches what should be common sense, *i.e.*, that the quality of images in different categories should be assessed using different assessment parameters. Images in different categories would be expected to

include only a partially overlapping set of anatomic structures. Users would elect to use images from one category over another because of which anatomic structures are included and would expect to be able to clearly resolve such structures. For example, in ultrasound medical imaging, distinct standardized planes exist to enable visualization and quantification of different anatomic structures. It would follow that image quality would depend on which structures in the image are required for successful analysis, and therefore no single set of assessment parameters would be sufficient to analyze all images. Lee describes selecting an appropriate "classifier" for evaluating an image after first determining the category of the image. Ex1006, [0009], [0152]-[0153]. When this teaching is applied to Krishnan—particularly the embodiment in which Krishnan's quality assessment classifier is based on a neural network—a POSITA would have been motivated to use respective view-specific neural networks to assess the quality of echocardiographic images in the respective view categories.

126. Alternatively, it would have been obvious to a POSITA to combine the teachings of Krishnan and Lee because such combination would merely amount to applying known work from the field of automatic image processing (Lee) to an echocardiographic image use case (Krishnan) to yield predictable results. Whereas Krishnan is directed to assessing the quality of images provided from different view categories, a POSITA would know from the teachings in Lee

that different assessment parameters can be used to assess the quality of images in different categories. Thus, it would have been within the ordinary skill and knowledge of a POSITA practicing Krishnan to evaluate the quality of echocardiographic images using neural network classifiers to use a plurality of view-category-specific neural networks.

g) [1(j)/(m)]: "determining that a [first/second] set of assessment parameters of the sets of assessment parameters is associated with the [first/second] view category; and;"

127. Below I analyze claim elements 1(j) and 1(m) together. Claim elements 1(j) and (m) disclose the same functionality for a "first" and "second" echocardiographic image, with additional requirements for how those images are processed in the contemplated workflow. Krishnan's system contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. *See* Section IX.A.1.b.

128. It is my opinion that Krishan-Lee discloses, teaches, or suggests limitations 1(j) and 1(m). Lee expressly discloses a computer-implemented system having a processor configured to "determine a classifier corresponding to the category of [an] image from among a plurality of classifiers." Ex1006, [0009]. Lee discloses a "classifier selecting module 530" that "may change an image quality classifier to correspond to an image scene category, and thereby chang[e] a

perspective of measurement." *Id.,* [0153]. Additionally, Lee states that "the classifier selecting module 530[] may be configured to select a classifier corresponding to the image scene category from among various image quality classifiers stored in advance in the memory." *Id*., [0177].

h) [1(k)/(n)]: "in response to determining that the [first/second] set of assessment parameters is associated with the [first/second] view category, inputting the [first/second] at least one echocardiographic image into the neural network defined by the [first/second] set of assessment parameters."

129. Below I analyze claim elements 1(k) and 1(n) together. Claim elements 1(k) and (n) disclose the same functionality for a "first" and "second" echocardiographic image, with additional requirements for how those images are processed in the contemplated workflow. Krishnan's system contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. *See* Section IX.A.1.b.

130. It is my opinion that Krishan-Lee discloses, teaches, or suggests limitations 1(k) and 1(n). As explained above, Lee discloses a "classifier selecting module" that may "select and provide an image quality classifier that is appropriate" for a given image. Ex1006, [0153], Fig. 5 (530). As depicted in Figure 5, below, the image is then input into "the image quality evaluating

module," and the "image quality evaluating module" may "extract a total image quality score with respect to the image using … the image quality classifier." *Id.,* [0160].

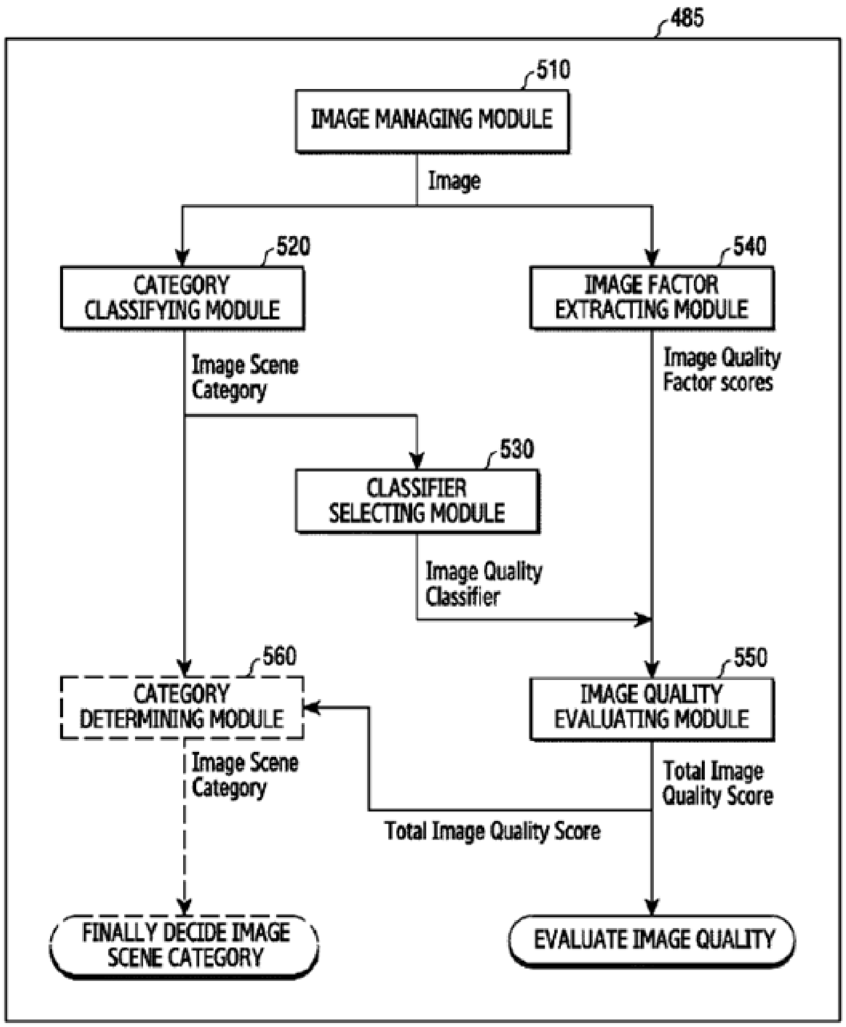


FIG.5

131. As discussed above, the combination of Krishnan-Lee discloses, teaches, or suggests that the image quality classifier may be a neural network having view-category-specific assessment parameters. Ex1005, [0042], [0043]; *see*

Section IX.A.1.f.

2. Claim 2: "The system of claim 1 wherein the [first/second] quality assessment value represents an assessment of suitability of the [first/second] at least one echocardiographic image for quantified clinical measurement of anatomical features"

132. Claim 2 depends from claim 1, which I explained above in Section IX.A.1 is rendered obvious by Krishnan in view of Lee. It is my opinion that Krishan also discloses the additional limitation of claim 2.

133. As previously discussed in Section IX.A.1, Krishnan discloses "systems and methods" for "processing a medical image to automatically identify the anatomy and view (or pose) from the medical image and automatically assess the diagnostic quality of the medical image." Ex1005, Abstract. Krishnan's system also contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. As explained in Krishnan, "it is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at <u>multiple views</u>." Ex1005, [0032] (emphasis added). Accordingly, Krishnan states that the acquired image dataset may be "one or more medical images." Ex1005, [0033]. For example, during a "stress-echo" examination, "[i]t is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at multiple views" including "up to four (and sometimes more) <u>loops of data for each view</u>, where

each loop represents a heart cycle." *Id.*, [0032] (emphasis added). By providing a quality check, the sonographer can be assured (in real time) "that <u>images</u> are being acquired of diagnostic quality." *Id.* (emphasis added).

