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. 10,751,029

Inter Partes Review No.: IPR2025-01422

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. 10,751,029 (“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 ultrasonic 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 1-30 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. US2019/0076127 (“Aase”) (Ex1006), a scientific journal article by Chen (“Chen”) (Ex1009), and a scientific journal article by Wu (“Wu”) (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 am currently adverse to the University of British Columbia in IPR2025-01066, also on behalf of GEHC and Caption Health. 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

August 31, 2018, which I understand is the date Provisional Application No. 62/725,913, identified on the cover of the Patent, was filed.

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 1-30 of the Patent.

C. Anticipation

21. I understand that patent claims are required to be novel. Therefore, a patent claim is invalid if a single prior art reference discloses each and every element of the claimed subject matter arranged in substantially the same way such

that a person of ordinary skill in the art could practice the patent claim. I understand that such a claim is said to be "anticipated" by said prior art reference.

22. I understand that, while courts generally go through element by element to find identicality and similarity in the juxtaposition of those elements, both inherency and equivalence may also influence whether a claim is anticipated. Inherency, as I understand it, means that some elements may be present in a prior art reference even when not explicitly mentioned when some technical reasoning with basis in fact shows that the inherent element necessarily flows from the teachings of the prior art reference. Equivalence, on the other hand, I understand to mean that an element from a prior art reference, although not identical to that of the corresponding element in the patent claim, may be interchangeable when an explanation exists such as a showing that the elements perform substantially the same function, in substantially the same way, to achieve substantially the same result or showing that an ordinarily skilled artisan would have recognized said interchangeability.

D. Obviousness

23. I understand that patents are also required to be nonobvious. Therefore, a patent claim may also be 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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.

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

31. 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.

32. 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.

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

33. 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.

34. 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.

35. I have undertaken to consider the knowledge the POSITA would have had as of August 31, 2018, 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

36. 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

37. 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

38. Ultrasound is a commonly used medical imaging modality and is employed to capture an anatomic representation of diverse organ systems in a patient's own organs or in a fetus, 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.

39. 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]. These standard views are used to derive specific measurements such as the area or thickness of cardiac chambers. Similarly, for obstetric ultrasound, the standard planes or views used for biometric measurement include the fetal abdominal standard plane (FASP), fetal face axial standard plane (FFASP), and the fetal four-chamber view standard plane (FFVSP). Ex1009, p.507; Ex1010, p.1338 (pdf p.3) ("fetal [ultrasound] views for the depiction of fetal face, fetal four cardiac chambers, etc."). Image quality assessment in ultrasound imaging is typically view-specific and includes the ability to visualize key structures, which differ by view. Salomon LJ et al. *A score-based method for quality control of fetal images at routine second-trimester ultrasound examination*. Prenat Diagn. 2008 Sep;28(9):822-7. doi: 10.1002/pd.2016. PMID: 18646244 Ex1026 ("Salomon"); Ex1005, [0005, 0019].

40. However, acquisition of these "standard" views can be challenging for non-experts. The skill and experience threshold for operators to perform proper manual acquisition is relatively high. Ex1009, p.508. It has thus been a longstanding area of interest to use artificial intelligence methods to assist users in capturing and confirming standardized views produced by ultrasound technology. Ex1009, p.508; Ex1005, [0028]. Moreover, automating the process for assessing diagnostic quality of ultrasound images could eliminate variability and error due to

subjective interobserver feedback and thus facilitate the creation and provision of real time operator feedback. Ex1010, 1336-1337 (pdf p.1-2); Ex1005, [0032].

2. Artificial Intelligence

41. 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.

42. 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).

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

44. 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.

45. 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

46. 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").

47. 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.

48. 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. Ex1027 (LeCun).

49. Neural networks trained for medical image recognition were known in the art several decades before 2018. In fact, no later than 1996 the scientific article Itchhaporia, *Artificial Neural Networks: Current Status in Cardiovascular Medicine* reported that "Artificial neural networks are under investigation in the fields of image processing and interpretation. They are being used to process images, to facilitate complex pattern recognition , which will aid <u>classification of images into clinically relevant categories</u>." Ex1012, p. 519. By 2016, it was recognized that neural networks could be implemented in a wide variety of applications within medical imaging. For example, Hao Chen et al., *Standard Plane Localization in Fetal Ultrasound via Domain Transferred Deep Neural Networks*, (Sept. 2015) (Ex1016) (Chen) used convolutional neural networks to analyze fetal ultrasound images. *See also* Ex1028 (Bouzerdoom). Methods of training such networks were also well documented in the art. Ex1017, 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.")

50. 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. Ex1023. 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") (Ex1024) 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. 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. Ex1025. 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. Ex1020. Once trained, the neural network demonstrated good results in cardiac

view recognition.

4. Neural Network Architecture

51. 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. For example, in 2014, Donahue et al. described a neural network architecture to process videos (temporal sequences of images). Ex1021, pp.2626-2628. Donahue's contemplated neural network consisted of one or more convolutional neural network (CNN) layers followed by one or more recurrently neural network layers (RNNs). *Id.* Donahue's work was seminal in demonstrating that a common architecture could be applied to a wide range of video analysis tasks, simply by tailoring one or more output layers within the network and providing appropriately labeled training data. Building upon this work, a 2015 published study (Chen) described the use of deep learning convolutional neural networks (CNNs) in combination with recurrent neural networks (RNNs) to recognize anatomic features in a set of sequential ultrasound images (e.g., video) and automatically determine whether the images correspond to standard views. *See generally*, Ex1009. And, by May 2017, another published study reported using deep CNNs for "automatic quality assessment" of ultrasound images in specific view categories, which could be "easily generalized" to assess the quality of other views. *See generally* Ex1010 ("Wu").

52. 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. As taught in Kong, *Recognizing End-Diastole and End-Systole Frames via Deep Temporal Regression Network*, and Chen, *Iterative Multi-domain Regularized Deep Learning for Anatomical Structure Detection and Segmentation from Ultrasound Images*, 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. *E.g.*, Ex1014, pp.266-267 ("Kong") ("we employ a CNN as the feature extractor"); Ex1013, pp.487-488. ("Chen I") ("(CNNs) have gained prevalence on image classification and segmentation tasks"). 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.

53. RNNs are designed recursively such that output from the previous step or node is fed as input into the current one. This architecture, which allows the network to operate with memory and linear connectedness, in contrast to the independently functioning nodes of other types of neural networks, is particularly adept at processing sequential data where the order is significant. In the context of

medical imaging, RNNs are very effective at identifying temporal patterns from a sequence of images (e.g., a set of image frames from an ultrasound video). Ex1009, pp.508-509; Ex1014, pp.266-267.

5. Implementation and Training of Neural Networks

54. The CNN described in Donahue et al. consisted of a series of layers, focused on feature extraction. The first layer applies a convolution or linear transformation to individual pixels within the input image in order to extract useful features (e.g., edges), while subsequent layers apply transformations to arrays from the preceding layer. The overall purpose of the CNN is to convert the input image into a more useful representation for subsequent tasks. The CNN is followed by one or more recurrent neural network (RNN) layers which integrated information from the preceding or following image in a temporal sequence. Ex1021, pp.2625,2627-2629. The type of RNN Donahue proposed to use is called long-short term memory (LSTM). *See* Ex1021, pp.2625-2627. 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. Ex1009, 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).")

55. Understanding the implementation and training of neural networks at the intersection of artificial intelligence and medical imaging is inherent in understanding their architecture. Donahue et al in 2014 outline how to train CNN-RNN hybrid architectures, emphasizing the benefits of learning the parameters "end-to-end," such that the parameters V of the visual field extractor learn to pick out the aspects of the visual input that are relevant to the sequential classification problem. Ex1021, pp.2625-2629. They describe using the standard methods of stochastic gradient descent with backpropagation and sampling minibatches, which continue to be used today. They also demonstrate a variety of different possible tasks that can be achieved using variations of the same architecture, where the outputs of the RNN vary depending on the task of interest. *Id.* In Chen as well as Wu (so no later than 2017), the training of CNNs in conjunction with RNNs in a pipeline architecture for marked improvements on the processing of sequential ultrasonic data including for image quality/view category identification and quality assessment scoring was well-known in the art. See, Ex1009 (Chen), p.509, 511. Ex1010 (Wu), p.1338 (pdf p.3). Thus, nearly 10 years ago, the state of the art provided multiple well-developed and well-known perspectives on training and implementation such that accepted best practices had already started to emerge. *See, e.g.*, Ex1012, p.516 (Itchaporia). And, as for

training specifically, the knowledge base is just as old and robust, as training techniques were honed and in some cases perfected for feature identification in natural image processing (Ex1017, p.450 ("Miller" explaining "Supervised learning") as well as for sequential data such as loops, video, or vignettes, cines, or other serial temporal image sets.

6. Multi-Task Learning

56. 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.

57. 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* Ex1022. 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. Ex1009, 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 '029 PATENT AND PROSECUTION HISTORY

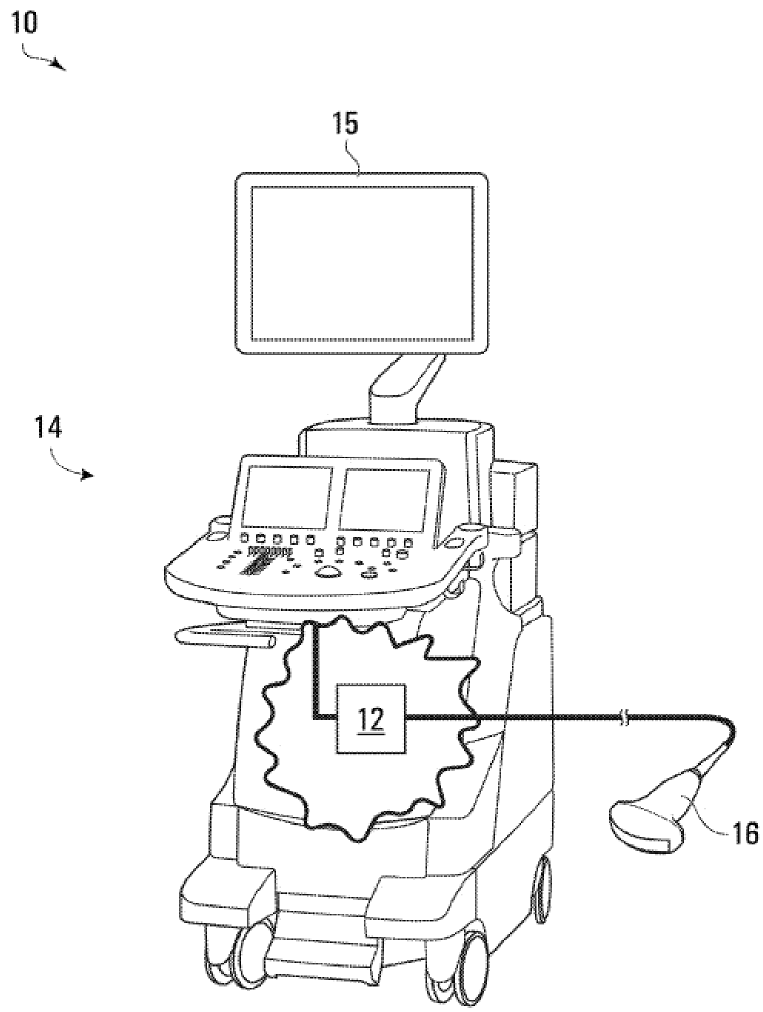
58. I understand that the Patent, entitled "ULTRASONIC IMAGE ANALYSIS," was filed on August 30, 2019 and issued on August 25, 2020. Ex1001, cover. I have been instructed by counsel to assume August 31, 2018 is the priority date of the Patent, which is the filing date of Provisional Application No. 62/725,913.

59. The Patent explains that "[a]ccurate diagnosis in ultrasound requires high quality ultrasound images, which may need to show or contain different

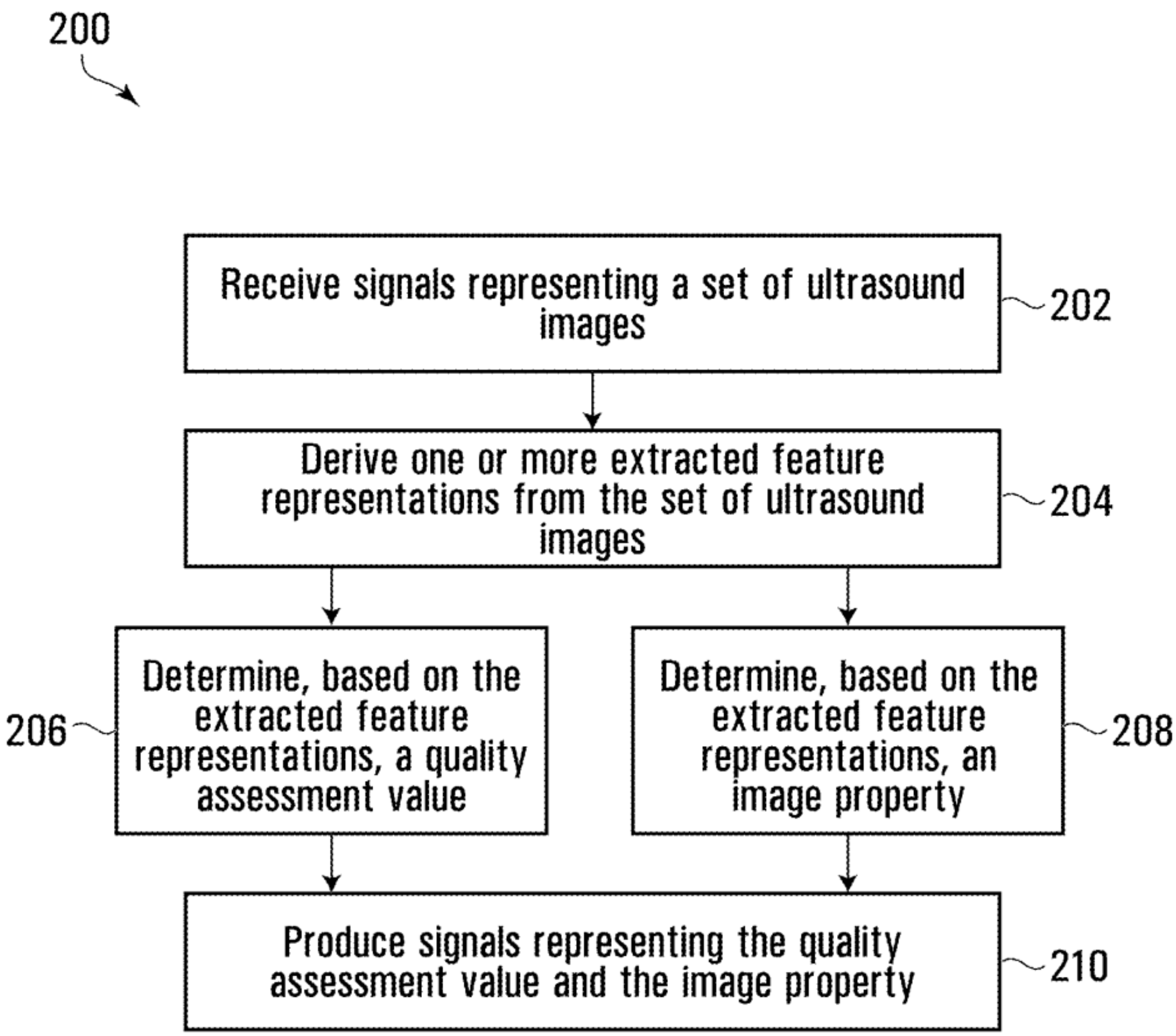
specific features and structures depending on various properties of the images." Ex1001, 1:22-25.

60. According to the Patent, "[s]ome ultrasound systems may not provide feedback to operators regarding the quality of the image and/or other image properties. Inexperienced ultrasound operators may have a great deal of difficulty using such known systems to recognize feature sin the ultrasound images and thus can fail to capture diagnostically relevant ultrasound images." Ex1001, 1:25-31. The Patent purports to relay disclosures concerning "ultrasonic image analysis and more particularly to ultrasonic image analysis for determining image quality and image properties." *Id.*, 1:16-18.