134. As previously discussed in Section IX.A.1.d, Krishnan explains that the quality assessment module (105) may provide a quality assessment as "an indication as the quality level of the acquired images." Ex1005, [0020]; *see also id.* [0035], [0036], Figure 2. "The automatic image quality assessment can be implemented to provide general feedback on the diagnostic quality of an image," *id.,* [0032], which may take the form of a "quality score (within a predefined range)." *Id.*, [0036]. The "quality score" may provide "an indication a diagnostic quality level of the medical images." *Id.*, [0020]. A POSITA would recognize that one (of several) indications of diagnostic quality may be the images' suitability for "clinical measurement of anatomical features." In fact, one common application of medical images is measurement of anatomic structures and comparison to normal values for the population. *See* Ex1020 (Lang). For example, the thickness of the left ventricle, a heart chamber, is used to diagnose a disease known as left ventricular hypertrophy and specific standardized ultrasound views are used towards this end (e.g., PLAX). The PLAX view is also used to estimate the size of another cardiac chamber, the left atrium. One measure of PLAX quality is thus whether a user can visualize and make accurate measurements of these specific

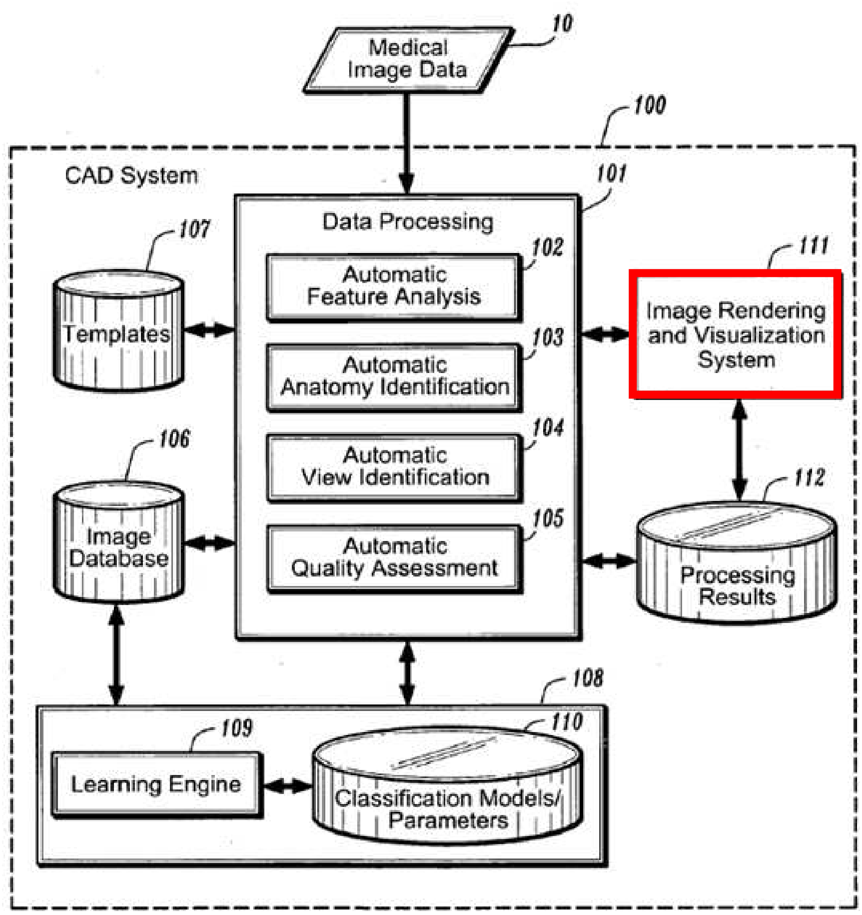
structures (left ventricular wall and left atrium) so that medical diagnoses can be made. This quality measure would be meaningless for other views which do not include these same structures.

3. Claim 3: "The system of claim 1 wherein the at least one processor is configured to: produce signals for causing a representation of the [first/second] quality assessment value to be transmitted to at least one display for causing the at least one display to display the [first/second] quality assessment value in association with the [first/second] at least one echocardiographic image, to assist one or more operators of an echocardiographic device in capturing at least one subsequent echocardiographic image"

135. Claim 3 depends from claim 1, which I explained above in Section IX.A.1 is rendered obvious by Krishnan in view of Lee. It is my opinion that Krishan also discloses the additional limitation of claim 3.

136. As previously discussed in Section IX.A.1, Krishnan discloses "systems and methods" for "processing a medical image to automatically identify the anatomy and view (or pose) from the medical image and automatically assess the diagnostic quality of the medical image." Ex1005, Abstract. Krishnan's system also contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. As explained in Krishnan, "it is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at <u>multiple views</u>." Ex1005, [0032] (emphasis added).

137. Krishnan discloses that its system and methods "can be implemented for providing real-time feedback during image acquisition regarding the diagnostic quality of the acquired images, allowing for changes in the image acquisition." Ex1005, [0020]. Krishnan expressly discloses an "image rendering and visualization system (111)," shown in Figure 1, below, that processes, generates, and displays "2D and/or 3D images on a computer monitor." *Id.*, [0025]; *see also id.* [0032]



138. Krishnan also discloses that "for anatomy and view identification, a medical image will be labeled with the appropriate anatomy and view

identification. In addition, for each anatomy/view ID label, a confidence or likelihood measure that the identified anatomy/view is properly labeled. Moreover, for image quality assessment, the medical images may include a quality score (within a predefined range) that provides an indication a diagnostic quality level of the medical images." Ex1005, [0036].

4. Claim 4: "The system of claim 1 wherein the at least one processor is configured to: [] apply one or more view categorization functions to the [first/second] at least one echocardiographic image to determine that the [first/second] at least one echocardiographic image falls within the [first/second] view category"

139. Claim 4 depends from claim 1, which I explained above in Section IX.A.1 is rendered obvious by Krishnan in view of Lee. It is my opinion that Krishan and Lee also both disclose the additional limitations of claim 4.

140. With reference to Figure 1, Krishnan discloses that "[t]he view identification module (103) implements methods for using the extracted features/parameters to automatically identify the view of an acquired image. In other words, the view identification module (104) implements methods for pose estimation and label a medical image with respect to what view of the anatomy the medical image contains." Ex1005, [0019]; *see also id.*, [0023].

141. As explained in Krishnan, "automated anatomy identification, view identification and/or image quality assessment" may be "performed using associated classifiers that process the extracted feature data. The classifiers can be

implemented using machine learning methods, model-based methods, or any combination of machine learning and model-based methods." *Id.,* [0006]. Those methods could include "database querying methods (*id*., [0021]), "template-based methods" (*id*., [0022]), or "principle (machine) learning" methods (*id*., [0023]).

142. Figure 5, below, discloses "a flow diagram illustrating methods for implementing automated decision support for medical images using classification according to exemplary embodiments of the invention." Ex1005, [0042]. In this embodiment, "the feature data extracted from the image dataset would be input to classifiers (step 500) that are trained or designed to process the feature data to classify the image data (step 501). The classification results would be used to determine the most likely anatomy or view, or assess image quality (step 502)." *Id.; see also id.*, [0043]-[0044].

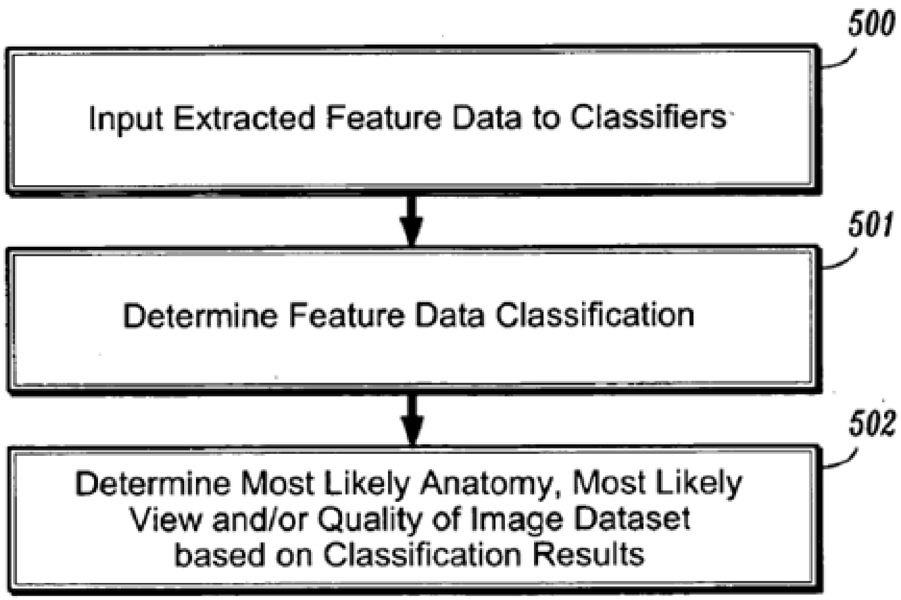


FIG. 5

143. Lee likewise discloses a "category classifying module 520" that may define a "category or class" of an image using, for example, "deep learning." Ex1006, [0151], [0168], [0176] ("classify the image through various algorithms"), Fig. 5 (520).

5. Claim 5: "The system of claim 1 wherein the first at least one echocardiographic image comprises a plurality of echocardiographic images and wherein the at least one processor is configured to determine the first quality assessment value by determining a single quality assessment value representing a view category specific assessment of the plurality of echocardiographic images."

144. Claim 5 depends from claim 1, which I explained above in Section IX.A.1 is rendered obvious by Krishnan in view of Lee. It is my opinion that Krishan also discloses the additional limitations of claim 5.

145. Krishnan's system contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. Krishnan states that the acquired image dataset may be "one or more medical images." Ex1005, [0033]. For example, during a "stress-echo" examination, "[i]t is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at multiple views" including "up to four (and sometimes more) <u>loops of data for each view</u>, where each loop represents a heart cycle." *Id*., [0032] (emphasis added). Krishnan teaches that its "automatic image quality assessment" can provide "feedback … to the operator of the imaging device in real time" and can "automatically select the images of the highest quality" from the loops of images. *Id*.

6. Claims 15-19: Method Claims

146. Claim 10 recites a "a computer-implemented method of facilitating echocardiographic image analysis" that is substantively identical to the "computer-implemented system for facilitating echocardiographic image analysis" recited in claim 1, addressed above. Whereas claim 1 (the system claim) recites a "processor" configured to perform various functions, claim 15 (the method claim) recites a series of steps performing the functions identified in claim 1. Similarly, dependent claims 16-19 are substantively identical to dependent claims 2-5 discussed above.