61. The Patent identifies Figure 1, below, as "a schematic view of a system for facilitating ultrasonic image analysis in accordance with various embodiments of the invention." Ex1001, 4:9-11, Fig. 1.



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



Ex1001, 9:9-10:16, 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 disclosure." *Id.*, 4:15-18. At blocks 204, 206, and 208, the workflow utilizes at least one neural network which is trained to perform each of the disclosed functions with the ultimate goal of "generating an output of a quality assessment value and an image property, which in some embodiments may be a view category.

Id. 9:64-10:8, 1:35-50, 3:22-27. While the Patent discloses that feature representation extraction from block 204 occurs first in this process, "blocks 206 and 208 may sequentially or in parallel." *Id.* 12: 52-57. And, the claimed "set of ultrasound images" may be "a temporally ordered set of ultrasound images representing a video or cine of the subject" where "[e]ach image of the set of ultrasound images may be referred to herein as a frame." *Id.*, 9:26-33; 6:4-9, 6:29-31, 9:51-58.

63. Figure 4, below, refers to an embodiment of an exemplary neural network according to the disclosure of the Patent. *Id*. 4:19-21. Each image from the set of ultrasound images is input into a respective, but "commonly defined" "first feature extracting neural network (labeled as 304, 306, and 308 in Fig. 4 and further described as subnetworks). *Id.* 10:21-42; 23:60-1. The first feature extracting neural networks are disclosed as being attuned to extract features that are "encodings of image patterns of a single echo frame" or "a vector of real valued numbers" where each "may be considered as the level of presence of a specific spatial pattern." *Id*. 11:30-42. But, because "alternative or additional feature extracting functions and/or neural networks may be used to extract features of the input set of ultrasound images" and "more than one of the commonly defined first feature extracting neural networks may be run concurrently, the Patent contemplates embodiments in three "commonly defined… [and] identical" CNNs

are implemented "in separate threads at the same time in order to prevent lag during particularly long interference times. *Id.* 11:39-50.

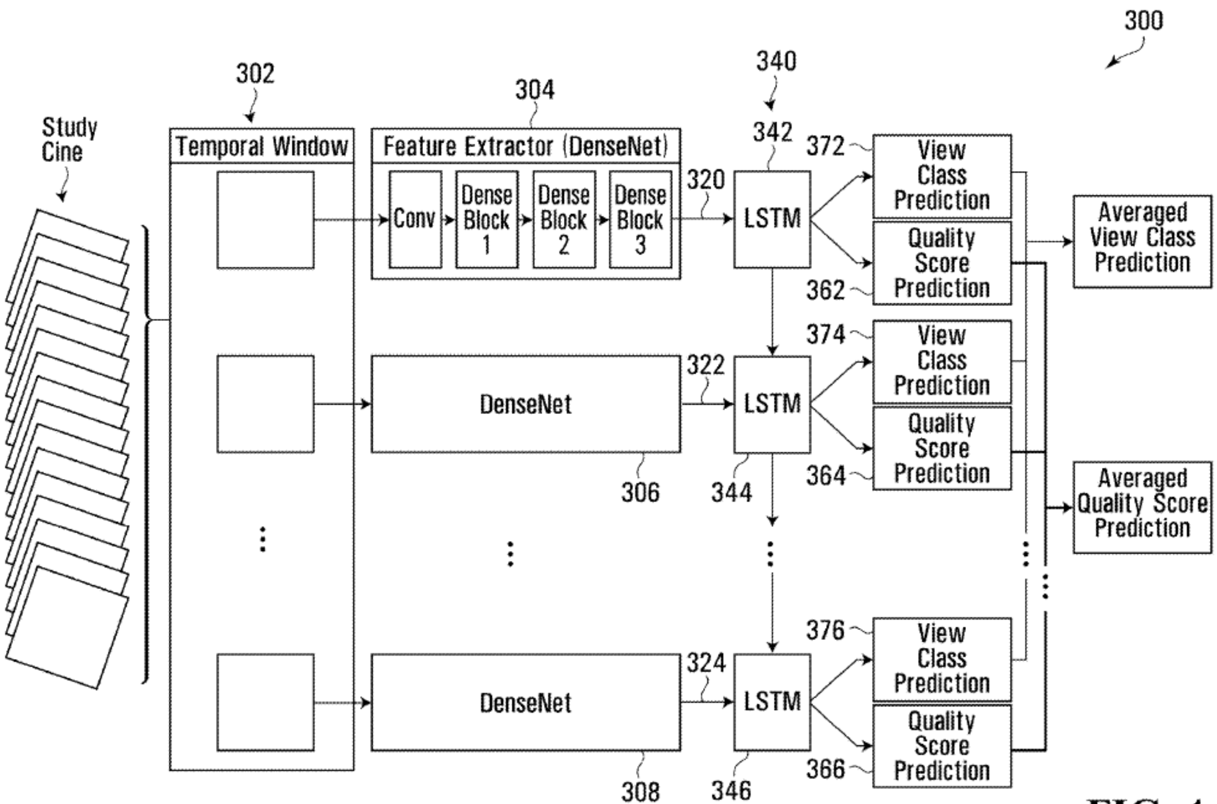


FIG. 4

64. The extracted first feature representations, are input into second feature extracting neural networks. *Id*. 11:51-12:13. With the temporal nature of the ultrasound image datasets in mind, "the second feature extracting neural networks may include a plurality of… RNNs… [which] may be implemented using along short term memory module (LSTM)." *Id.* 12: 10-15. The output second feature representation from one image in the set may therefore be "used as input for further processing." *Id*. 12:20-24.

65. As further depicted in Figure 4, the respective second extracted

feature representations in turn become the inputs to respective quality assessment value specific neural networks (or "subnetworks"), depicted as 362, 364, and 366 in the figure, to produce a quality assessment value for each of the input second feature representations. *Id*., 12:62-66, 13:1-5. This allows the system described in the Patent to determine and assign a quality assessment value to the set of ultrasound images that was originally input as, for example, "an average or mean of the quality assessment values output by the quality assessment value specific determining neural subnetworks." *Id*., 13:43-46. As with the respective feature extracting neural networks described above, each of the respective quality assessment neural networks may be "commonly defined … by the same neural network parameters." *Id*., 13:1-8, 13:25-27.

66. The Patent further teaches that the system may "input each of the second feature representations into an implementation of a commonly defined view category specific subnetwork… to determine a view category for each of the input second feature representations." *Id.* 13:63-67. Furthermore, "each of the commonly defined view category specific neural subnetworks may apply a softmax to the input second feature representations to generate a probability vector wherein each position in the vector corresponds to a view category and the value stored therein represents a probability that the ultrasound image is in the view category corresponding to the vector position. For example, where there are fourteen (14)

possible view categories, the output of the view category specific neural subnetwork 372 may be a 14-element length probability vector… [and] each position in the output probability vector may represent a determined probability that the input set of ultrasound images depicts a particular view category, such as, for example, one chosen from AP2, AP3, AP5, PLAX, RVIF, PSAXA, PSAXM, PSAXPM, PSAXAP, SC4, SC5, IVC, and SUPRA Referring to Figure 9, below, there is shown a detailed representation of the view category specific neural subnetwork 372 in accordance with various embodiments.. *Id.* 14:9-27.

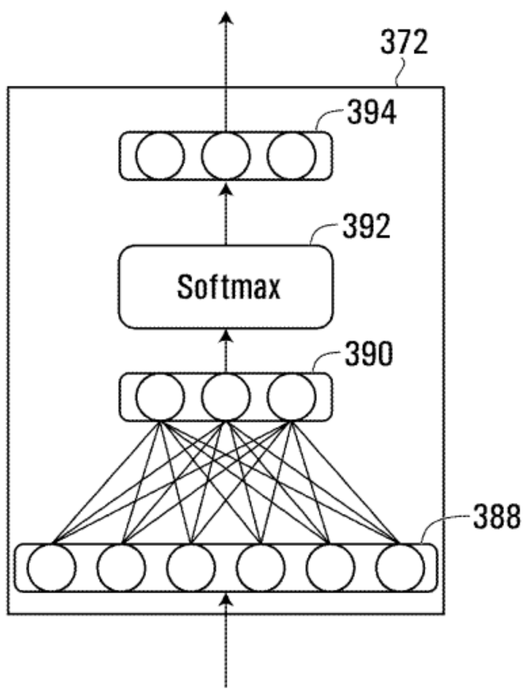


FIG. 9

67. As shown in Figure 11, below, the Patent describes "training" neural

networks for its workflow by using signals representing "plurality of ultrasound training images" and signals for "quality assessment values" and "image properties" and which are associated with said ultrasound training images. *Id.* 2:31-49, Figs. 11, 12. More specifically, as shown below in Figure 11, the Patent "storage memory includes a plurality of storage locations including location for storing training date, location for storing first feature extracting neural network data, location for storing second feature extracting neural network parameter data, location for storing quality assessment value specific neural network parameter data, and location for storing view category specific neural network parameter data" (640, 642, 646, 648 in Fig. 11). *Id.* 16:1-8.

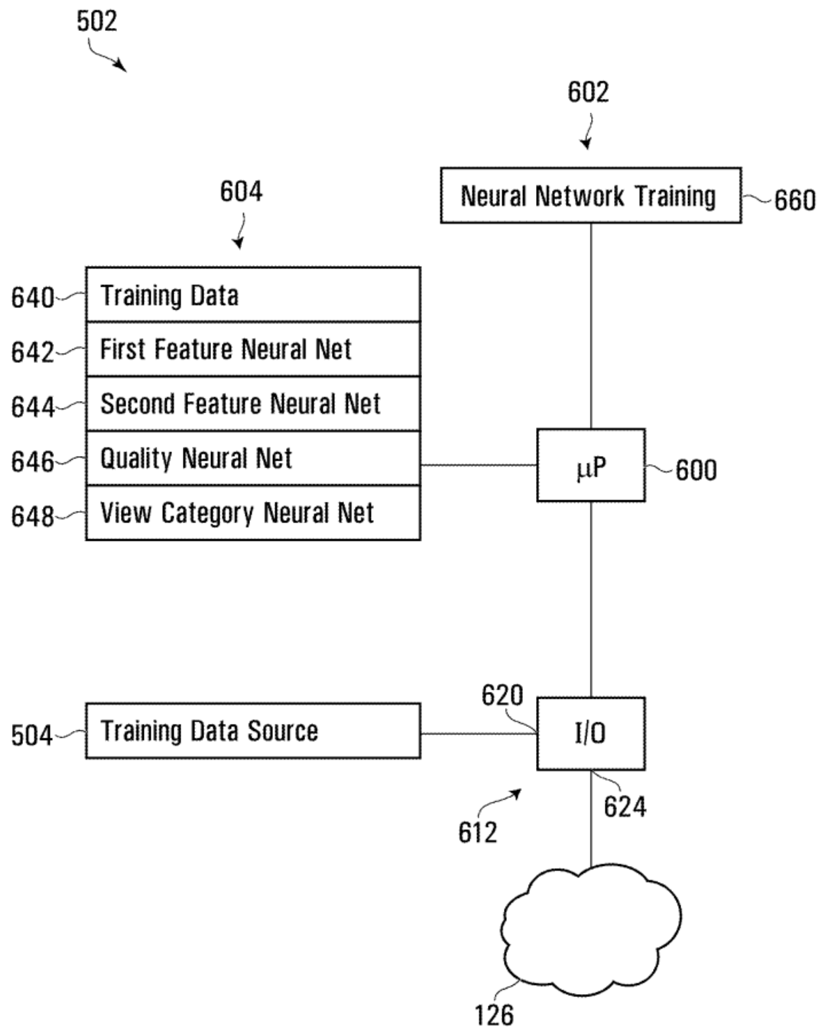


FIG. 11

68. Figure 12, below, depicting the Patent's "neural network training functions" shows receipt of "signals representing a plurality of ultrasound training images," which may be "a temporally ordered set of ultrasound images representing a video or cine of a respective subject," receipt of "signals representing quality assessment values" associated with the sets of images which

"may have been previously provided to the training data source" such as "by an expert who has been trained to determined quality of the sets of ultrasound images" with a score, and, finally, receipt of "signals representing image properties" which may entail "receiv[ing] signals representing view categories" such as "AP2, AP3, AP4, AP5, PLAX, RVIF, PSAXA, PSAXM, PSAXPM, PSAXAP, SC4, SC5, IVC, and SUPRA. Ex1001, 4:43-45, 16:24-25, 39-40, 65-67, 17:1-2, 14-16.

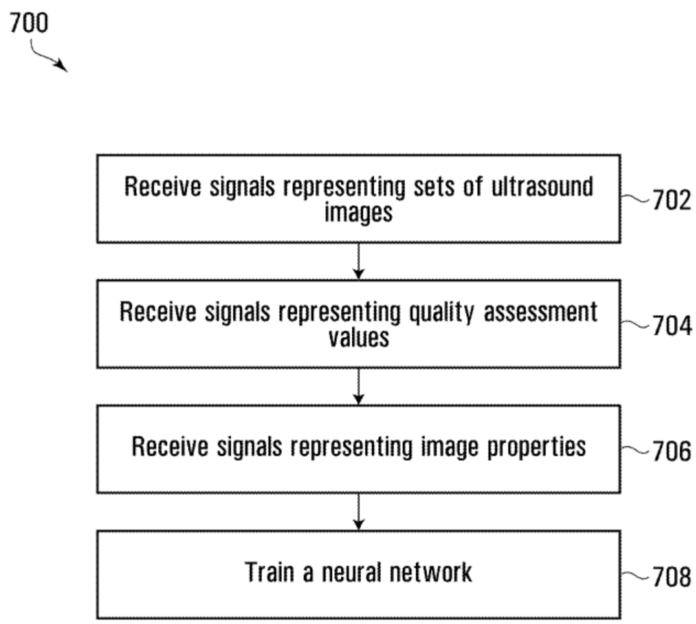


FIG. 12

69. Some embodiments, as shown in Figure 3 of the Patent "may include a block of codes for directing the analyzer processor 100 to store an ultrasound image associated with the highest quality assessment value for each view category… such that the ultrasound image stored is an ultrasound image that is

associated with the highest quality assessment value for that view category." *Id.* 19:37-40, 44-46. Furthermore, the Patented system may "direct the analyzer processor 100 to replace any previously stored quality assessment value and ultrasound image stored…in associate with the determined view category with the determined quality assessment value and the associated ultrasound images. In various embodiments, this may facilitate the storage of ultrasound images associated with the highest determined quality assessment values, for each view category…" *Id.* 20:6-7, 8-13. The Patent states that the ultrasound operator "may not even know this is happening, but when it comes to review the high quality cines afterwards, it may be a very useful tool to find the best quality images for each cine" such that "the operator may easily view the best quality images for each view category." *Id.* 20: 15-18, 24-26.

70. 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.

71. The Patent issued from U.S. Patent Application No. 16/557,261 ("the Application"), which I understand was filed on August 30, 2019.

72. In a first Office Action, dated January 8, 2020, I understand that the Examiner rejected all claims (1-30) under 35 U.S.C. § 102(a)(2) as being anticipated by US2019/0125298, which I understand later issued as U.S. Patent

Number 11,129,591 on which I am opining in IPR2025-01066. Ex1004, p. 265-288.

73. On March 19, 2020, I understand that the Applicant removed US2019/0125298 as prior art under the exception "common ownership" exception in 35 U.S.C. §102(b)(2)(C). Ex1004, pp. 290-343. I understand that the Examiner did not make any further rejections of any claim on prior art grounds.

74. On June 25, 2020, I understand that the Examiner issued a notice of allowance citing US2019/0130554 ("Rothberg et al.") as the "closest prior art." Ex1004, pp. 345-407. The Examiner stated: "Rothberg et al. nor any other prior art of record teaches, regarding claim 1, the features of 'determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images; and producing signals representing the quality assessment value and the image property for causing the equality assessment value and the image property to be associated with the set of ultrasound images….'" *Id.*, p. 354. Thus, from my reading of the prosecution history record, the Examiner did not substantively address any of the prior art references presented here, including Krishnan.

75. I address below claims 1-30 of the Patent in the context of the identified prior art. I have reviewed claims 1-30 for purposes of this analysis and include herewith as **Attachment A**, an appendix of Claims 1-30.

VII. OPINIONS REGARDING CLAIM CONSTRUCTION

76. Except as explained below in this section (regarding claims drafted in "means-plus-function" format, 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 (that are not drafted in terms of means-plus-function), 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.

77. As I further address below in my detailed opinion regarding claim 30 of the Patent (Section IX.A.10), I understand that this claim is drafted in a means-plus-function format. Briefly, I understand that a patentee is allowed to claim a function that is accomplished by their invention and state that their invention provides a means to accomplish this function—provided that said means is supported by and limited to the specific structures and examples identified in the

[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.

specification of the patent and disclosed by the patentee. I understand that in this case the parties have agreed to a construction of the means-plus-function terms of claim 30 of the Patent, which I adopt in turn below.

A. "means for receiving signals representing a set of ultrasound images of the subject" (Claim 30)

78. I understand that Petitioner and Patent Owner have agreed that "means for receiving signals representing a set of ultrasound images of the subject" should be construed as a means-plus-function claim limitation and that the corresponding structure in the specification which supports and limits this term for performing the recited function is: "a processor with I/O interface." Ex1015, p.2.; Ex1001, Fig. 2 (100, 112), 7:50-54, 7:61-63, 8:17-22.

B. "means for deriving one or more extracted feature representations from the set of ultrasound images" (Claim 30)

79. I understand that Petitioner and Patent Owner have agreed that "means for deriving one or more extracted feature representations from the set of ultrasound images" should be construed a means-plus-function claim limitation and that the corresponding structure/algorithm identified in the specification which supports and limits this term for performing the recited function is: "a processor and memory operating a neural network." Ex1015, p.2.; Ex1001, Fig. 2 (100, 102, 104, 154, 156, 170), 1:55-2:7, 6:35-41, 7:50-52, 8:23-9:3, 9:64-10:2, 10:21-11:60, Fig. 4 (300, 304, 306, 308, 340, 342, 344, 346).

C. "means for determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images" (Claim 30)

80. I understand that Petitioner and Patent Owner have agreed that "means for determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images" should be construed as a means-plus-function claim limitation and that the corresponding structure identified in the specification which supports and limits this term for performing the recited function is: "a processor and memory operating a neural network." Ex1015, p.2; Ex1001, Fig. 2 (100, 102, 104, 142, 144, 158, 170), 2:8-10, 2:14-19, 6:42-48, 7:50-52, 8:23-9:3, 9:64-10:8, Fig. 4 (300, 362, 364, 366), 12:58-13:48.

D. "means for determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images" (Claim 30)

81. I understand that Petitioner and Patent Owner have agreed that this term should be construed as a means-plus-function claim limitation and that the corresponding structure identified in the specification which supports and limits this term for performing the recited function is: "a processor and memory operating a neural network." Ex1015, p.2; Ex1001, Fig. 2 (100, 102, 104, 142, 144, 160, 170), 2:11-13, 2:19-23, 6:56-64, 7:50-52, 8:23-9:3, 9:64-10:8, Fig. 4 (300, 372, 374, 376), 13:49-14:53.

E. "means for producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images" (Claim 30)

82. I understand that Petitioner and Patent Owner have agreed that "means for producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images" should be construed as a means-plus-function claim limitation and that the corresponding structure identified in the specification which supports and limits this term for performing the recited function is: "a processor and memory." Ex1015, p.3; Ex1001, Fig. 2 (100, 102, 104, 140, 150, 152, 170), 7:4-14, 7:50-58, 8:23-9:3, 14:54-15:21.

VIII. SUMMARY OF THE PRIOR ART

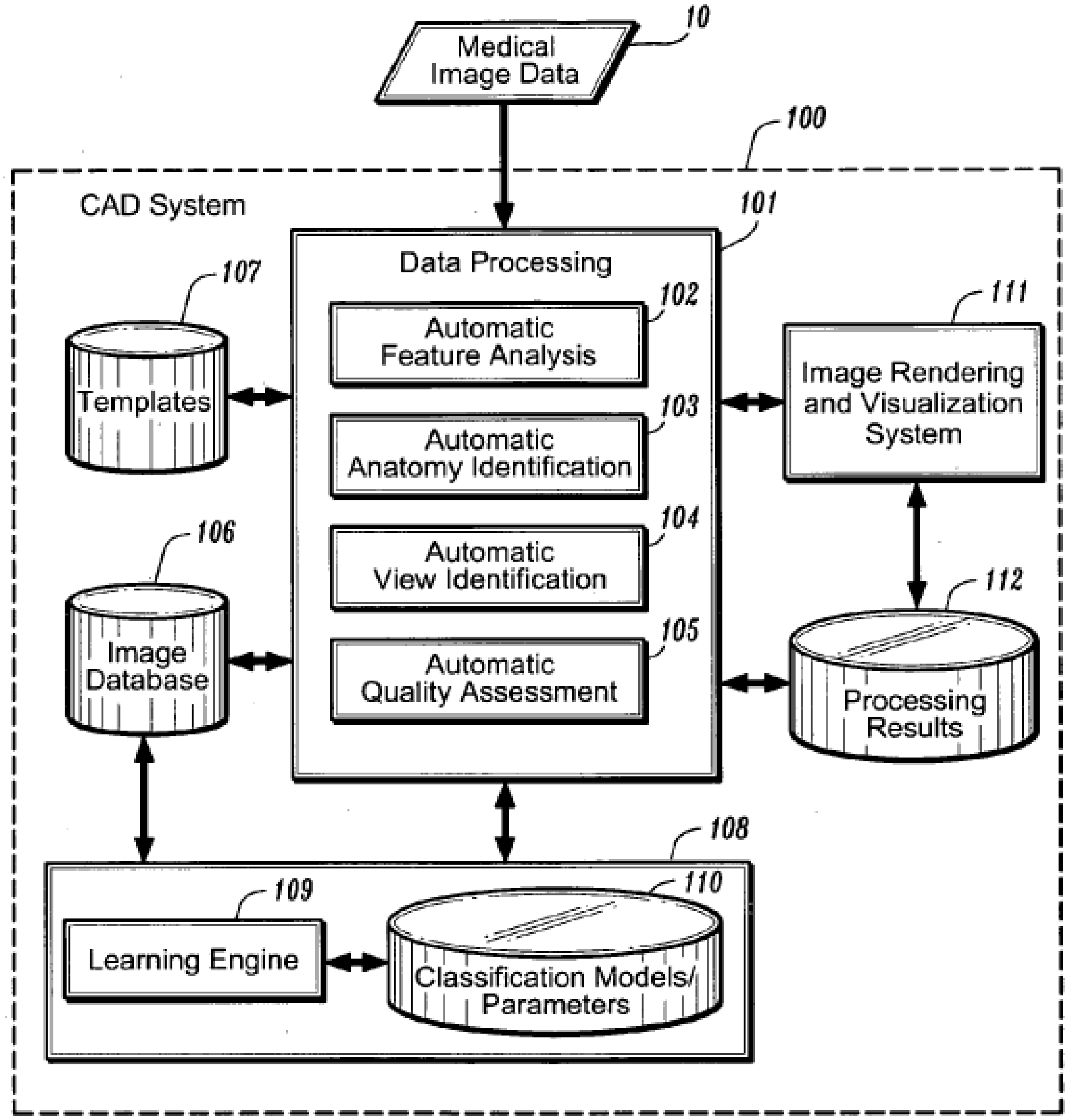
A. US2005/0251013 ("Krishnan")

83. 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 August 31, 2018.

84. 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

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].

85. 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
101
Data Processing
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

86. 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]).

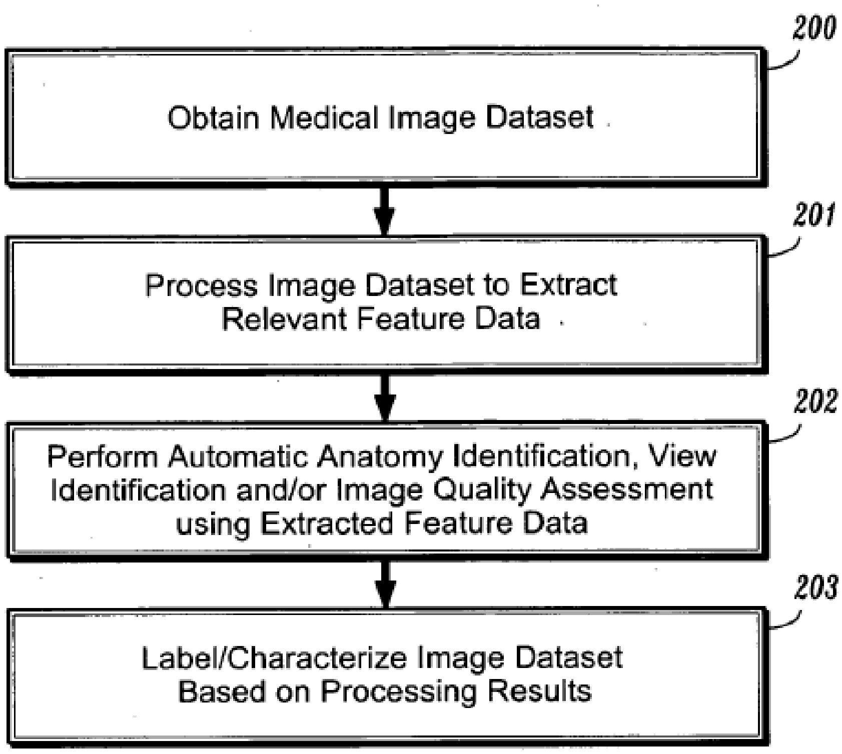


FIG. 2

87. 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*.

88. 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…”).

89. 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]. In my opinion, a POSITA would understand the "classifier bank" of Krishnan to contemplate different neural networks that are trained and adapted to accomplish myriad tasks in an efficient and continuous matter, with different networks for each function operating once, multiple times, or continuously and repeatedly.

B. US2019/0076127 ("Aase")

90. Aase is a U.S. patent application filed on September 12, 2017, and published on March 14, 2019. Ex1006, cover. I understand, therefore, that Aase is prior art to the Patent, even if I assume that the Patent is entitled to a priority date of August 31, 2018.

91. Like Krishnan, Aase is directed to a system and method for analyzing sets of ultrasound images of the heart ("loops") to automatically assign an image view type and a quality assessment value. Ex1006, Abstract, Fig. 5 (404, 406, 408, 410), [0031]-[0032], [0034], [0035] ("image quality score"), [0043]-[0046]. Aase describes: (a) an "image intake module 150" that "separates [a] continuously captured stream of ultrasound image data into image loops" (*id.*, [0031], [0044]);

(b) an "image loop view assignment module 160" that is "operable to automatically assign an image view type" (*id.*, [0032], [0045]); and (c) an "image characteristic metric assignment module 170" that is "operable to assign an image characteristic metric to each image loop" "based on image quality characterizations" (*id.*, [0034], [0046]).

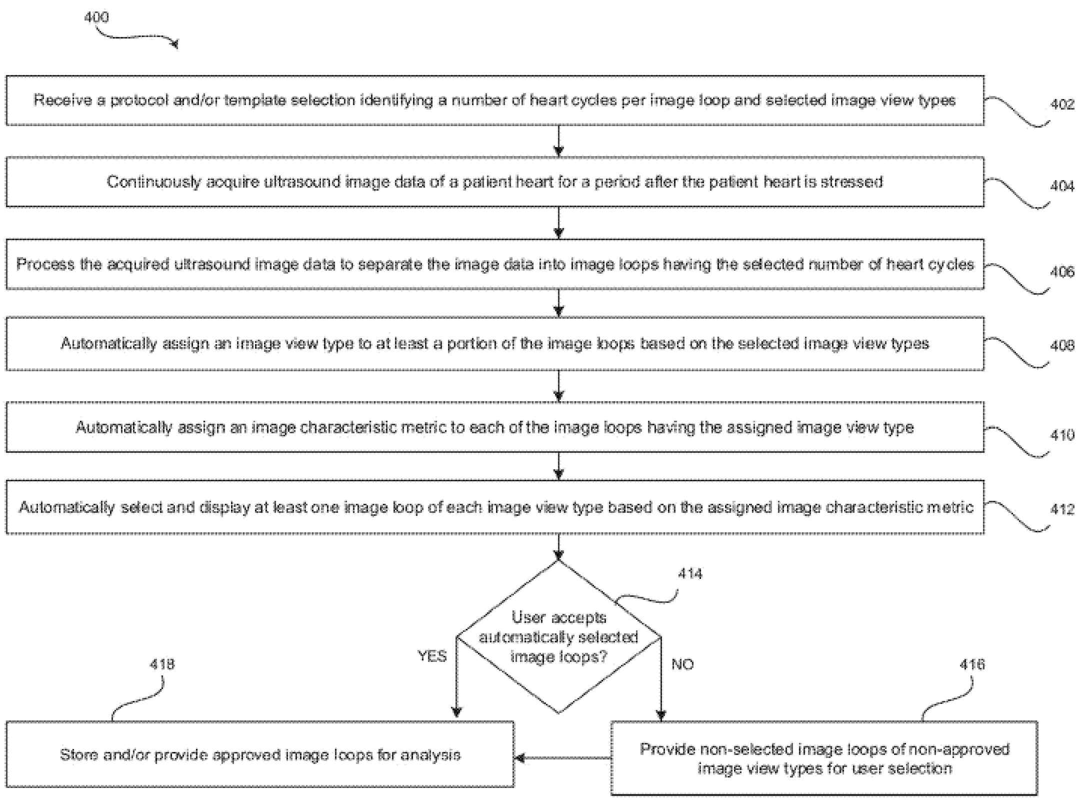


FIG. 5

92. The image loop view assignment module 160 "may apply image

detection mechanisms” (*id.*, [0032]) and “may include one or more deep neural networks” made up of multiple layers (*id.*, [0033]). For example, “a first layer may learn to recognize edges of structures in the ultrasound image data” and “a second layer may learn to recognize shapes based on the detected edges from the first layer.” *Id.*, [0033]. Likewise, the “image characteristic metric assignment module 170 may include one or more deep neural networks … for scoring the quality of the image loops.” *Id.*, [0035].

C. Automatic Fetal Ultrasound Standard Plan Detection (“Chen”)

93. 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. Ex1009. 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 August 31, 2018.

94. Chen describes methods for automatically detecting when an acquired

image corresponds to a standard fetal ultrasound plane (*i.e.*, view) using trained neural networks. Ex1009, p.507. Specifically, Chen explores the feasibility of using jointly trained convolutional neural networks (J-CNNs) in combination with recurrent neural networks (RNNs) to accurately identify ultrasound video frames from image sets or cines 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*. Whereas the J-CNNs extract spatial features from the ultrasound frames (*id*., pp.508 ("deep learning based spatial feature representations"), 509 ("features … extracted from the … CNN model"), Fig 2 ("Spatial features"), 511 ("Features in the penultimate layer … of the J-CNN model are then extracted from … each frame."), the RNN, which is based on an LSTM model, extracts temporal features based on the extracted features of consecutive images (*id*., pp.508-509). 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. Ex1009, p.509.