147. For the reasons discussed above and the additional reasons in the table below, it is my opinion that Krishnan-Lee-Pagoulatos renders method claims 15-19 obvious.

Limitation	**Reasoning {referenced limitation}**
[15(pre)]	*See* Section VIII.A.1.a) {[1(pre)]}
[15(a)/(e)]	*See* Section VIII.A.1.b) {[1(a)/(e)]}
[15(b)/(f)]	*See* Section VIII.A.1.c) {[1(b)/(f)]}
[15(c)/(g)]	*See* Section VIII.A.1.d) {[1(c)/(g)]}
[15(d)/(h)]	*See* Section VIII.A.1.e) {[1(d)/(h)]}
[15(i)/(l)]	*See* Section VIII.A.1.f) {[1(i)/(l)]}
[15((j)/(m))]	*See* Section VIII.A.1.g) {[1(j)(m)]}
[15(k)/(n)]	*See* Section VIII.A.1.h) {[1(k)(n)]}
[16]	*See* Section VIII.A.2 {[2]}
[17]	*See* Section VIII.A.3){[3]}
[18]	*See* Section VIII.A.4 {[4]}
[19]	*See* Section VIII.A.5 {[5]}

B. Ground B: Krishnan-Lee, in view of Pagoulatos

1. Claim 7:

148. Claim 7 depends from claim 1, which I explained above in Section IX.A.1 is rendered obvious by Krishnan in view of Lee. As detailed below, Claim 7 adds limitations relating to neural network "training" and is rendered obvious by Krishnan-Lee in further view of Pagoulatos.

a) [7(pre)]: "The system of claim 1 wherein the at least one processor is configured to train the neural networks by:"

149. The Patent describes "training" the disclosed neural network using a "plurality of echocardiographic training images" and "associated expert quality

assessment values to determine sets of neural network parameters defining the neural networks, at least a portion of each of said neural networks associated with one of the plurality of predetermined echocardiographic image view categories." Ex1001, 2:2-11, Figs. 14, 16.

150. As a general matter, the "training" framework disclosed in the Patent—use of pre-analyzed images to train neural network parameters—was already known in the art. *See* Section V.A.3, 5.

151. As already explained in Section IX.A.1.f above, it is my opinion that a POSITA would be motivated to combine Krishnan and Lee based on Lee's express teaching that different assessment parameters/classifiers should be used to assess the quality of images from different categories differently. Additionally, a POSITA would be motivated to combine Pagoulatos with Krishnan because, whereas Krishnan *generally* discloses a "learning engine (109) … for training/building one or more classifiers" to assess echocardiographic images (Ex1005, [0023]), Pagoulatos describes *in detail* techniques for training neural network classifiers to assess echocardiographic images (Ex1007, [0037]-[0038], [0040]-[0042], [0046]-[0047], Figs. 2, 8; Ex1008, p. 7-10, 37 (6:12-7:12, 7:17-8:14, 9:9-27, Fig. 2); Ex1009, p. 22-24, 28-29, 41 (8:20-9:24, 10: 1-26, 14:6-15:2, Fig. 3)) that are consistent with then-known techniques for training such classifiers. For example, Pagoulatos describes an iterative training process (*id.*, [0040]) using training

images having a wide variety of known characteristics, and mapping—through a back-propagation learning algorithm (*id*., [0041])—the training images provided to the input layer of a neural network to known information produced at the output layer of the neural network (*id*., [0046]). *See also* Ex1008, p. 8-9 (7:17-8:5), p. 10 (9:9-19); Ex1009, p. 24 (10:1-16), p. 28 (14:6-19). The advantage of this process, according to Pagoulatos, is that the trained neural network classifier "may learn to modify its behavior" and "alter the manner in which it makes determinations with respect to new input, such as, for example, ultrasound image information received from [an] ultrasound device." Ex1007, [0043]; Ex1008, p. 9 (8:15-18); Ex1009, p. 27 (13:9-16).

152. In my opinion, applying the neural network training technique described in Pagoulatos to the neural network classifiers disclosed in Krishnan would merely have amounted to applying a known technique to known device to yield predictable results. A POSITA would have been motivated to implement training methods described in Pagoulatos with Krishnan based on the advantages described in Pagoulatos. Both Krishnan and Pagoulatos are directed to automatically assessing the quality of images using machine learning. Ex1005, [0023]; Ex1007, [0037]-[0038], [0040]-[0042], [0046]-[0047], Figs. 2, 8; Ex1008, p.7-10 (6:12-22, 7:17-8:5, 9:9-19); Ex1009, p. 22-24, 28 (8:20-9:4, 10:1-16, 14:6-19). And a POSITA would have had a reasonable expectation of success in doing

so, since Pagoulatos explicitly describes its disclosed technique as "a common method of training artificial neural networks." Ex1007, [0041]; Ex1008, p. 8-9 (7:23-8:5); Ex1009, p. 24 (10:6-16).

153. In my opinion, Krishnan-Lee-Pagoulatos discloses, teaches, or suggests limitation [7(pre)].

154. Krishnan discloses that its quality assessment module 105 may be implemented using one or more "trained" classifiers that may be built from "neural networks." Ex1005, [0023], [0042]-[0044]. Additionally, Krishnan discloses a "learning engine (109) [that] includes methods for training/building one or more classifiers using training data that is learned from … previously diagnosed/labeled cases." *Id*., [0023], [0045] ("special purpose processors"), Fig. 1 ("Learning Engine 109") ("Classification Models/Parameters 110").

155. Pagoulatos likewise discloses a processor configured to train one or more neural networks. Ex1007, Abstract, [0036]-[0037], [0040], [0044], [0046]-[0047]; Ex1008, p. 7-10 (6:6-22, 7:17-22, 8:19-26, 9:9-27); Ex1009, p. 21-24, 27-29 (7:4-17, 8:20-9:4, 10:1-5, 13:17-24, 14:6-15:2). Pagoulatos discloses an "ultrasound image recognition module 120" that can implement artificial neural networks (*id*., [0044]), and states that [t]he ultrasound image recognition module 120 may include, or otherwise be executed by, a computer processor configured to perform the various functions and operations described herein" (*id*. [0036],

including "an iterative training process" (*id*., [0040]). *See also* Ex1008, p. 9 (8:19-26), p. 7 (6:6-11), p. 8 (7:17-22); Ex1009, p. 27 (13:17-24), p. 21 (7:4-17), p. 24 (10:1-5).

b) [7(a)]: "receiving signals representing a plurality of echocardiographic training images, each of the plurality of echocardiographic training images associated with one of the plurality of predetermined echocardiographic image view categories; and"

156. Claim element 7(a) discloses on type of "signal" received as part of the Patent's contemplated "training" framework. In my opinion, Pagoulatos discloses, and Krishnan teaches or suggests, [7(a)].

157. Krishnan's learning engine (109) utilizes a "database (106) of previously diagnosed/labeled medical images." Ex1005, [0023]. Because the images in this database are used as "training data" to "to train classifiers for performing" automated view identification, a POSITA would understand the "training data" as including images associated with one of the plurality of predetermined echocardiographic image view categories. Ex1005*,* [0007]; *see also id.* Ex1005, Fig. 1 ("Learning Engine 109") ("Classification Models/Parameters 110").

158. Pagoulatos describes training "based on training images" that "may include a variety of ultrasound image information associated with known views of an organ, such as the heart." Ex1007, [0037]; *see also id.* [0025] (describing

training via "a large number of ultrasound images representing known or clinically determined views."); Ex1008, p. 6-7, 10 (5:23-6:5, 6:12-22, 9:9-19); Ex1009, p. 18-19, 22-23, 28 (4:17-5:3, 8:20-9:4, 14:6-19). Additionally, Pagoulatos explains that an example "neural network 300 may be trained by providing training images 210 to the input layer 310" where "the training images may include ultrasound image information having a wide variety of known characteristics, including, for example, various organ views." *Id.*, [0046]; Ex1008, p.10 (9:9-19); Ex1009, p. 28 (14:6-19).

c) [7(b)]: "receiving signals representing respective expert quality assessment values representing view category specific quality assessments of the plurality of echocardiographic training images, each of the expert quality assessment values provided by an expert echocardiographer and associated with one of the plurality of echocardiographic training images; and."

159. Claim element 7(b) discloses a second type of "signal" received as part of the Patent's contemplated "training" framework. In my opinion, Pagoulatos discloses, and Krishnan teaches or suggests, [7(b)].

160. As explained in the preceding section, Krishnan discloses "training/building one or more classifiers using training data … of previously diagnosed/labeled cases") Ex1005, [0023], [0043]. Because the training images are used to train classifiers to perform view identification and determine image quality, a POSITA would understand that the training images would be labelled according

to view category and quality. This is confirmed by Krishnan's explanation of a "database querying method" in which the view identification and quality assessment modules (104, 105) can "search for similar labeled cases" in a database of "labeled/diagnosed medical images" to "identify the particular … view, or help identify the quality of the image." Ex1005, [0021].

161. Pagoulatos likewise discloses training one or more classifiers, including a neural network, using training image data that is labelled with view-category-specific quality assessments. Pagoulatos states that its classifiers "may be trained using a large number of ultrasound images representing known or clinically determined views" (Ex1007, [0025]), for example, "ultrasound images which have been <u>pre-determined (e.g., by a physician) as adequately showing a clinically desirable … view of a heart</u>" (*id*., [0037] (emphasis added)). *See also* Ex1008, p. 6-7 (5:23-6:5), p. 7 (6:12-22); Ex1009, p. 18-19 (4:17-5:3), p. 22-23 (8:20-9:4). Additionally, Pagoulatos states that "the training images may include … information having a wide variety of <u>known characteristics</u>, including, for example, various organ views, <u>various image qualities</u> or characteristics, various imaging angles, and so on." *Id*., [0046] (emphasis added); Ex1008, p.10 (9:9-19); Ex1009, p. 28 (14:6-19).

d) [7(c)]: "training the neural networks using the plurality of echocardiographic training images as inputs and the associated expert quality assessment values as desired outputs to determine the sets of neural network parameters defining the neural networks"

162. In my opinion, Krishan-Lee-Pagoulatos discloses element 7(c). As discussed in Section IX.A.1 above, Krishnan-Lee discloses, teaches, or suggests the use of multiple view-category-specific neural networks (e.g., a "bank of classifiers")—the desired output of which are quality assessment values. In my opinion, Pagoulatos discloses the training of such neural networks as described in [7(c)].

163. Pagoulatos states that a "neural network 300 may be trained by providing training images 210 to the input layer 310." Ex1007, [0046]; Ex1008, p.10 (9:9-19); Ex1009, p. 28 (14:6-19). As previously discussed, Pagoulatos also explains that the training images can include a variety of information including "known characteristics" such as "various image qualities." *Id.*, [0037], [0046]; Ex1008, p. 7, 10 (6:12-22, 9:9-19); Ex1009, p. 22-23, 28 (8:20-9:4, 14:6-19). In the case of quality assessment neural networks, like those described in Krishnan, where the desired outputs of the neural networks are predicted quality scores, a POSITA would understand that the training images would be labeled with pre-determined quality values, and the object of training would be to minimize the error between the output predictions and the input labels.

164. Pagoulatos teaches that through an "iterative training process" the parameters of the neural network are updated "until performance of the network is satisfactory." Ex1007, [0040]-[0041]; Ex1008, p. 8-9 (7:17-8:5); Ex1009, p. 24 (10:1-16). Once trained, "the neural network 300 may make determinations about the received ultrasound image information at the output layer 330." Ex1007, [0047]; Ex1008, p. 10 (9:20-27); Ex1009, p. 28-29 (14:20-15:2).

165. With reference to Figures 2 and 3, below, Pagoulatos explains that "through training, the neural network 300 may generate and/or modify the hidden layer 320, which represents weighted connections mapping the training images 210 provided at the input layer 310 to known output information at the output layer 330." Ex1007, [0046]; Ex1008, p.10, 37-38 (9:9-19, Figs. 2-3); Ex1009, p. 28, 41-42 (14:6-19, Figs. 3-4).

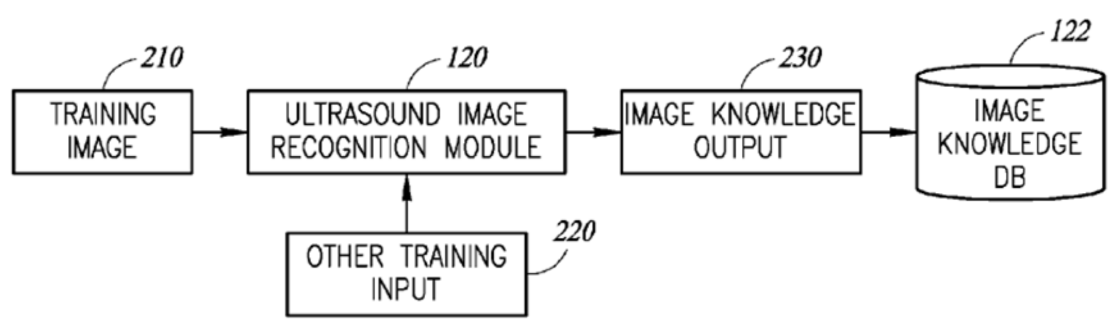


FIG. 2

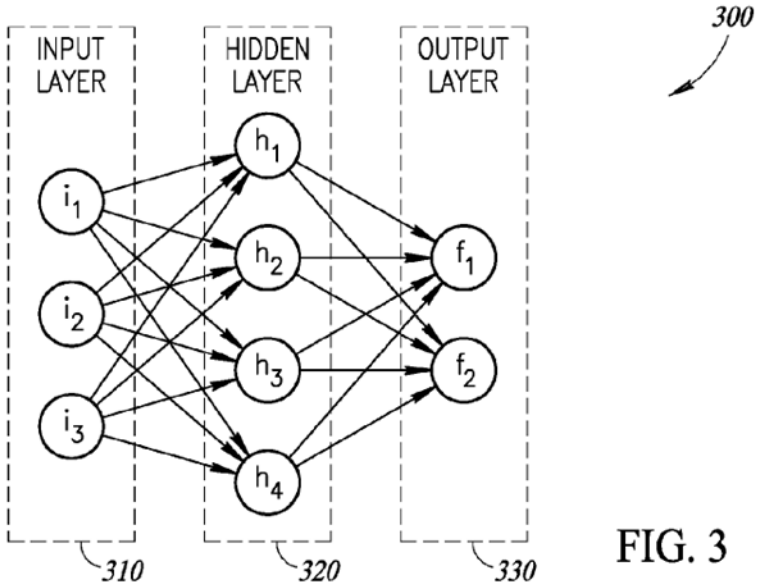


FIG. 3

166. The "[r]elationships between neurons of the input layer 310, hidden layer 320 and output layer 330, formed through the training process and which may include weight connection relationships" constitute "ultrasound image knowledge 230," which is stored in an "ultrasound image knowledge database 122." Ex1007, [0046], [0042]; Ex1008, p.10, 9 (9:9-19, 8:6-14); Ex1009, p. 28, 24 (14:6-19, 10:17-26). Thus, in my opinion, Krishnan-Lee-Pagoulatos teach the use of training image data to determine neural network parameters as recited in [7(c)].

2. Claim 8: "The system of claim 7 wherein each of the expert quality assessment values represents an assessment of suitability of the associated echocardiographic image for quantified clinical measurement of anatomical features"

167. Claim 8 depends from claim 7, which I explained above in Section IX.B.1 is rendered obvious by Krishnan in view of Lee and Pagoulatos. It is my opinion that Krishan also discloses the additional limitation of claim 8.

168. Krishnan discloses "systems and methods" for "processing a medical image to automatically identify the anatomy and view (or pose) from the medical image and automatically assess the diagnostic quality of the medical image." Ex1005, Abstract. Krishnan's system also contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. As explained in Krishnan, "it is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at <u>multiple views</u>." Ex1005, [0032] (emphasis added). Accordingly, Krishnan states that the acquired image dataset may be "one or more medical images." Ex1005, [0033]. For example, during a "stress-echo" examination, "[i]t is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at multiple views" including "up to four (and sometimes more) <u>loops of data for each view</u>, where each loop represents a heart cycle." *Id.*, [0032] (emphasis added). By providing a quality check, the sonographer can be assured (in real time) "that <u>images</u> are being acquired of diagnostic quality." *Id.* (emphasis added).

169. As previously discussed in Section IX.A.1.d, Krishnan explains that the quality assessment module (105) may provide a quality assessment as "an indication as the quality level of the acquired images." Ex1005, [0020]; *see also id.* [0035], [0036], Figure 2. "The automatic image quality assessment can be

implemented to provide general feedback on the diagnostic quality of an image," *id.,* [0032], which may take the form of a "quality score (within a predefined range)." *Id.*, [0036]. The "quality score" may provide "an indication a diagnostic quality level of the medical images." *Id.*, [0020]. A POSITA would recognize that one (of several) indications of diagnostic quality may be the images' suitability for "clinical measurement of anatomical features." A POSITA would recognize that one (of several) indications of diagnostic quality may be the images' suitability for "clinical measurement of anatomical features." In fact, one common application of medical images is measurement of anatomic structures and comparison to normal values for the population. *See* Ex1020 (Lang). For example, the thickness of the left ventricle, a heart chamber, is used to diagnose a disease known as left ventricular hypertrophy and specific standardized ultrasound views are used towards this end (e.g., PLAX). The PLAX view is also used to estimate the size of another cardiac chamber, the left atrium. One measure of PLAX quality is thus whether a user can visualize and make accurate measurements of these specific structures (left ventricular wall and left atrium) so that medical diagnoses can be made. This quality measure would be meaningless for other views which do not include these same structures.