95. As shown on the left side of Figure 2, which is reproduced below,

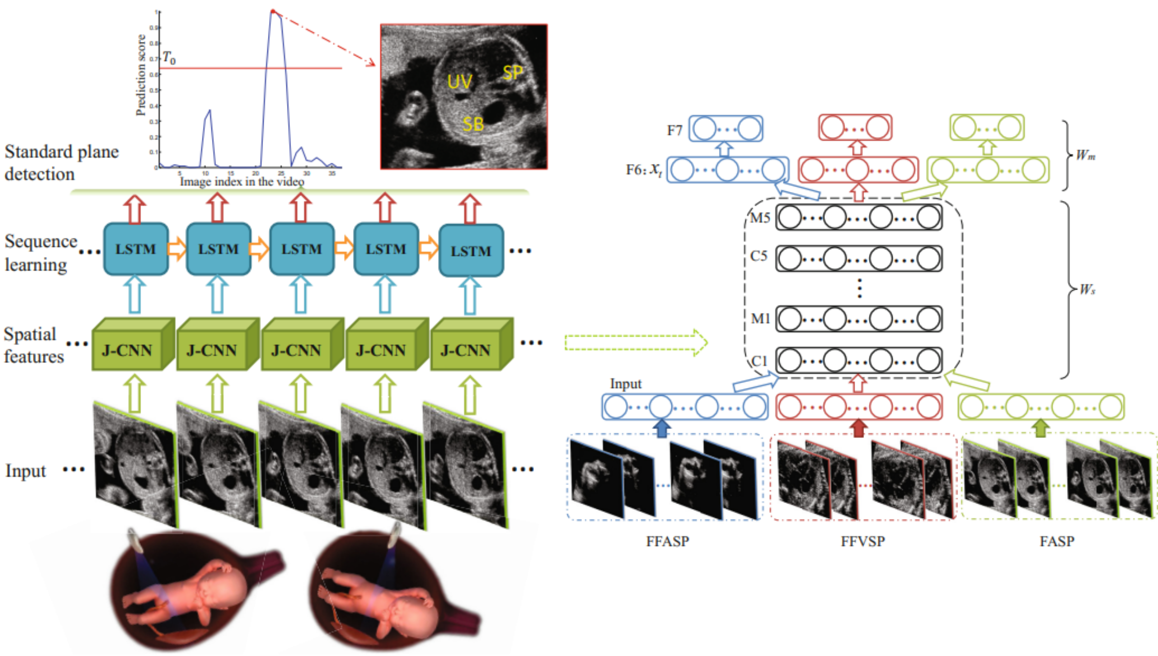


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

Chen also depicts *concurrently* inputting a sequence of ultrasound image frames into a plurality of commonly defined J-CNNs to extract spatial features. Ex1009, p.509.

96. Chen further 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." Ex1009, p.510. Accordingly, Chen proposes "a joint learning model with CNN across multiple detection tasks of US standard planes, as illustrated in Figure 2."

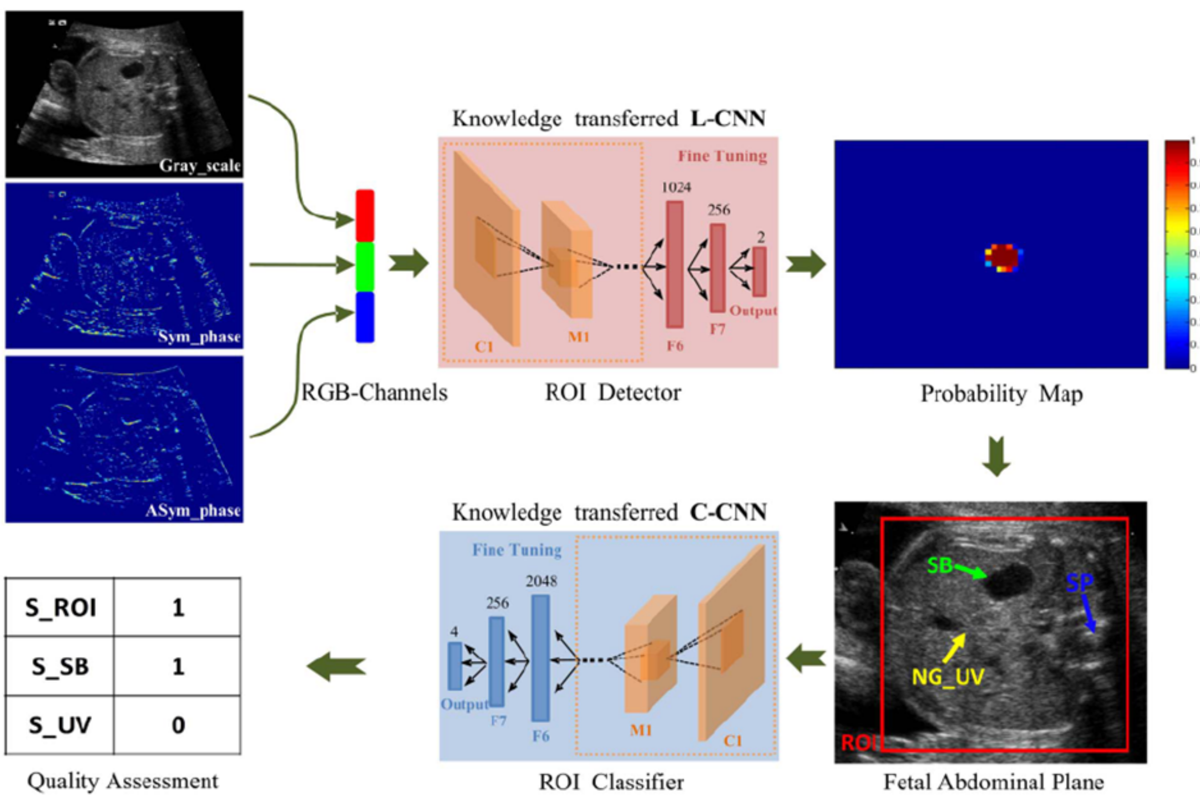
97. Referring to the right side of Figure 2, above, Chen states: "In the figure, the matrix W_s denoting the parameters of layers from C1 to M5 is trained from all training samples of the three detection tasks [(i.e., FFASP, FFVSP, FASP)] and shared among these tasks." Ex1009, p.510 (emphasis added). 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.

D. Fetal Ultrasound Image Quality Assessment With Deep Convolutional Networks ("Wu")

98. Wu is a scientific journal article published in May 2017 by the Institute of Electrical and Electronics Engineers ("IEEE"). Ex1010. In my opinion, an interested member of the public could have reasonably located this reference by searching the National Library of Medicine's PubMed® database or

the article's DOI reference (*e.g.*, at crossref.org). I understand, therefore, that Wu is prior art to the Patent, even if I assume that the Patent is entitled to a priority date of August 31, 2018.

99. Wu describes techniques and methods for providing an automatic fetal ultrasound image quality assessment (FUIQA). Ex1010, pp.1336-1337 (pdf pp.1-2). Referring to Figure 3, which is reproduced below, Wu uses a set of ultrasound images as input to a first convolutional neural network (labelled as L-CNN), which extracts features from the images by "identify[ing] the region of interest (ROI) of the fetal abdominal region in the US image." *Id.*, pp.1337 (pdf pp.2).



100. The extracted ROI is provided as input to a second neural network

classifier (C-CNN) that evaluates key features within the ROI and outputs a quality assessment value. Ex1010, pp.1337, 1339 (pdf pp.2,4)(Fig. 3). Although the exemplary embodiment described by Wu relates to the fetal abdominal view/plane, Wu also states that "the proposed FUIQA scheme can be easily generalized to other types of fetal US views for the depiction of fetal face, fetal four cardiac chambers, etc." *Id.*, p.1338 (pdf p.3). It is my opinion that a POSITA would indeed be able to adapt the teachings of Wu to any of these applications.

IX. DETAILED OPINIONS REGARDING INVALIDITY

101. As detailed below, in my opinion, claims 1-30 of the Patent are unpatentable as anticipated and/or obvious in view of the prior art identified and described herein.

102. The following table sets forth the grounds, individual prior art references, and combinations of prior art references that anticipate or render obvious each of claims 1-30:

Ground	Prior Art	Basis	Claims Challenged
A	Krishnan	Anticipation	1-3, 9, 11, 21-22, 27, 29, 30
B	Krishnan in view of Chen	Obviousness	3-8, 23-26
C	Krishnan in view of Aase	Obviousness	9-10, 27-28
D	Krishnan in view of Chen and Wu	Obviousness	12-20

A. Ground A: Anticipation by Krishnan

1. Claim 1: Claimed Method

103. As an initial matter, I note that the claimed subject matter of the

Patent and the illustrative diagrams disclosed in Krishnan are markedly similar. This is particularly apparent when the method recited in illustrative claim 1 (as schematically depicted in Figure 3 of the Patent) is compared to Figure 2 of Krishnan, highlighted and shown below side-by-side:

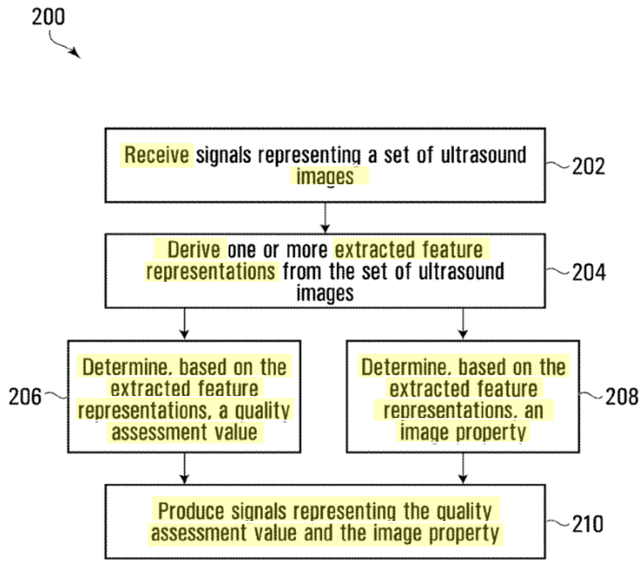


Fig. 3 of the Patent (Ex1001)

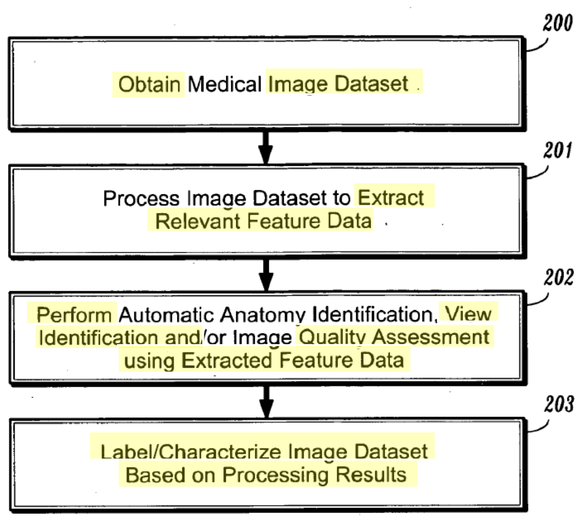


Fig. 2 of Krishnan (Ex1005)

104. In my opinion, as set forth below, each and every element 1-3, 9, 11, 21-22, 27, 29, and 30 is found recited in Krishnan in substantially the same arrangement as claimed, and therefore I understand that Krishnan anticipates these claims.

a) [1(pre)]: "A computer-implemented method of facilitating ultrasonic image analysis of a subject, the method comprising:"

105. 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[,]" precisely as claimed in the Patent.

106. 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 states that an "exemplary system (100) comprises a data processing module (101) that implements various methods for analyzing medical image data (10) in one or more image modalities (e.g., ultrasound image data …) to automatically extract and process relevant information from the medical image data to provide various decision support function(s) for evaluating the medical images." *Id.*, [0016]. Krishnan also states that the "methods described herein … may be implemented in various forms of hardware, software, firmware, special purpose processors, or a combination thereof." *Id.*, [0045]; *see also Id.*, [0005], [0009], Fig. 1.

107. It is therefore my opinion that Krishnan discloses all the elements of the preamble of claim 1 of the patent, arranged in the same way.

b) 1[(a)]: "receiving signals representing a set of ultrasound images of the subject;"

108. Krishnan discloses element [1(a)], "receiving signals representing a set of ultrasound images of the subject[.]" In Figure 1 (reproduced below), the data processing module 101 of the medical imaging processing technology from Krishnan's 100 receives "Medical Image Data 10" which Krishnan elaborates may be "ultrasound image data." Ex1005, [0016]; see also [0009] ("ultrasound imaging (e.g., 2-D echocardiography)"). Krishnan further states that "[t]he system (100) can process digital image data (10) in the form of raw image data, 2-D-reconstructed data (e.g., axial slices), or 3D-reconstructed data." *Id.*, [0017].

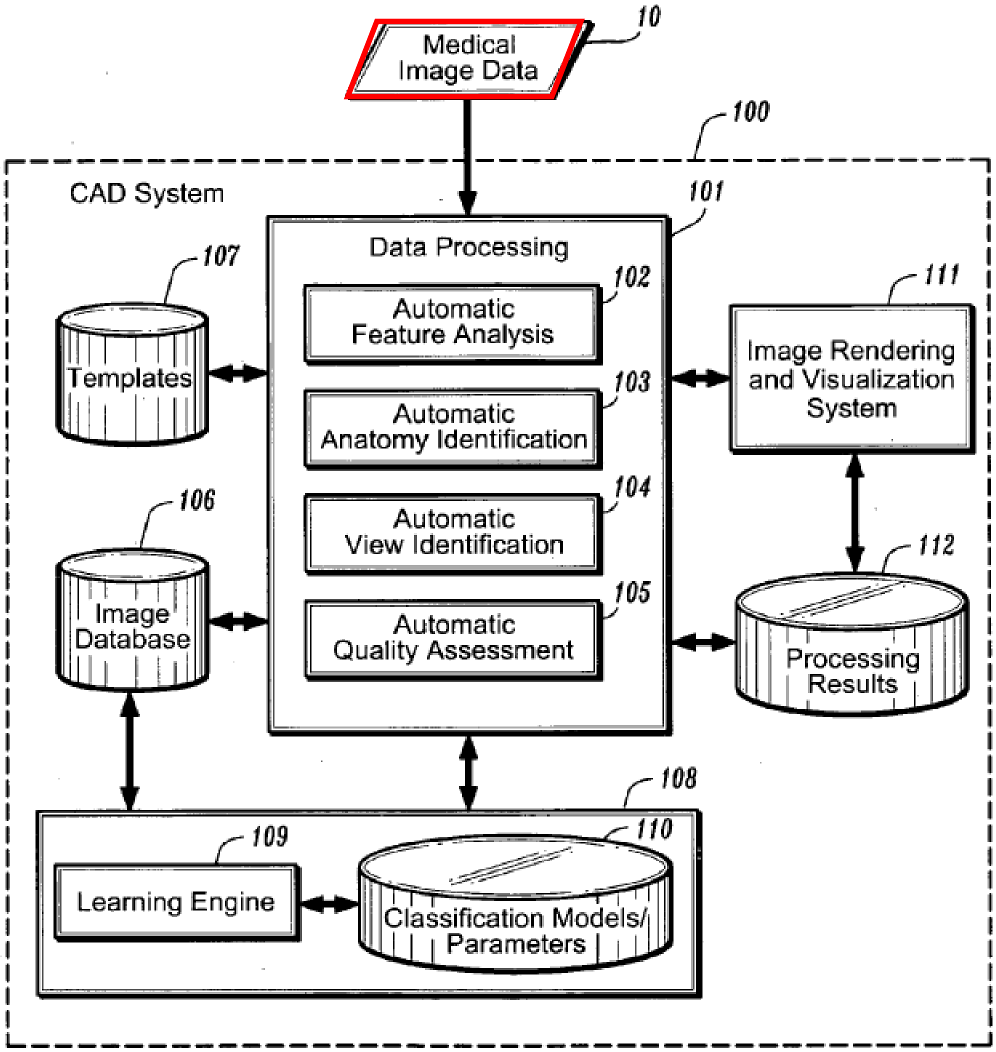


FIG. 1

109. As mentioned above, with reference to Figure 2 (shown below), Krishnan further states: "Initially, a physician, clinician, radiologist, etc., will obtain a medical image dataset comprising one or more medical images of a region of interest of a subject patient (step 200)." Ex1005, [0033] (emphasis added).