3. Claim 9: "The system of claim 7 wherein the at least one processor is configured to derive each of the expert quality assessment values at least in part from a clinical plane assessment value representing an expert opinion whether the associated echocardiographic training image was taken in an anatomical plane suitable for quantified clinical measurement of anatomical features"

170. Claim 9 depends from claim 7, which I explained above in Section IX.B.1 is rendered obvious by Krishnan in view of Lee and Pagoulatos. It is my opinion that Krishan and Pagoulatos also disclose or suggest the limitations of claim 9.

171. A POSITA would understand the functionality of claim 9 of the Patent to teach a particular "expert quality assessment value" derived, at least in part, from an assessment of the planar orientation of the image as against a clinically desirable planar orientation.

172. Krishnan teaches that its image quality classifiers may be built/trained using "previously diagnosed/labeled cases" (Ex1005, [0023], where the "image quality assessment… may include a quality score … that provides an indication [of] a diagnostic quality level of the medical images" (*id.*, [0036]). Similarly, Pagoulatos states that "the training images … may be ultrasound images which have been pre-determined (e.g., by a physician) as adequately showing a clinically desirable … view of the heart" (Ex1007, [0037]) and "the training images may include ultrasound image information having a wide variety of known

characteristics, including, for example, … various image qualities …, various imaging angles, and so on (*id*., [0046]). *See also* Ex1008, p. 7 (6:12-22), p. 10 (9:9-19); Ex1009, p. 22-23 (8:20-9:4), p. 28 (14:6-19).

4. Claim 11:

a) [11(pre), 11(a), 11(b)]:

173. The preamble and elements (a)-(b) of claim 11 are substantively identical to claim 7 of the Patent, which is discussed above. For the reasons discussed above and the additional reasons in the table below, it is my opinion that Krishnan-Lee-Pagoulatos discloses or teaches these claim elements.

Limitation	Reasoning {referenced limitation}
[11(pre)]	*See* Section IX.B.1.a) {[7(pre)]}
[11(a)]	*See* Section IX.B.1.b) {[7(a)]}
[11(b)]	*See* Section IX.B.1.b) {[7(b)]}

b) [11(c)]: "at least a portion of each of said neural networks associated with one of the plurality of predetermined echocardiographic image view categories"

174. Element 11(c) details the Patent's claimed "training" functionality. Element 11(c) overlaps substantially with the Element 7(c) but requires additional functionality: "at least a portion of each of said neural networks [are] associated with one of the plurality of predetermined echocardiographic image view categories." Stated another way, element 11(c) requires the claimed "neural networks" to interface with ("associate" with) predetermined "image view

categories." In my opinion, Krishan-Lee-Pagoulatos discloses element 11(c).

175. For the same reasons previously explained with respect to claim 1 in (Section IX.A.1.f) above, Krishnan-Lee discloses, teaches, or suggests, a plurality of view-category-specific neural networks (i.e., "bank of classifiers") having different view-category-specific parameters (e.g., weights and biases). Because each of the neural network classifiers taught by Krishnan-Lee is specific to one of a plurality of predetermined view categories, at least a "portion of each neural network" is also associated with view category, as claimed in [11(c)].

c) [11(d)-(r)]:

176. Element 11(d) begins a recitation of functions that occur "once the neural networks are trained." This post-training functionality—recited in elements (e)-(j) of claim 11—is substantively identical to the functionality set forth in claim 1 of the Patent, which is discussed above. *See* Section IX.A.1. For the reasons discussed above and the additional reasons in the table below, Krishnan-Lee-Pagoulatos discloses or teaches these claim elements.

Limitation	**Reasoning {referenced limitation}**
[11(e)/(i)]	*See* Section IX.A.1.b) {[1(a)/(e)]}
[11(f)/(j)]	*See* Section IX.A.1.c) {[1(b)/(f)]]}
[11(g)/(k)]	*See* Section IX.A.1.d) {[1(c)/(g)]}
[11(h)/(l)]	*See* Section IX.A.1.e) {[1(d)/(h)]}
[11(m)/(p)]	*See* Section IX.A.1.f) {[1(i)/(l)]}
[11(n)/(q)]	*See* Section IX.A.1.g) {[1(j)/(m)]}
[11 (o)/(r)]	*See* Section IX.A.1.h) {[1(k)/(n)]}

5. Claim 12: "The system of claim 11 wherein each of the expert quality assessment values represents an assessment of suitability of the associated echocardiographic image for quantified clinical measurement of anatomical features."

177. Claim 12 depends from claim 11, which I explained above in Section IX.B.4 is rendered obvious by Krishnan in view of Lee and Pagoulatos. It is my opinion that Krishan also discloses the additional limitation of claim 12.

178. Krishnan discloses "systems and methods" for "processing a medical image to automatically identify the anatomy and view (or pose) from the medical image and automatically assess the diagnostic quality of the medical image." Ex1005, Abstract. Krishnan's system also contemplates a multi-image workflow; the same functionality that may be applied to one echocardiographic image may be applied to another, second (or successive) image. As explained in Krishnan, "it is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at <u>multiple views</u>." Ex1005, [0032] (emphasis added). Accordingly, Krishnan states that the acquired image dataset may be "one or more medical images." Ex1005, [0033]. For example, during a "stress-echo" examination, "[i]t is important for the sonographer to acquire, as quickly as possible, diagnostic quality images at multiple views" including "up to four (and sometimes more) <u>loops of data for each view</u>, where each loop represents a heart cycle." *Id.*, [0032] (emphasis added). By providing a quality check, the sonographer can be assured (in real time) "that <u>images</u> are being acquired of diagnostic quality." *Id.* (emphasis

added).

179. As previously discussed in Section IX.A.1.d, Krishnan explains that the quality assessment module (105) may provide a quality assessment as "an indication as the quality level of the acquired images." Ex1005, [0020]; *see also id.* [0035], [0036], Figure 2. "The automatic image quality assessment can be implemented to provide general feedback on the diagnostic quality of an image," *id.,* [0032], which may take the form of a "quality score (within a predefined range)." *Id.*, [0036]. The "quality score" may provide "an indication a diagnostic quality level of the medical images." *Id.*, [0020]. A POSITA would recognize that one (of several) indications of diagnostic quality may be the images' suitability for "clinical measurement of anatomical features." A POSITA would recognize that one (of several) indications of diagnostic quality may be the images' suitability for "clinical measurement of anatomical features." In fact, one common application of medical images is measurement of anatomic structures and comparison to normal values for the population. *See* Ex1020 (Lang). For example, the thickness of the left ventricle, a heart chamber, is used to diagnose a disease known as left ventricular hypertrophy and specific standardized ultrasound views are used towards this end (e.g., PLAX). The PLAX view is also used to estimate the size of another cardiac chamber, the left atrium. One measure of PLAX quality is thus whether a user can visualize and make accurate measurements of these specific

structures (left ventricular wall and left atrium) so that medical diagnoses can be made. This quality measure would be meaningless for other views which do not include these same structures.

6. Claim 13: "The system of claim 11 wherein the at least one processor is configured to derive each of the expert quality assessment values at least in part from a clinical plane assessment value representing an expert opinion whether the associated echocardiographic training image was taken in an anatomical plane suitable for a quantified clinical measurement of anatomical features."

180. Claim 13 depends from claim 11, which I explained above in Section IX.B.4 is rendered obvious by Krishnan in view of Lee and Pagoulatos. It is my opinion that Krishan also discloses the additional limitation of claim 13.

181. A POSITA would understand the functionality of claim 13 of the Patent to teach a particular "expert quality assessment value" derived, at least in part, from an assessment of the planar orientation of the image as against a clinically desirable planar orientation.

182. Krishnan teaches that its image quality classifiers may be built/trained using "previously diagnosed/labeled cases" (Ex1005, [0023], where the "image quality assessment… may include a quality score … that provides an indication [of] a diagnostic quality level of the medical images" (*id.*, [0036]). Similarly, Pagoulatos states that "the training images … may be ultrasound images which have been pre-determined (e.g., by a physician) as adequately showing a clinically

desirable … view of the heart" (Ex1007, [0037]) and "the training images may include ultrasound image information having a wide variety of known characteristics, including, for example, … various image qualities …, various imaging angles, and so on (*id*., [0046]). *See also* Ex1008, p. 7 (6:12-22), p. 10 (9:9-19); Ex1009, p. 22-23 (8:20-9:4), p. 28 (14:6-19).

C. Ground C: Krishnan-Lee, in Further View of Chen [Cls. 6, 20]

1. Claims 6 and 20: wherein each of the sets of assessment parameters includes: a set of common assessment parameters, which are common to each of the sets of assessment parameters; and a set of view category specific assessment parameters, which are unique to the set of assessment parameters

183. Claims 6 and 20 of the Patent depend from claims 1 and 15, which I explained above in Section IX.A.1 are rendered obvious by Krishnan in view of Lee. Claims 6 and 20 are identical except they depend from system claim 1 and method claim 15, respectively.