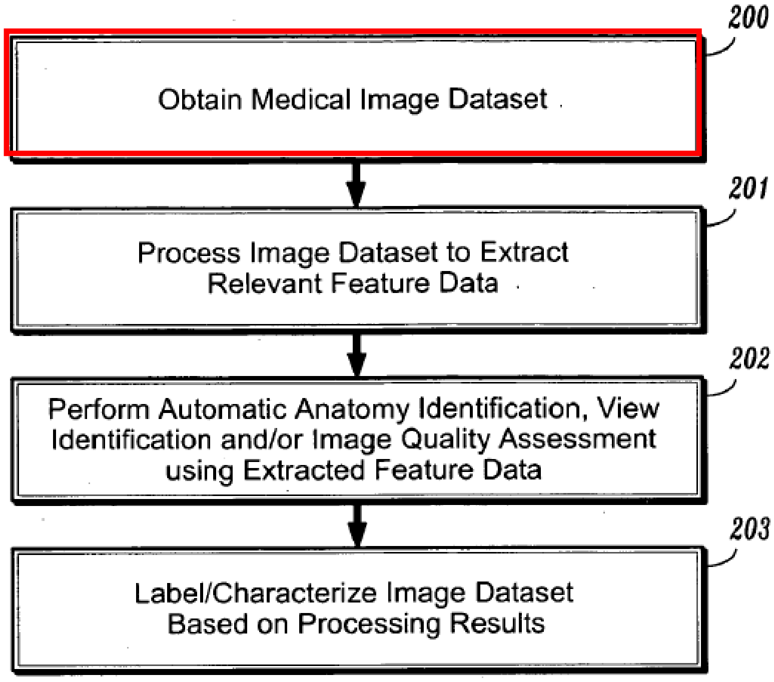


FIG. 2

110. "The image dataset may be obtained using a medical imaging system for real-time acquisition and processing" or "the image dataset may be obtained by accessing a previously acquired, and persistently stored image dataset." Ex1005, [0033]. Additionally, Krishnan states that "[t]he digital image data (10) may comprise one or more 2D slices," or "multiple views of a beating heart acquired with a 3D Ultrasound probe." *Id.*; *see also* [0032] (describing providing automatic quality checks for "loops of data" obtained by a sonographer "where each loop represents a heart cycle.") Thus, in my opinion, Krishnan discloses "receiving signals representing a set of ultrasound images of the subject," as claimed.

c) [1(b)]: "deriving one or more extracted feature representations from the set of ultrasound images;"

111. Krishnan discloses element [1(b)], "deriving one or more extracted feature representations from the set of ultrasound images[.]" Referring to Figure 1 (shown below), Krishnan discloses a data processing module 101 that includes an "Automatic Feature Analysis" module 102 for extracting feature data from the received medical image dataset 10.

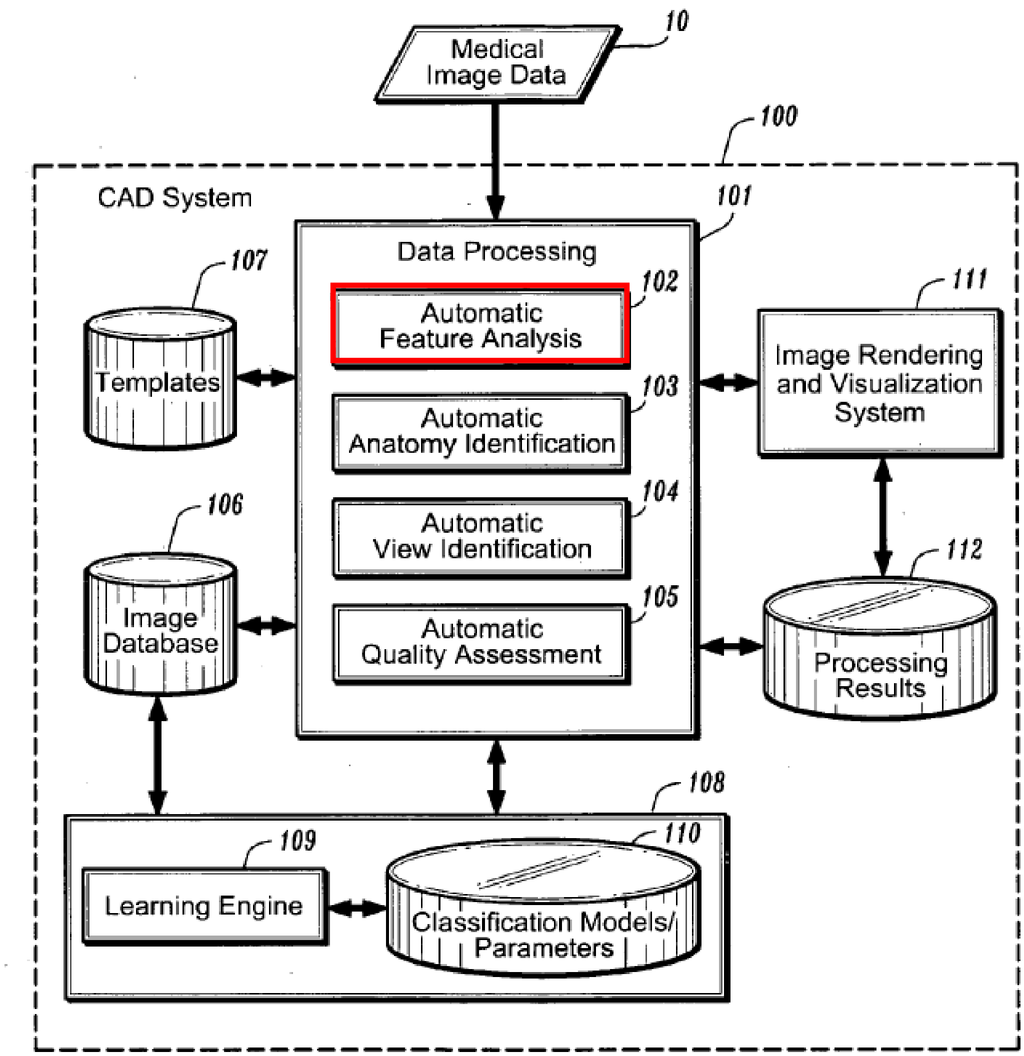


FIG. 1

112. Krishnan further explains: "In general, the feature analysis module (102) implements methods for automatically extracting one or more types of features/parameters from input medical image data <u>and combining the extracted features/parameters in a manner that is suitable for processing by the decision support modules (103, 104 and/or 105)</u>."). Ex1005, [0017] (emphasis added); *see*

also [0034] ("feature data may include … combinations of different features").

113. Referring to Figure 2 (reproduced below), Krishnan further states: "[T]he image dataset will be processed to … extract relevant feature data from the image dataset (step 201) which is utilized to perform one or more decision support functions such as automatic anatomy identification, view identification, and/or image quality assessment (step 202)." Ex1005, [0034].

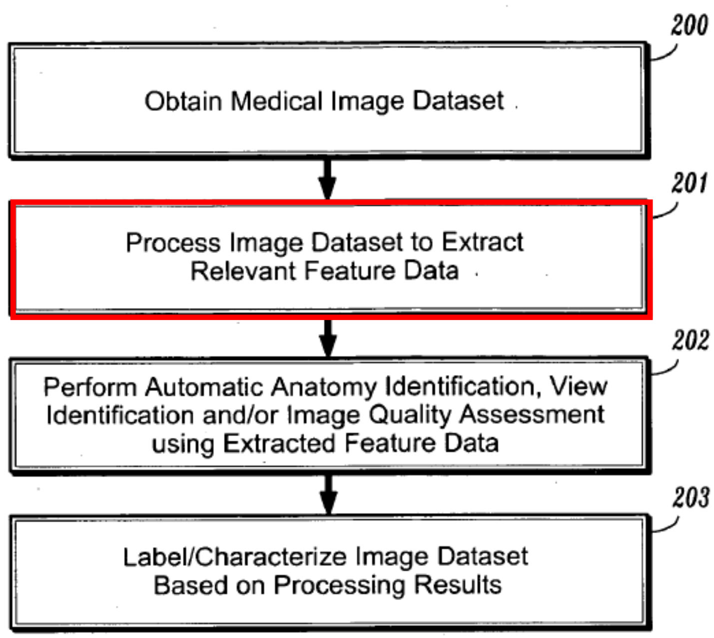


FIG. 2

114. Krishnan also states that "feature extraction can implement known segmentation and/or filtering methods for segmenting features or anatomies of interest by reference to known or anticipated image characteristics, such as edges, identifiable structures, boundaries, changes or transitions in colors or intensities, changes or transitions in spectrographic information, etc, using known methods."

Ex1005, [0034]. "These features could include any kind of characteristic that could be extracted from the image, such as a particular shape or texture" and "can be obtained across images, such as motion of a particular point, or the change in a particular feature across images." *Id*. (emphasis added). Thus, in my opinion, Krishnan discloses "deriving one or more extracted feature representations from the set of ultrasound images," as claimed.

d) [1(c)]: "determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images;"

115. Krishnan discloses element [1(c)], "determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images[.]" "For example, in one exemplary embodiment [of Krishnan], a method for automated decision support for medical imaging includes obtaining image data, extracting feature data from the image data, and automatically … determining a diagnostic quality of the image data, using the extracted feature data." Ex1005, [0005]. Referring to Figure 1 (shown below), Krishnan states: "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 and determine whether errors occurred in the image acquisition process." *Id.*, [0020].

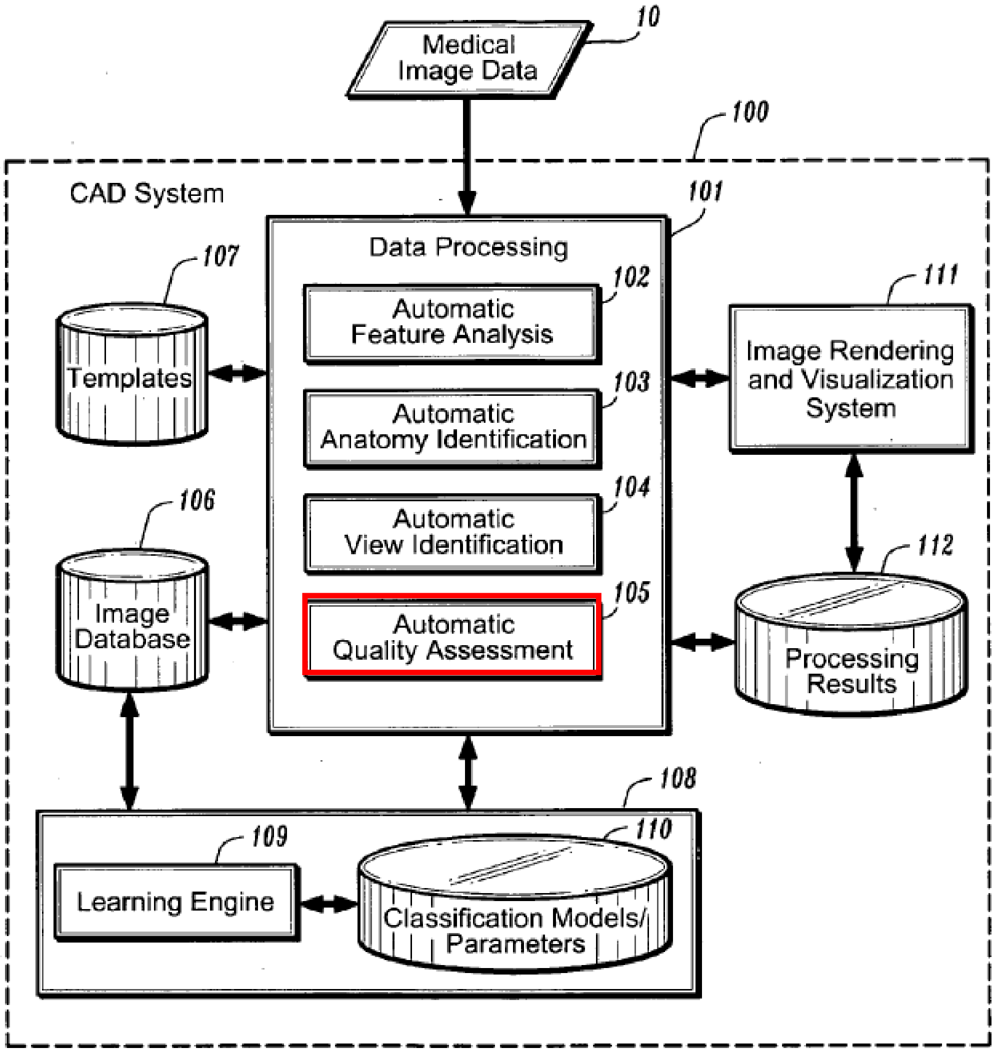


FIG. 1

116. As already explained in Section IX.A.1.b, above, the image dataset can include one or more ultrasound images of a subject, including loops of data depicting a beating heart. *See, e.g.*, Ex1005, [0016]-[0017], [0032]-[0033]. For example, Krishnan explains that "with 2-D echocardiography, particularly stress-echo, the sonographer has very limited time to acquire images during a stress

stage." *Id*., [0032]. "Often in stress-echo, the sonographer acquires up to four (and sometimes more) loops of data for each view, where each loop represents a heart cycle…." *Id*. Krishnan states that "[t]ypically, either the sonographer or cariologist selects <u>which of the loops</u> provides the best images from a diagnostic standpoint." *Id*. (emphasis added). But, "[b]y providing a quality check, this could be done automatically." *Id*.

117. Krishnan further states that "methods can be implemented for determining a quality measure <u>within a predefined range of values</u> to provide an indication as [to] the quality level of the acquired images based on some specified criteria." *Id*. For example, "for image quality assessment, the medical images may include a quality score (within a predetermined range) that provides an indication [of] a diagnostic quality level of the medical images." *Id*., [0036].

118. Referring to Figure 2 (below), Krishnan states that "methods for automatic … image quality assessment (step 202) according to exemplary embodiments of the invention can be implemented using one or more techniques including a database query approach (e.g., FIG. 3), a template processing approach (e.g., FIG. 4) and/or classification (e.g., FIG. 5) that utilize the extracted features." *Id*., [0035].

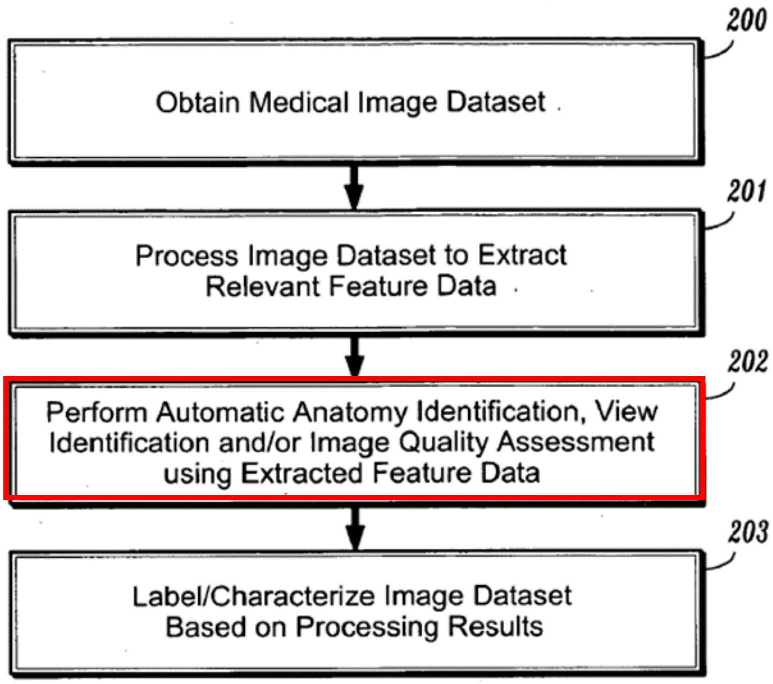


FIG. 2

119. "For example, a bank of classifiers could be constructed to classify the images based on the features extracted." *Id.*, [0043]. Krishnan further explains that "these classifiers would use the set of features as an input, and classify the image as belonging to a particular … level of quality." *Id*. Thus, in my opinion, Krishnan discloses "determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images," as claimed in the Patent.

e) [1(d)]: "determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images; and"

120. Krishnan discloses element [1(d)], "determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images." As the Patent explains, the "image property" recited in claim 1 can be a "view category" associated with the set of ultrasound images. *See* Ex1001, claim 2, 1:50, 13:49-53 ("the image property may be a view category"). Krishnan states: "[I]n one exemplary embodiment, a method for automated decision support for medical imaging includes obtaining image data, extracting feature data from the image data, and automatically performing … view identification … using the extracted feature data." Ex1005, [0005]. As previously described, the image data obtained by Krishnan can be one or more ultrasound images (i.e., a set), including "loops of data, where each loop represents a heart cycle." *See* Section IX.A.1.b (citing Ex1005, [0016] ("ultrasound image data"), [0032], [0033] ("one or more medical images") ("image data (10) may comprise one or more 2D slices").

121. Krishnan further explains that "in stress-echo, the sonographer has very limited time (90 seconds or so for exercise stress) to acquire images from four different views. To save time, the sonographer often just records for a significant portion of the 90 seconds, and then proceed[s] to label the views after imaging is

done.” Ex1005, [0028]. The “automated view identification methods according to [Krishnan] could provide significant workflow enhancement” because “[t]his is a cumbersome process, and could be improved by automatically identifying the views.” *Id.*

122. Referring to Figure 1 (below), Krishnan states: “In the exemplary embodiment, the data processing module (101) comprises … a view identification module (104) ….” *Id.*, [0016].

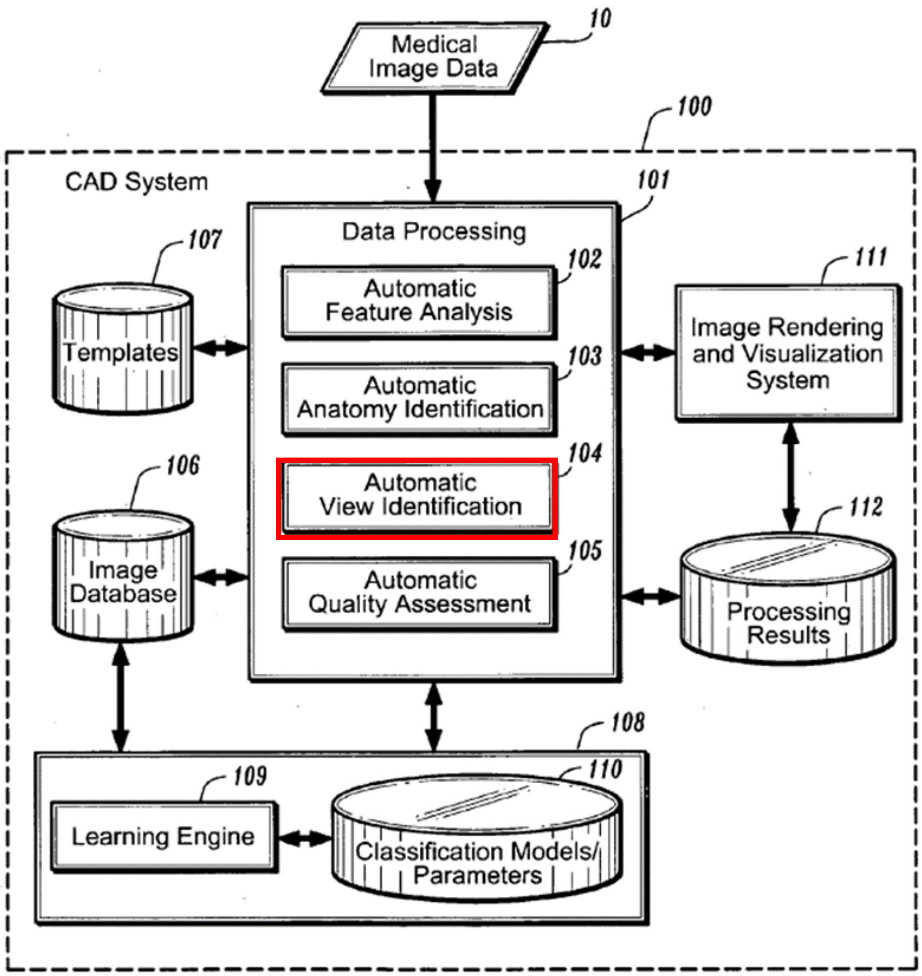


FIG. 1

123. "The view identification module (103) [sic] implements methods for using the extracted features/parameters to automatically identify the view of an acquired image." *Id.*, [0019].

124. Referring to Figure 2 (below), Krishnan states: "Methods for … automatic view identification … (step 202) … can be implemented using one or more techniques including … classification (*e.g.*, FIG. 5) that utilize the extracted

features to provide automated decision support functions." *Id.*, [0035].

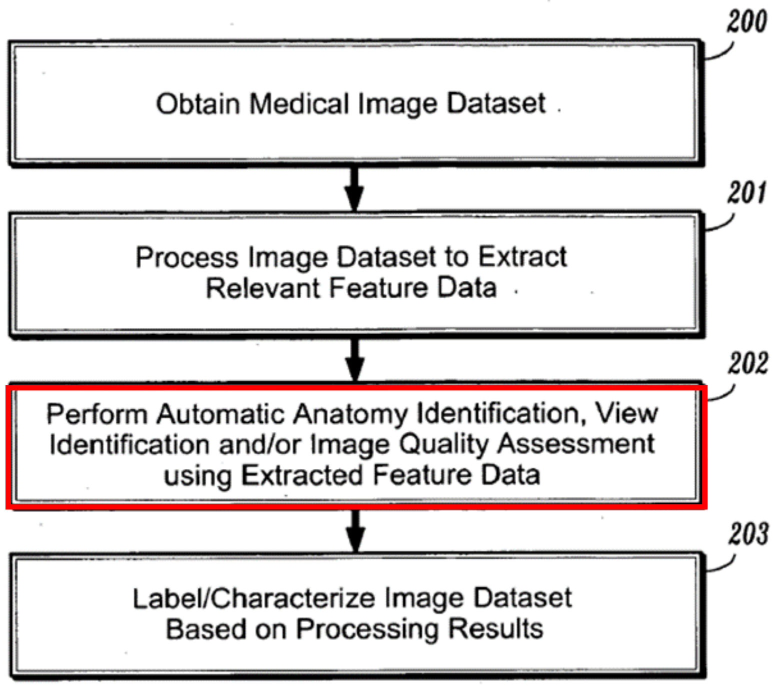


FIG. 2

125. Referring to Figure 5 (below), Krishnan states: "In this exemplary 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)" for example "to determine the most likely … view … (step 502)." Ex1005, [0042]; *see also*, *Id.*, Fig. 5 ("Determine … Most Likely View … of Image Dataset"). Thus, in my opinion, Krishnan discloses "determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images," as claimed.

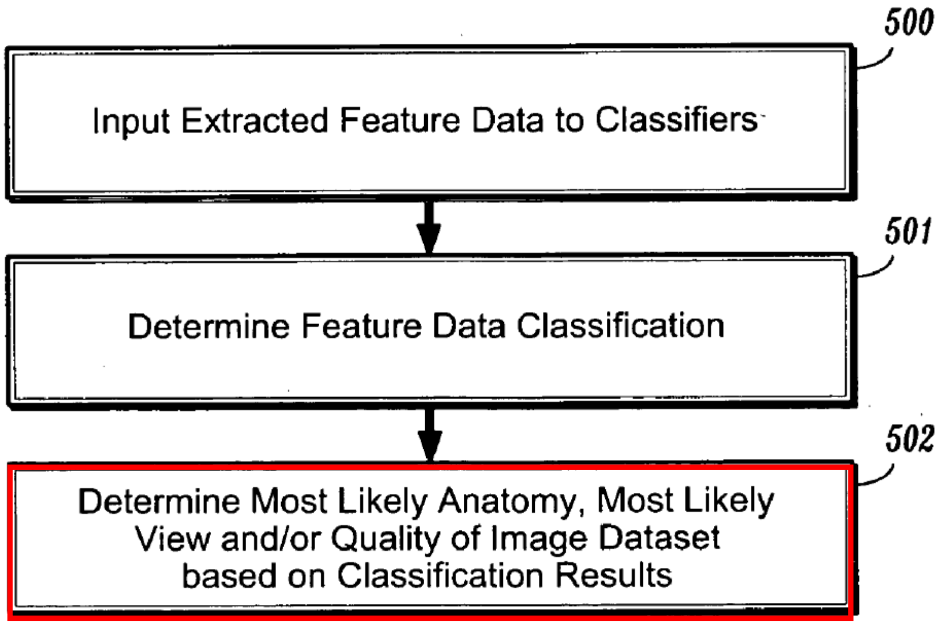


FIG. 5

f) [1(e)]: "producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images."

126. Krishnan discloses element [1(e)], "producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images." As already explained in the previous section, with reference to Figure 1 (below), Krishnan's data processing module 101 includes a view identification module 104 and a quality assessment module 105 for automatically determining a view category and quality assessment value of an image dataset, respectively. *See* Sections IX.A.1.d) and IX.A.1.e).

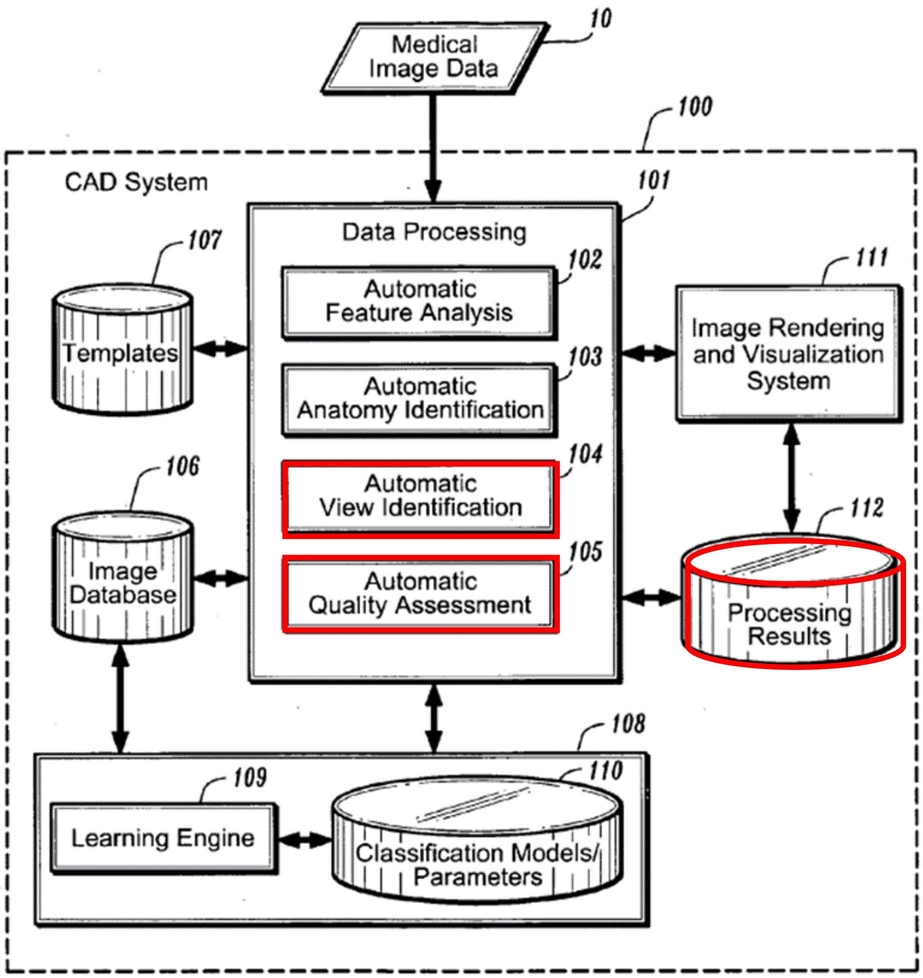


FIG. 1

127. With respect to view category (i.e., the image property), Krishnan states that "the view identification module (104) implements methods for pose estimation and label[s] a medical image with respect to what view of the anatomy the medical image contains." Ex1005, [0019]. With respect to the quality assessment module (105), Krishnan states that "methods can be implemented for determining a quality measure within a predefined range of values to provide an

indication as [to] the quality level of the acquired images" and "methods can be implemented for providing real-time feedback during image acquisition regarding the diagnostic quality of the acquired images." *Id*., [0020].

128. In additional reference to Figure 1, Krishnan states: "The processing results generated by the various modules of the data processing module (101) [i.e., view and quality assessment score] can be persistently stored in a repository (112) in association with the corresponding image dataset." Ex1005, [0024]. Additionally, "[t]he processing results … can be rendered as overlays on the associated image data." *Id*.

129. Furthermore, referring to Figure 2 (below), Krishnan states: "The image dataset will be labeled or otherwise classified based on the processing results obtained (step 203). For instance, for … view identification, a medical image will be labelled with the appropriate … view identification." Ex1005, [0036].

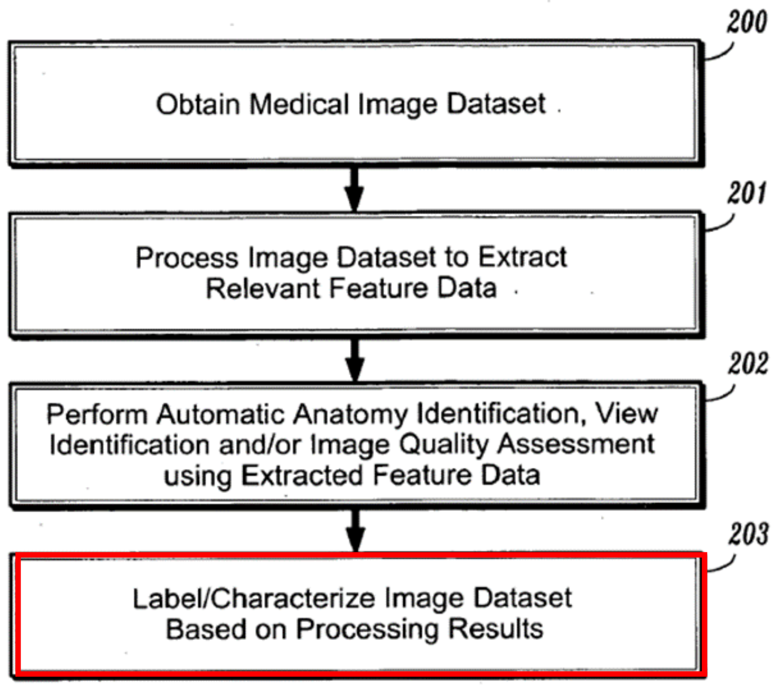


FIG. 2

130. Moreover, "for image quality assessment, the medical images may include a quality score (within a predefined range) that provides an indication [of] a diagnostic quality of the medical images." Ex1005, [0036]. Thus, Krishnan discloses "producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images," as claimed.

131. Because, as detailed above, Krishnan explicitly describes, shows, and discloses every element of claim 1, it is my opinion that Krishnan anticipates claim 1.

2. Claim 2: "The method of claim 1, wherein the image property is a view category."

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

133. As I previously explained in Section IX.A.1.e), the image property determined by Krishnan can be a "view category" associated with a set of ultrasound images. Specifically, "in one exemplary embodiment, a method for automated decision support for medical imaging includes obtaining image data, extracting feature data from the image data, and automatically performing … view identification … using the extracted feature data." Ex1005, [0005]. Consequently, it is my opinion that Krishnan discloses this additional limitation and also anticipates claim 2.

3. Claim 3: "The method of claim 2 wherein deriving the one or more extracted feature representations from the ultrasound images comprises, for each of the ultrasound images, deriving a first feature representation associated with the ultrasound image."

134. Claim 3 depends from claim 2, which depends from claim 1, which as I explained in Sections IX.A.1-2, are anticipated by Krishnan. It is my opinion that Krishnan also discloses the additional limitations of claim 3.

135. As also explained in Section IX.A.1.c, "the image dataset will be processed to … extract relevant feature data from the image dataset" where

"[t]hese features could include any kind of characteristic" and "can be obtained across images, such as motion of a particular point, or the change in a particular feature across images." Ex1005, [0034]. Because Krishnan is described as extracting data features from one image to later track the same feature across multiple images, it is my opinion that "deriving a first feature representation" for each ultrasound image within the dataset, is also clearly disclosed by Krishnan. Krishnan therefore contains each additional limitation of claim 3 and anticipates claim 3.

4. Claim 9: "[W]herein determining the quality assessment value comprises inputting the one or more extracted feature representations into a quality assessment value specific neural network and wherein determining the image property comprises inputting the one or more extracted feature representations into an image property specific neural network."

136. Claim 9 depends from claim 2, which depends from claim 1, which as I explained in Sections IX.A.1-2, are anticipated by Krishnan. It is my opinion that Krishnan also discloses the additional limitations of claim 9.

137. Claim 9 adds the additional limitation to the quality assessment value determination of "inputting the one or more extracted feature representations into a quality assessment value specific neural network" and adds the additional limitation to the image property determination of "inputting the one or more extracted feature representations into an image property specific neural network."

Beyond anticipating the independent claim, it is my opinion that Krishnan also anticipates claim 9 because it discloses a "set of classifiers," which can be neural networks, for performing the described functions of quality assessment and view identification.