184. Dependent claims 6 and 20 detail additional neural network structure to be implemented in the claimed image analysis system and method. More specifically, dependent claims 6 and 20 of the Patent claim two distinct sets of "[neural network assessment] parameters"—a "set of common [neural network assessment] parameters, which are common to each of the sets of neural network parameters" and "a set of view category specific [neural network assessment] parameters, which are unique to the set of neural network parameters." This neural

network structure is shown in Figure 8 of the Patent below.

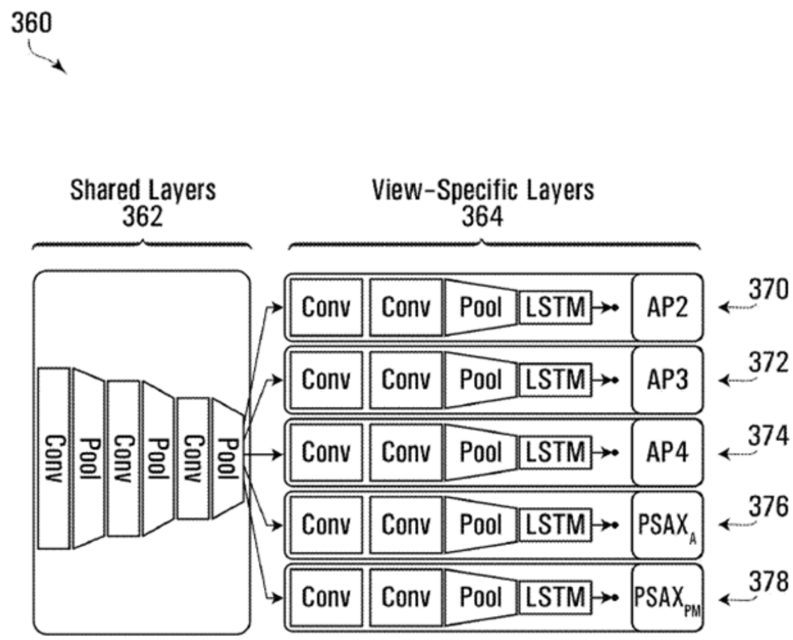


FIG. 8

185. Referring to Figure 8, above, the Patent states: "the neural network shown at 360 includes 5 image quality assessment neural networks, each including the same shared layers 362 but including a different set of view category specific layers 370, 372, 374, 376, and 378." Ex1001, 12:10-14.

186. A "[common] set of parameters defining the shared layers 362 … is shown at 320 in FIG. 9." Ex1001, 13:13-20, Figs. 8, 9.

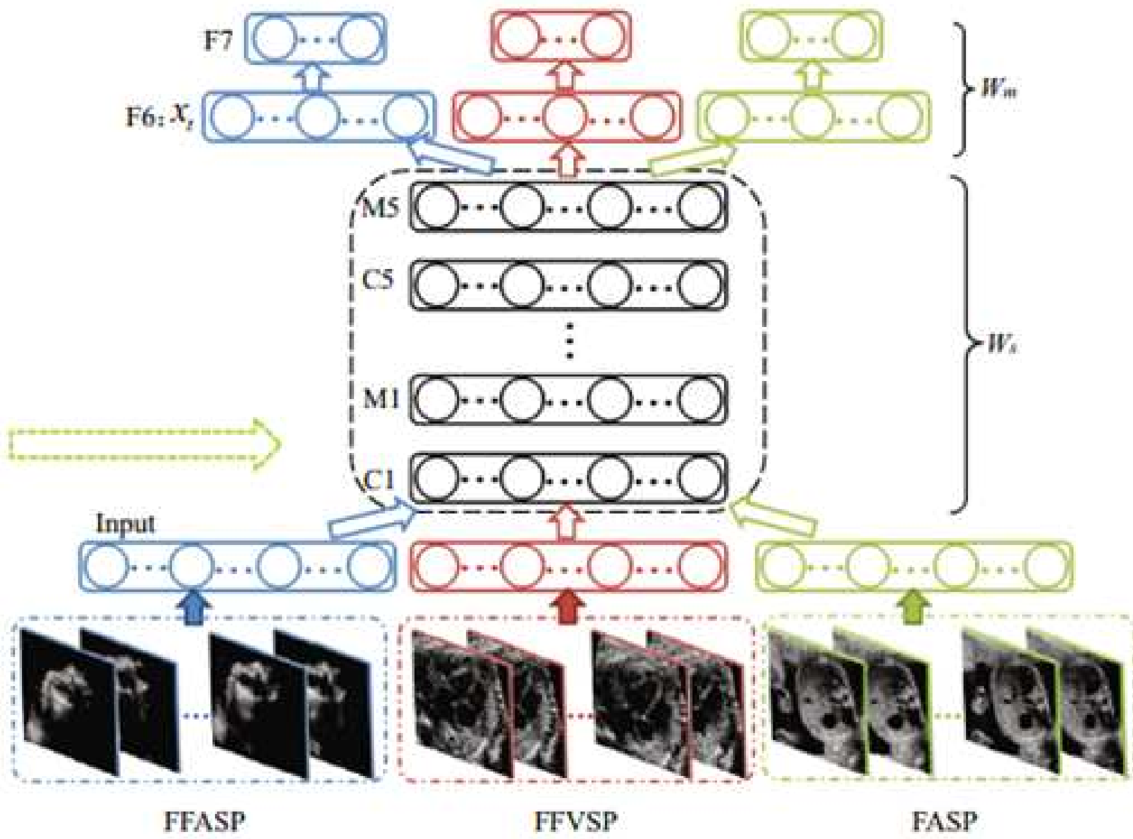
187. A "[unique] set of parameters defining the set of view category specific layers 374 … is shown at 40 in FIG. 10" Ex1001, 13:26-37, Figs.

8, 9, 10.

188. A neural network structure of common (shared) layers and category-specific neural network layers was known in the art as of the priority date of the Patent. Indeed, Caruana (Ex1018) described this approach, termed multi-task learning, as early as 1993. Subsequent applications of multi-task learning have been seen in computer vision including for image classification. *See* Ex1025 (Long and Wang). Chen is also one such example.

189. Chen describes a joint learning framework that produces a multi-stream convolutional neural network (J-CNN) with shared layers that were trained jointly, followed by branching layers that were individually trained. Ex1010, pp.507, 509-510. The purpose of jointly training early layers, Chen teaches, is "to address the insufficiency issue of limited training data" (*id.*, Abstract), "which reduces the overfitting problem caused by the inadequacy of training data" (*id.*, p.509).

190. Referring to the right side of Figure 2, which is enlarged below, Chen's multi-stream J-CNN contains 3 sets of assessment parameters, each with a "set of common [neural network assessment] parameters, which are common to each of the sets of neural network parameters" and "a set of view category specific [neural network assessment] parameters, which are unique to the set of neural network parameters," as claimed in the Patent.



191. In the figure above, "the matrix W_s denoting the parameters of layers from C1 to M5 is trained from all training samples of the three detection tasks [(i.e., FFASP, FFVSP, FASP)] and shared among these tasks." Ex1010, p.510 (emphasis added). These layers contain the "common assessment parameters." By contrast, "[t]he W_m (m = 1, 2, 3 represents the task of FFASP, FFVSP and FASP, respectively) denotes the parameters of F6 and F7 layers and is trained individually on each task for the discrimination of different standard planes." *Id*. (emphasis added). These view category-specific layers contain unique assessment parameters.

192. It is my opinion that a POSITA would have been motivated to

improve Krishnan-Lee based on the express teachings and suggestions in Chen.

193. Whereas Krishnan-Lee teaches, suggests, and renders obvious the use of multiple view-category-specific neural network classifiers having different assessment parameters for each view-category, Chen teaches the advantages of combining such separate neural networks into a neural network having common layers and separate task-specific layers. Specifically, Chen teaches that by combining separate task-specific neural networks in a manner that they share some commonly trained layers, the problems of insufficient training data and overfitting can be reduced. Ex1010, pp.507, 509 ("joint learning … across multi-tasks … reduces the overfitting problem caused by the inadequacy of training data"). This same rationale is parroted in the later-filed Patent, which states that "splitting the neural network 360 into a common portion and view category specific portions may facilitate more efficient training" and "may result in requiring fewer learning parameters than would be required if using fully separate neural networks." Ex1001, 13:53-59. Again, this is the standard description of how multi-task learning is used in training neural networks, and the concomitant benefits of the structure was known in the art as of 2015.

194. To achieve the training benefits explicitly described in Chen, a POSITA would have been motivated to structure the separate view-category-specific "bank of classifiers" taught by Krishnan-Lee to have a structure like that

depicted in Figure 8 of the Patent with common and view-specific layers/assessment parameters. A POSITA would have had a reasonable expectation of success combining Krishnan-Lee with Chen since the combinations merely involve the implementation of a specific neural network architecture, whereas Krishnan is open to the use of any machine learning classifier and/or neural network. Ex1005, [0006], [0023], [0042]-[0044]. Indeed, Chen contemplates that its proposed neural network framework "can be easily extended to other … anatomical structure detection problems." Ex1010, p.509.