138. As I explained in Section IX.A.1.c, Krishnan discloses a "feature analysis module (102) … 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 decision support modules (103, 104 and/or 105)." Ex1005, [0016]. The view identification module 104 "use[s] the extracted features/parameters to automatically identify the view of acquired image." *Id.*, [0019]. The quality assessment module 105 "use[s] the extracted features/parameters to assess a level of diagnostic quality of an acquired image data set." *Id.*, [0020].

139. Krishnan states that "the various modules (103) (104), and (105) can implement classification methods that utilize [a] classification module (108)." *Id.*, [0023]. The classification module 108 maintains "one or more trained classification models," also referred to as a "bank of classifiers" or a "set of classifiers" (*id.*, [0043]), which Krishnan states can be "built using neural networks" (*id.*, [0044]). "The classifiers are implemented by the various decision support modules (102-105) for performing their respective functions." *Id.*, [0023].

In one example, "[t]hese classifiers would use the set of features as an input, and classify the image as belonging to a particular anatomy, view, or level of quality." *Id.*, [0043].

140. It is my opinion that the bank of neural network classifiers for performing the respective functions of quality assessment and view identification disclosed by Krishnan disclose the elements of claim 9 and anticipate the claim.

5. Claim 11: "[W]herein producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images comprises producing signals for causing a representation of the quality assessment value and a representation of the image property to be displayed by at least one display in association with the set of ultrasound images."

141. Claim 11 depends from claim 2, which depends from claim 1, which as I explained in Sections IX.A.1-2, are anticipated by Krishnan. It is my opinion that Krishnan also discloses the additional limitations of claim 11.

142. Claim 11 adds the additional claim element of "producing signals for causing a representation of the quality assessment value and a representation of the image property to be displayed by at least one display in association with the set of ultrasound images." Referring to Figure 1, Krishnan discloses "an image rendering and visualization system (111) to process digital image data (10) of an acquired image dataset (or a portion thereof) and generate and <u>display 2D and/or 3D images on a computer monitor</u>." Ex1005, [0025] (emphasis added). Additionally, as I

explain below, Krishnan further discloses displaying the image dataset with its quality assessment value and view category to provide real-time feedback during image acquisition.

143. Krishnan states that "[t]he image dataset will be labeled … based on the processing results obtained." Ex1005, [0036]. For example, "a medical image will be labeled with the appropriate … view identification" and "a quality score." *Id*.; *see also Id.* [0024] ("The processing results … can be rendered as overlays on the associated image data."). Krishnan also explains that "automatic anatomy and view identification and image quality assessment are powerful tools that provide substantial assistance … in medical imaging acquisition." *Id*., [0027]. For example, during a stress echocardiography examination, "the sonographer has a very limited time … to acquire images from four different views." *Id*., [0028]. The "automated view identification methods according to [Krishnan] could provide significant workflow enhancement" by "automatically identifying the views." *Id*. Additionally, Krishnan explains that "automated anatomy identification, view identification, and image quality assessment are performed in real-time during image acquisition, wherein the results of image quality assessment are presented to a user in real-time during image acquisition." *Id*., [0009].

144. It is my opinion that Krishnan's disclosure of producing signals for causing the quality assessment value and image property (i.e., view category) to be

displayed in association with a set of ultrasound images to a user in real time discloses each and every element of claim 11. Therefore, Krishnan anticipates claim 11.

6. Claim 21: Claimed System

145. Upon review of Claim 21, I find that it is substantially the same as claim 1 except, whereas claim 1 claims a method, claim 21 recites a system comprising a "processor configured to" perform the steps set forth claim 1. As I previously explained, it is my opinion that Krishnan discloses all elements of claim 1. *See* Section IX.A.1. For the same reasons provided with respect to claim 1, and as repeated in part below, it is my opinion that Krishnan discloses each and every element of claim 21 and thus is also anticipated by Krishnan.

a) [21(pre)]: "A system for facilitating ultrasonic image analysis comprising at least one processor configured to:"

146. It is my opinion that Krishnan discloses [21(pre)], "[a] system for facilitating ultrasonic image analysis comprising at least one processor... ." *See* Section IX.A.1.a). Specifically, Krishnan discloses an "exemplary system (100) comprises a <u>data processing module (101)</u> that implements various methods for <u>analyzing medical image data (10)</u> in one or more image modalities (e.g., <u>ultrasound image data</u> …)."Ex1005, [0016] (emphasis added). Alternatively, the "data processing module (101)" is also referred to as "[t]he data processing system

(101)," which "executes in a computing system (e.g., workstation)." *Id*., [0026]. Additionally, Krishnan states that the "methods described herein … may be implemented in various forms of hardware, software, firmware, special purpose processors, or a combination thereof.". *Id*., [0045] (emphasis added). Thus, Krishnan discloses a "system for facilitating ultrasonic image analysis comprising at least one processor," identical to the elements and configuration of claim 1. And, as addressed below, Krishnan also discloses that its processor (e.g., "data processing module 101") is "configured to," as claimed, perform each function recited in the remaining claim elements using special purpose modules that may be implemented as software. *See* Ex1005, [0045] ("[T]he constituent system modules and method steps depicted in the accompanying Figures can be implemented in software….").

147. It is therefore my opinion that Krishnan discloses all the elements of the preamble of claim 21 of the patent, arranged in the same way.

b) [21(a)]: "receive signals representing a set of ultrasound images of the subject;"

148. It is my opinion that Krishnan discloses [21(a)], wherein the processor is configured to "receive signals representing a set of ultrasound images of the subject" in the same way Krishnan discloses the corresponding method claim element [1(a)]. *See* Section IX.A.1.b). Per Figure 1 (below), Krishnan's data processing module 101 is configured to, and does, receive "Medical Image Data

10," which Krishnan states may be "ultrasound image data." Ex1005, [0016].

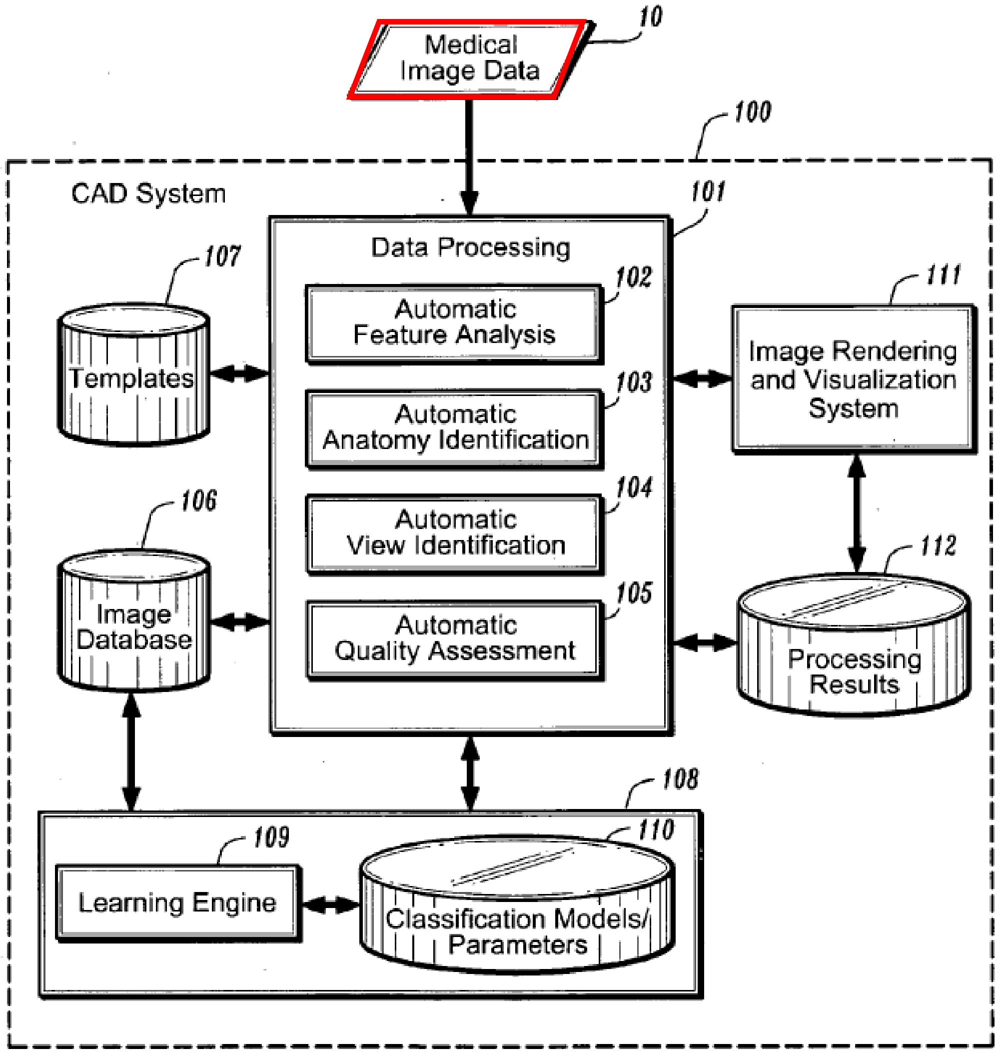


FIG. 1

149. Referring to Figure 2 (below), Krishnan states that the obtained "medical image dataset" comprises "<u>one or more medical images</u> of a region of interest of a subject patient (step 200)." Ex1005, [0033] ("one or more 2D slices" or "multiple views of a beating heart"); *see also* [0032] ("loops of data for each

view, where each loop represents a heart cycle”).

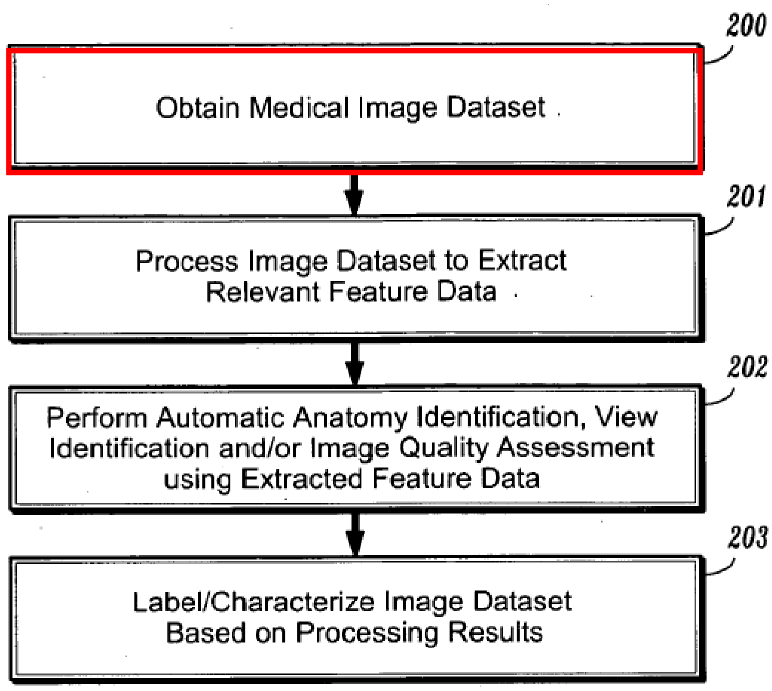


FIG. 2

150. It is therefore my opinion that Krishnan discloses “at least one processor configured to … receive signals representing a set of ultrasound images of the subject,” as claimed.

c) [21(b)]: “derive one or more extracted feature representations from the set of ultrasound images;”

151. It is my opinion is that Krishnan discloses [21(b)], wherein the processor is configured to “derive one or more extracted feature representations from the set of ultrasound images” in the same way Krishnan discloses the corresponding method claim element [1(b)]. *See* Section IX.A.1.c). Referring to Figure 1, below, Krishnan states: “In the exemplary embodiment, the data

processing module (101) [(i.e., processor)] comprises an automatic feature analysis module (102) ….” Ex1005, [0016].

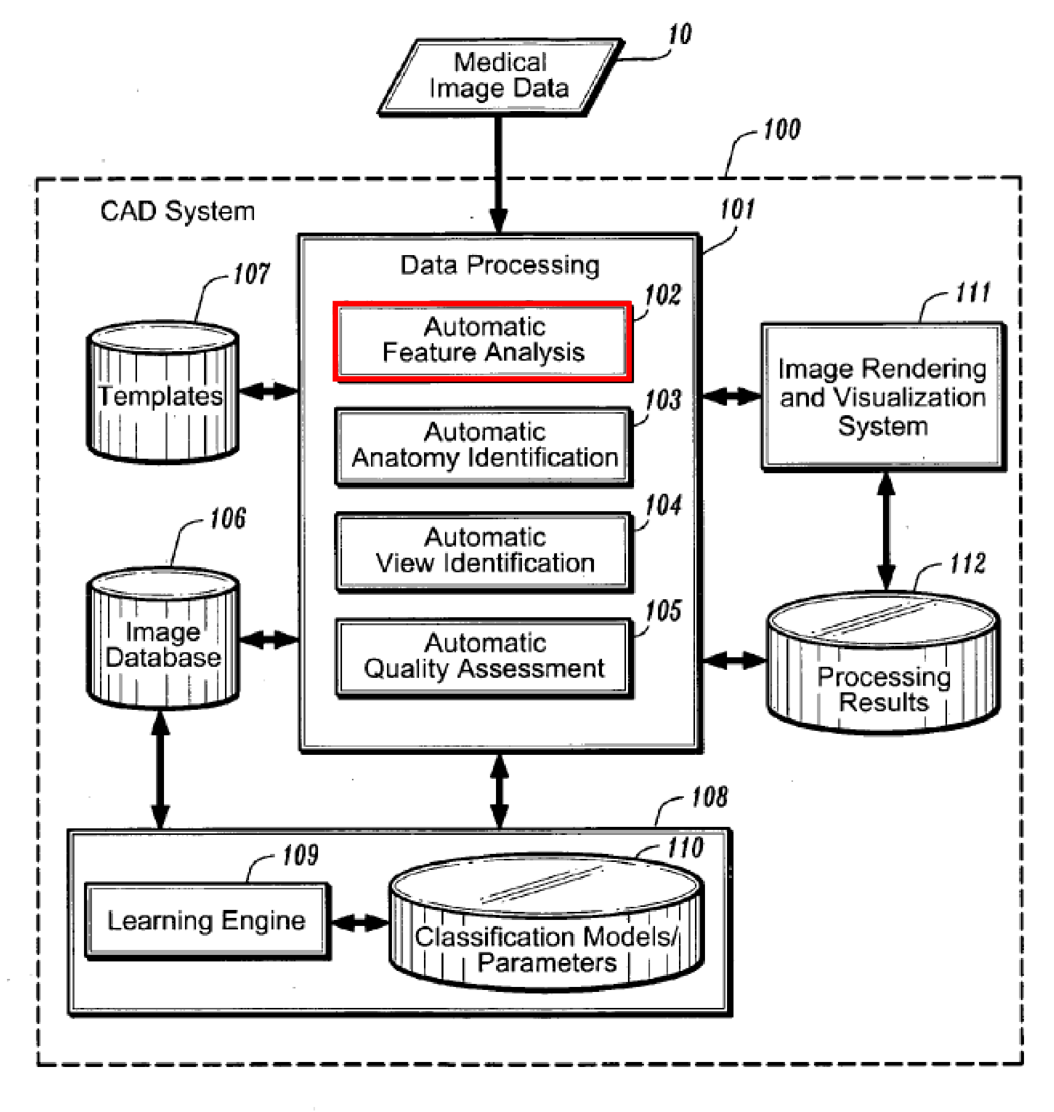


FIG. 1

152. Krishnan also states: “In general, the feature analysis 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 decision support modules (103, 104 and/or 105).”). Ex1005, [0017]; *see also* [0034] (“feature data may include … combinations of different features”), Fig. 2 (“Process Image Dataset to Extract Relevant Feature Data”). As already explained, the input medical image data may comprise a set of ultrasound images. *See* Section IX.B.6.b). Thus, it is my opinion that Krishnan discloses “at least one processor configured to … derive one or more extracted feature representations from the set of ultrasound images,” as claimed.

d) [21(c)]: “determine, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images;”

153. It is my opinion is that Krishnan discloses [21(c)], wherein the processor is configured to “determine, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images” in the same way Krishnan discloses the corresponding method claim element [1(c)]. *See* Section IX.A.1.d). Referring to Figure 1, below, Krishnan states: “In an exemplary embodiment, the data processing module (101) [(i.e., processor)] comprises … an image quality assessment module (105).” Ex1005, [0016]. “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 and determine whether

errors occurred in the image acquisition process." *Id.*, [0020].