D. Ground D: Krishnan-Lee, in Further View of Chen [Cls. 10, 14]

1. Claims 10 and 14: [10(pre)/14(pre)], [10(a)/14(a)], and [10(b)/14(b)]

195. Dependent Claims 10 and 14 are substantively the same but depend from claims 7 and 11, respectively. In my opinion, claims 7 and 11 are each rendered obvious by Krishnan-Lee-Pagoulatos. *See* Sections IX.B.1 and IX.B.4.

196. Elements [10(pre)]/[14(pre)], [10(a)]/[14(a)], and [10(b)]/[14(b)] are substantially identical to the elements of claims 6 and 20, which are addressed above in Section IX.C. Whereas claims 6 and 20 recite "sets of assessment parameters," claims 10 and 14 recite "sets of neural network parameters." However, each "set of assessment parameters" recited in claims 6 and 20 is defined as "being a set of neural network parameters" in underlying independent claims 1 and 15, respectively. Accordingly, elements [10(pre)]/[14(pre)], [10(a)]/[14(a)],

and [10(b)]/[14(b)] are disclosed by Chen for the same reasons provided in Section IX.C.

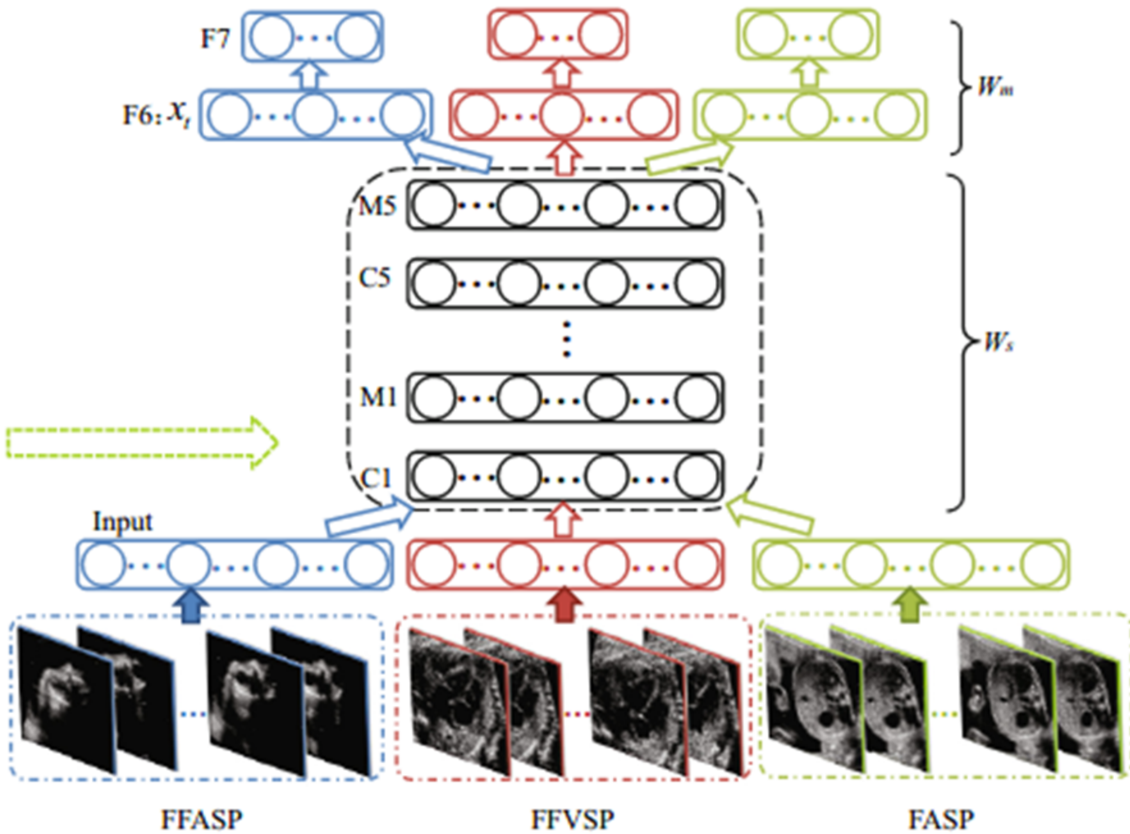
197. In my opinion, it would have been obvious to a POSITA to combine the teachings of Chen with Krishnan-Lee-Pagoulatos for the same reasons already explained in Section IX.C above. The mere addition of Pagoulatos to Krishnan-Lee does not alter or diminish the motivation to combine Chen with Krishnan-Lee. Pagoulatos is not inconsistent, or in conflict, with Chen. Accordingly, in my opinion, Claims 10 and 14 are rendered obvious by Krishnan-Lee-Pagoulatos in view of Chen.

2. [10(c)/14(c)]: "wherein the at least one processor is configured to, for each echocardiographic training image:"

198. [10(c)]/[14(c)] merely recite that the at least one processor of the underlying claims (i.e., 1 and 11, respectively) is configured to perform the functions described in the subsequent claim elements. Krishnan explains that its systems and methods "may be implemented in various forms of hardware, software, firmware, special purpose processors, or a combination thereof." Ex1005, [0045]; *see also* Ex1005, [0005], [0009], Fig. 1. And Chen discloses a computer-implemented artificial neural network training technique that performs the functions described in the subsequent claim elements. Accordingly, Krishnan and Chen disclose [10(c)]/[14(c)].

3. [10(d)/14(d)]: "select one of the sets of view category specific neural network parameters based on the predetermined echocardiographic image view category associated with the echocardiographic training image; and:"

199. In my opinion, Chen discloses elements [10(d)]/[14(d)]. Chen discloses a neural network training technique in which ultrasound images that are labeled by view category are used to train both view-category-specific neural network layers and common neural network layers that are used to assess each view category. Chen states that "[f]or training the … classifier under the framework of J-CNN [(*i.e.*, joint learning CNN)], training samples of [each standard view] FASP, FFASP, and FFVSP were generated" and "[t]hey were manually annotated [(*i.e.*, labelled)] by an experienced obstetrician." Ex1010, p.512. With reference to the J-CNN depicted in Figure 2, below, Chen further teaches that the parameters (W_s) of the common layers from C1 to M5 are "trained from all training samples of the three detection tasks and shared among the tasks." Ex1010, p.510. By contrast, the parameters (W_m) of the view-category-specific layers (F6 and F7) are "<u>trained individually</u> on each task for the discrimination of different standard planes ([i.e., views])." Ex1010, p.510 (emphasis added).



200. In order to train the view-category-specific layers having view-category-specific parameters "individually," the view-category-specific network/layer/parameters would need to be "selected" as claimed. Accordingly, in my opinion, Chen discloses [10(d)]/[14(d)].

4. [10(e)/14(e)]: "using the echocardiographic training image as an input and the associated expert quality assessment value as a desired output, train a neural network defined by the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters to update the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters."

201. In my opinion, Chen discloses elements [10(e)]/[14(e)] for the same reasons detailed in the preceding section. Alternatively, in my opinion, Chen in combination with Krishnan renders obvious [10(e)]/[14(e)].

202. Chen teaches that labelled training images for each view category are used to train both common neural network layers, as well as view-category-specific neural network layers that are associated with the same view category as the respective training images. The training image is used as the training input, and the training label is used as the desired output. Ex1010, p.510 (describing loss function for training). To the extent Chen does not explicitly describe that an expert quality assessment value is the desired output of training, Chen in combination with Krishnan renders this limitation obvious since the purpose of Krishnan's neural network classifier is explicitly to predict a diagnostic quality score based on previously labelled cases.

203. Accordingly, in my opinion, Krishnan-Lee-Pagoulatos in further view of Chen renders obvious claims 10 and 14.

*   *   *

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 and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: Rahul C. Deo

Dr. Rahul C. Deo.

ATTACHMENT A

CLAIMS APPENDIX

Limitation	Claim Language
Claim 1	
[1(pre)]	A computer-implemented system for facilitating echocardiographic image analysis, the system comprising at least one processor configured to:
[1(a)]	receive signals representing a first at least one echocardiographic image;
[1(b)]	associate the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories;
[1(c)]	determine, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image;
[1(d)]	produce signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image;
[1(e)]	receive signals representing a second at least one echocardiographic image;
[1(f)]	associate the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category;
[1(g)]	determine, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one echocardiographic image; and
[1(h)]	produce signals representing the second quality assessment value for causing the second quality assessment value to be associated with the second at least one echocardiographic image;
[1(i)]	wherein each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that define a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an

	output layer configured to output one or more quality assessment values, and wherein the at least one processor is configured to determine the first quality assessment value by:
[1(j)]	determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and
[1(k)]	in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters; and
[1(l)]	wherein the at least one processor is configured to determine the second quality assessment value by:
[1(m)]	determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and
[1(n)]	in response to determining that the second set of assessment parameters is associated with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the second set of assessment parameters.
Claim 2	
[2]	The system of claim 1 wherein the first quality assessment value represents an assessment of suitability of the first at least one echocardiographic image for quantified clinical measurement of anatomical features and wherein the second quality assessment value represents an assessment of suitability of the second at least one echocardiographic image for quantified measurement of anatomical features.
Claim 3	
[3(pre)]	The system of claim 1 wherein the at least one processor is configured to:
[3(a)]	produce signals for causing a representation of the first quality assessment value to be transmitted to at least one display for causing the at least one display to display the first quality assessment value in association with the first at least one echocardiographic image, to assist one or more operators of an echocardiographic device in capturing at least one subsequent echocardiographic image; and
[3(b)]	produce signals for causing a representation of the second quality assessment value to be transmitted to the at least one display for causing the at least one display to display the second quality

	assessment value in association with the second at least one echocardiographic image, to assist the one or more operators in capturing at least one subsequent echocardiographic image.
Claim 4	
[4(pre)]	The system of claim 1 wherein the at least one processor is configured to:
[4(a)]	apply one or more view categorization functions to the first at least one echocardiographic image to determine that the first at least one echocardiographic image falls within the first view category; and
[4(b)]	apply one or more view categorization functions to the second at least one echocardiographic image to determine that the second at least one echocardiographic image falls within the second view category.
Claim 5	
[5]	The system of claim 1 wherein the first at least one echocardiographic image comprises a plurality of echocardiographic images and wherein the at least one processor is configured to determine the first quality assessment value by determining a single quality assessment value representing a view category specific assessment of the plurality of echocardiographic images.
Claim 6	
[6(pre)]	The system of claim 1 wherein each of the sets of assessment parameters includes:
[6(a)]	a set of common assessment parameters, which are common to each of the sets of assessment parameters; and
[6(b)]	a set of view category specific assessment parameters, which are unique to the set of assessment parameters.
Claim 7	
[7(pre)]	The system of claim 1 wherein the at least one processor is configured to train the neural networks by:
[7(a)]	receiving signals representing a plurality of echocardiographic training images, each of the plurality of echocardiographic training images associated with one of the plurality of predetermined echocardiographic image view categories;
[7(b)]	receiving signals representing respective expert quality assessment values representing view category specific quality assessments of the plurality of echocardiographic training images, each of the expert quality assessment values provided by an expert echocardiographer and associated with one of the plurality of

	echocardiographic training images; and
[7(c)]	training the neural networks using the plurality of echocardiographic training images as inputs and the associated expert quality assessment values as desired outputs to determine the sets of neural network parameters defining the neural networks.
Claim 8	
[8]	The system of claim 7 wherein each of the expert quality assessment values represents an assessment of suitability of the associated echocardiographic image for quantified clinical measurement of anatomical features.
Claim 9	
[9]	The system of claim 7 wherein the at least one processor is configured to derive each of the expert quality assessment values at least in part from a clinical plane assessment value representing an expert opinion whether the associated echocardiographic training image was taken in an anatomical plane suitable for quantified clinical measurement of anatomical features.
Claim 10	
[10(pre)]	The system of claim 7 wherein each of the sets of neural network parameters includes:
[10(a)]	a set of common neural network parameters, which are common to each of the sets of neural network parameters; and
[10(b)]	a set of view category specific neural network parameters, which are unique to the set of neural network parameters; and
[10(c)]	wherein the at least one processor is configured to, for each echocardiographic training image:
[10(d)]	select one of the sets of view category specific neural network parameters based on the predetermined echocardiographic image view category associated with the echocardiographic training image; and
[10(e)]	using the echocardiographic training image as an input and the associated expert quality assessment values as a desired output, train a neural network defined by the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters to update the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters.
Claim 11	
[11(pre)]	A computer-implemented system for training neural networks to

	facilitate echocardiographic image analysis, the system comprising at least one processor configured to:
[11(a)]	receive signals representing a plurality of echocardiographic training images, each of the plurality of echocardiographic training images associated with one of a plurality of predetermined echocardiographic image view categories;
[11(b)]	receive signals representing expert quality assessment values representing view category specific quality assessments of the plurality of echocardiographic training images, each of the expert quality assessment values provided by an expert echocardiographer and associated with one of the plurality of echocardiographic training images; and
[11(c)]	train the neural networks using the plurality of echocardiographic training images and the associated expert quality assessment values to determine sets of neural network parameters defining the neural networks, at least a portion of each of said neural networks associated with one of the plurality of predetermined echocardiographic image view categories;
[11(d)]	wherein the at least one processor is further configured to, once the neural networks are trained:
[11(e)]	receive signals representing a first at least one echocardiographic image;
[11(f)]	associate the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories;
[11(g)]	determine, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image;
[11(h)]	produce signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image;
[11(i)]	receive signals representing a second at least one echocardiographic image;
[11(j)]	associate the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category;
[11(k)]	determine, based on the second at least one echocardiographic

	image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one echocardiographic image; and
[11(l)]	produce signals representing the second quality assessment value for causing the second quality assessment value to be associated with the second at least one echocardiographic image;
[11(m)]	wherein each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that define a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values, and wherein the at least one processor is configured to determine the first quality assessment value by:
[11(n)]	determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and
[11(o)]	in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters; and
[11(p)]	wherein the at least one processor is configured to determine the second quality assessment value by:
[11(q)]	determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and
[11(r)]	in response to determining that the second set of assessment parameters is associated with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the second set of assessment parameters.
Claim 12	
[12]	The system of claim 11 wherein each of the expert quality assessment values represents an assessment of suitability of the associated echocardiographic image for quantified clinical measurement of anatomical features.
Claim 13	
[13]	The system of claim 11 wherein the at least one processor is configured to derive each of the expert quality assessment values at

	least in part from a clinical plane assessment value representing an expert opinion whether the associated echocardiographic training image was taken in an anatomical plane suitable for a quantified clinical measurement of anatomical features.
Claim 14	
[14(pre)]	The system of claim 11 wherein each of the sets of neural network parameters includes:
[14(a)]	a set of common neural network parameters, which are common to each of the sets of neural network parameters; and
[14(b)]	a set of view category specific neural network parameters, which are unique to the set of neural network parameters; and
[14(c)]	wherein the at least one processor is configured to, for each echocardiographic training image:
[14(d)]	select one of the sets of view category specific neural network parameters based on the predetermined echocardiographic image view category associated with the echocardiographic training image; and
[14(e)]	using the echocardiographic training image as an input and the associated expert quality assessment value as a desired output, train a neural network defined by the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters to update the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters.
Claim 15	
[15(pre)]	A computer-implemented method of facilitating echocardiographic image analysis, the method comprising:
[15(a)]	receiving signals representing a first at least one echocardiographic image;
[15(b)]	associating the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories;
[15(c)]	determining, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image;
[15(d)]	producing signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image;

[15(e)]	receiving signals representing a second at least one echocardiographic image;
[15(f)]	associating the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category;
[15(g)]	determining, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one echocardiographic image; and
[15(h)]	producing signals representing the second quality assessment value for causing the second quality assessment value to be associated with the second at least one echocardiographic image;
[15(i)]	wherein each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that defines a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values and wherein:
[15(j)]	determining the first quality assessment value comprises:
[15(k)]	determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and
[15(l)]	in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters applying a first function based on the first set of assessment parameters to the first at least one echocardiographic image; and
[15(m)]	determining the second quality assessment value comprises:
[15(n)]	determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and
[15(o)]	in response to determining that the second set of assessment parameters is associated with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the second set of assessment parameters.

Claim 16	
[16]	The method of claim 15 wherein the first quality assessment value represents an assessment of suitability of the first at least one echocardiographic image for quantified clinical measurement of anatomical features and wherein the second quality assessment value represents an assessment of suitability of the second at least one echocardiographic image for quantified measurement of anatomical features.
Claim 17	
[17(pre)]	The method of claim 15 wherein:
[17(a)]	producing the signals representing the first quality assessment value comprises producing signals for causing a representation of the first quality assessment value to be transmitted to at least one display for causing the at least one display to display the first quality assessment value in association with the first at least one echocardiographic image, to assist one or more operators of an echocardiographic device in capturing at least one subsequent echocardiographic image; and
[17(b)]	producing the signals representing the second quality assessment value comprises producing signals for causing a representation of the second quality assessment value to be transmitted to the at least one display for causing the at least one display to display the second quality assessment value in association with the second at least one echocardiographic image, to assist the one or more operators in capturing at least one subsequent echocardiographic image.
Claim 18	
[18(pre)]	The method of claim 15 wherein:
[18(a)]	associating the first at least one echocardiographic image with the first view category comprises applying one or more view categorization functions to the first at least one echocardiographic image to determine that the first at least one echocardiographic image falls within the first view category; and
[18(b)]	associating the second at least one echocardiographic image with the second view category comprises applying one or more view categorization functions to the second at least one echocardiographic image to determine that the second at least one echocardiographic image falls within the second view category.
Claim 19	
[19]	The method of claim 15 wherein the first at least one

	echocardiographic image comprises a plurality of echocardiographic images and wherein determining the first quality assessment value comprises determining a single quality assessment value representing a view category specific assessment of the plurality of echocardiographic images.
Claim 20	
[20(pre)]	The method of claim 15 wherein each of the sets of assessment parameters includes:
[20(a)]	a set of common assessment parameters, which are common to each of the sets of assessment parameters; and
[20(b)]	a set of view category specific assessment parameters, which are unique to the set of assessment parameters.