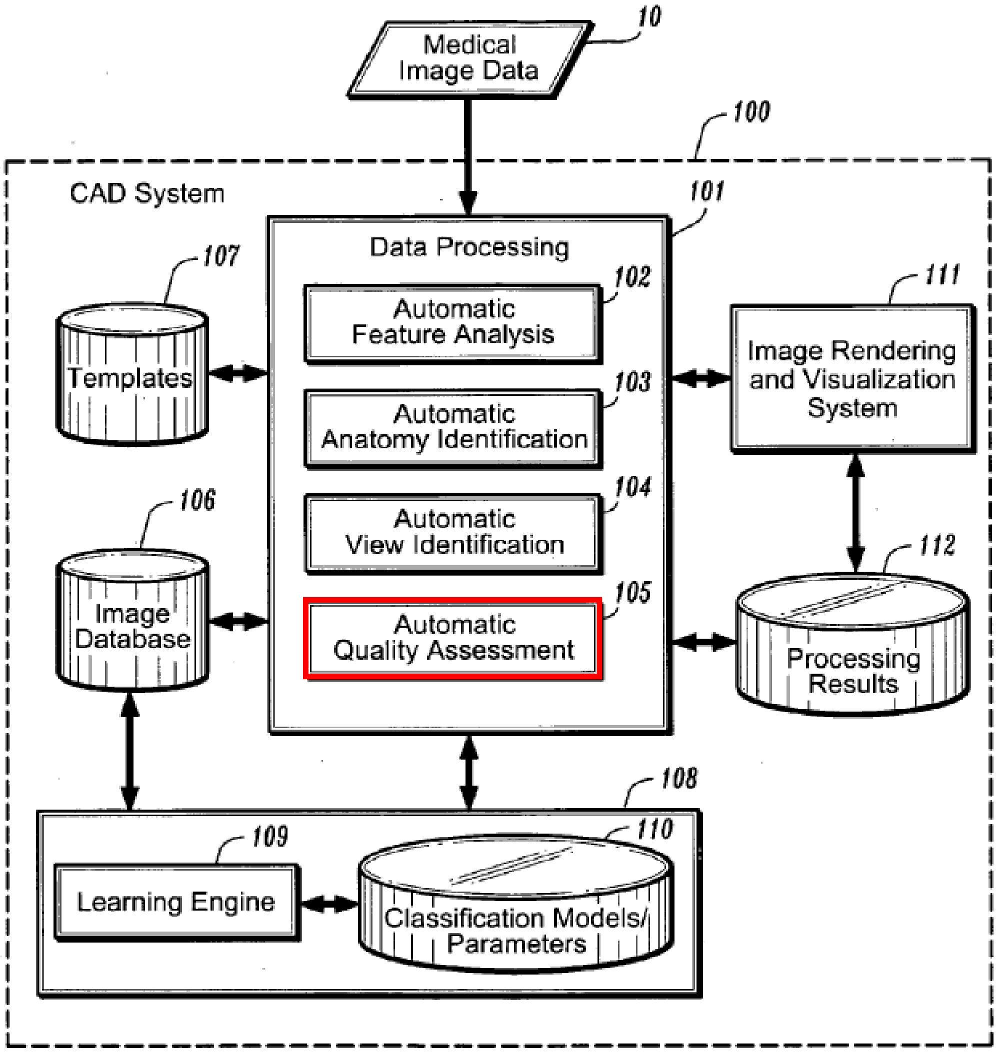


FIG. 1

154. As I explained with respect to the method claim element [1(c)] above, the "level of diagnostic quality" determined by the quality assessment module 105 may be "a quality measure <u>within a predefined range of values</u> to provide an indication as the quality level of the acquired images based on some specified

criteria." Ex1005, [0020]; *see also* [0036] ("quality score"). And, as I further explained with respect to [21(a)] above, the "acquired image data set" may include one or more ultrasound images. *See* Section IX.B.1.b); *see also* Ex1005, [0032] (describing providing an automatic quality check for "loops of data … where each loop represents a heart cycle" acquired by a sonographer). Thus, it is my opinion that Krishnan discloses "at least one processor configured to … determine, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images[,]" as claimed.

e) [21(d)]: "determine, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images; and"

155. It is my opinion is that Krishnan discloses [21(d)], wherein the processor is configured to "determine, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images" in the same way Krishnan discloses the corresponding method claim element [1(d)]. *See* Section IX.A.1.e). As I explained at length above, a "view category" is an "image property" as defined in the Patent. Krishnan states: "[I]n one exemplary embodiment, a method for automated decision support for medical imaging includes obtaining image data, extracting feature data from the image data, and automatically performing … view identification … using the extracted

feature data." *Id*., [0005]. Referring to Figure 1 (below), Krishnan states: "In the exemplary embodiment, the data processing module (101) [(i.e., processor)] comprises … a view identification module (104) …." Ex1005, [0016]. "The view identification module (103) [sic] implements methods for using the extracted features/parameters to automatically identify the view of an acquired image." *Id*. [0019].

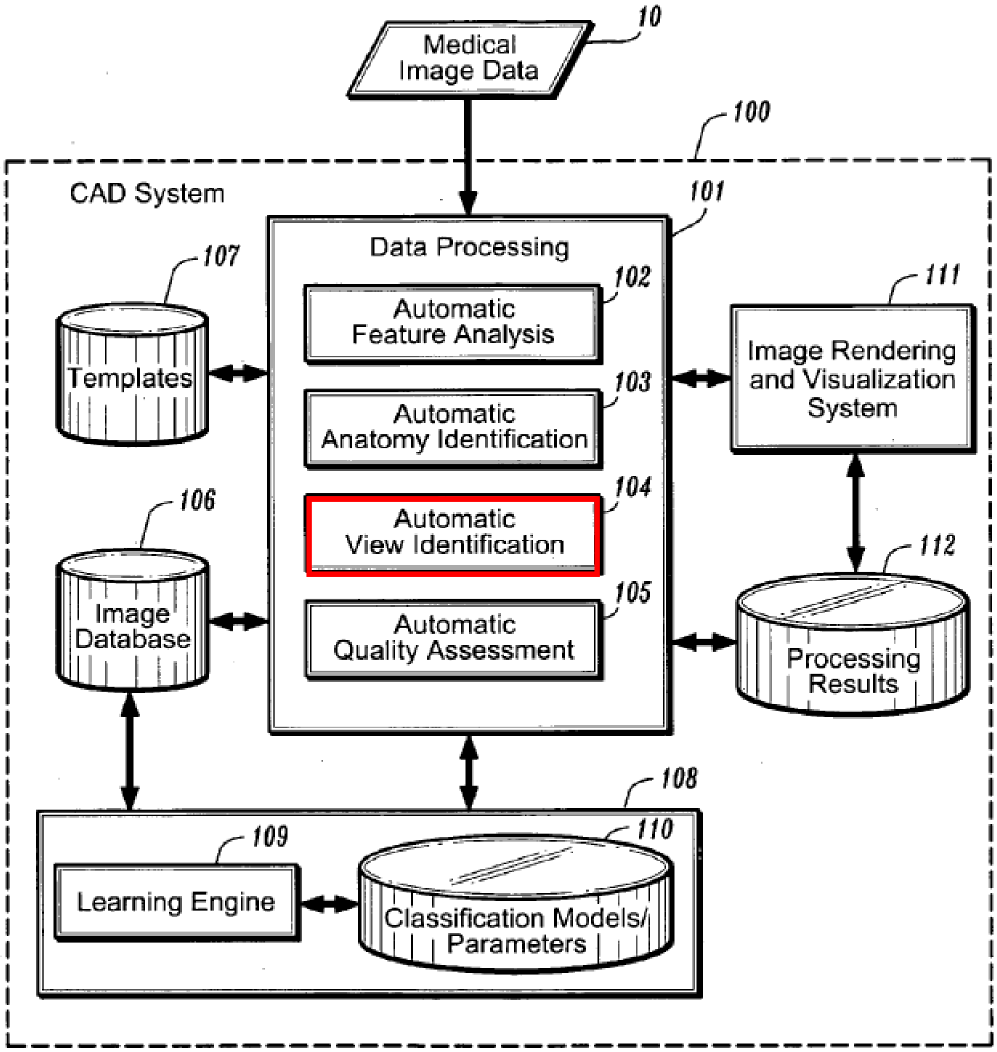


FIG. 1

156. Referring to Figure 2 (below), Krishnan further states that the obtained "medical image dataset compris[es] one or more medical images," e.g., "one or more 2D slices" or "multiple views of a beating heart acquired with a 3D Ultrasound probe." Ex1005, [0032].

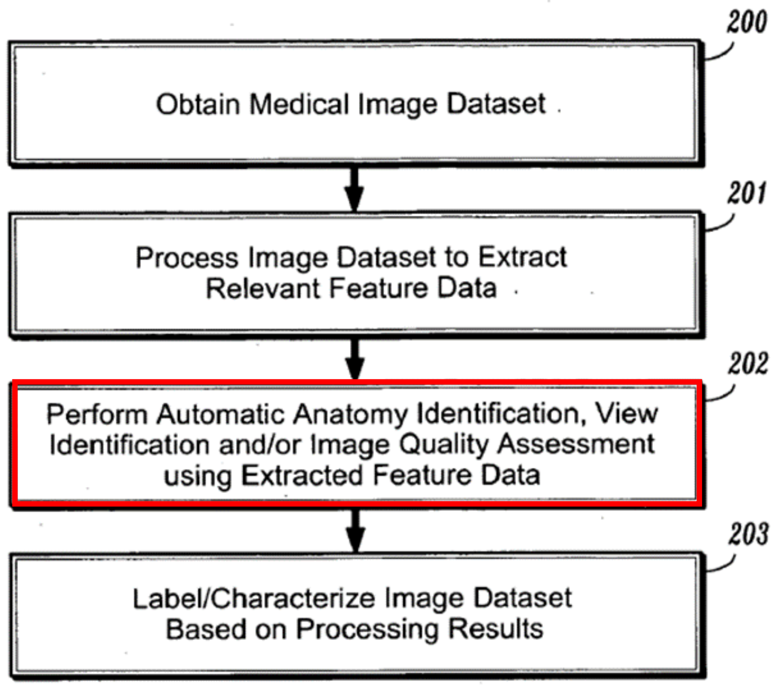


FIG. 2

157. In further reference to Figure 2, Krishnan explains that "automatic view identification … (step 202) … can be implemented using one or more techniques including … classification (e.g., FIG. 5) that utilize the extracted features." *Id.*, [0035]. Figure 5, which is provided below, states that extracted feature data is input into classifiers (step 500) to "Determine … Most Likely View … of Image Dataset" (step 502), where, as stated above, the dataset may include more than one ultrasound image.

158. Thus, it is my opinion that Krishnan discloses "at least one processor configured to … determine, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images[,]"

as claimed.

f) [21(e)]: "produce signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images."

159. It is my opinion is that Krishnan discloses [21(e)], wherein the processor is configured to "produce signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images" in the same way Krishnan discloses the corresponding method claim element [1(e)]. *See* Section IX.A.1.f). As I previously explained, Krishnan's data processing module 101 corresponds to the claimed "processor" and comprises a view identification module 104 and an image quality assessment module 105, which may be implemented as software. Ex1005, [0016], [0045]. Krishnan further states that "the view identification module (104) … label[s] a medical image with respect to what view of the anatomy the medical image contains." *Id.*, [0019]. Krishnan also states that the quality assessment module 105 "determine[es] a quality measure within a predefined range of values" and "provid[es] real-time feedback during image acquisition regarding the diagnostic quality of the acquired images." *Id.*, [0020]. Referring to Figure 1, Krishnan states: "The processing results generated by the various modules of the data processing module (101) [i.e., view and quality assessment score] can be persistently stored in a repository (112) in association

with the corresponding image dataset." Ex1005, [0024]. Additionally, "[t]he processing results may comprise meta information …, which can be rendered as overlays on the associated image data." *Id*.

160. Referring to Figure 2 (below), Krishnan states: "The image dataset will be labeled or otherwise classified based on the processing results obtained (step 203). For instance, for … view identification, a medical image will be labelled with the appropriate … view identification." Ex1005., [0036]. Additionally, "for image quality assessment, the medical images may include a quality score (within a predefined range) that provides an indication [of] a diagnostic quality of the medical images." *Id*.

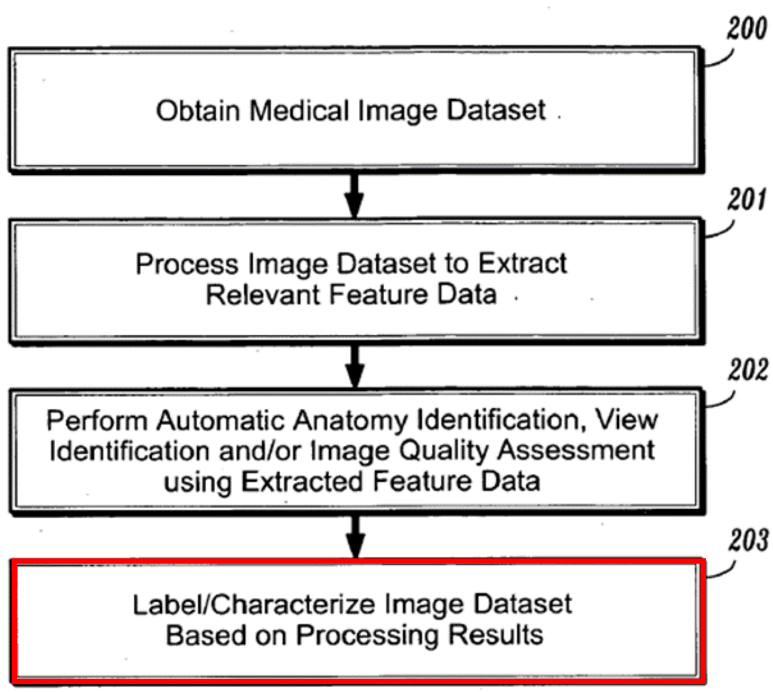


FIG. 2

161. Thus, it is my opinion that Krishnan discloses "at least on processor configured to … produce signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images[,]" as claimed.

162. Because Krishnan expressly describes, depicts, and discloses every element of claim 21 in the same arrangement, it is my opinion that Krishnan anticipates claim 21.

7. Claim 22: "[W]herein the image property is a view category."

163. Claim 22 depends from claim 21, which as I explained in Section IX.A.6, is anticipated by Krishnan. It is my opinion that Krishnan also discloses the additional limitations of claim 22.

164. As I previously explained in Sections IX.A.1.e), IX.A.6.e), the image property determined by Krishnan can be a "view category" associated with a set of ultrasound images. Specifically, "in one exemplary embodiment, a method for automated decision support for medical imaging includes obtaining image data, extracting feature data from the image data, and automatically performing … view identification … using the extracted feature data." Ex1005, [0005]; *see also Id.*, [0016], [0032], [0033]. Consequently, it is my opinion that Krishnan contains this additional limitation and also anticipates claim 22.

8. Claim 27: "[W]herein the at least one processor is configured to input the one or more extracted feature representations into a quality assessment value specific neural network and to input the one or more extracted feature representations into an image property specific neural network."

165. Claim 27 depends from claim 22, which depends from claim 21, which as I explained in Sections IX.A.6-7, are anticipated by Krishnan. It is my opinion that Krishnan also discloses the additional limitations of claim 27.

166. Claim 27 is substantially the same as claim 9, which is addressed in Section IX.A.4 above, except, whereas claim 9 is a method claim, claim 27 is a system claim that depends from claim 22 and recites "wherein the at least one processor is configured to" perform the same functions recited in claim 9. Additionally, Krishnan discloses the functions recited in claim 27 for the same reasons already discussed in with respect to claim 9 in Section IX.A.4. Generally, as addressed in Sections IX.A.6.d and IX.A.6.e, above, the data processing module/system 101 in Krishnan (Ex1005, [0016], [0026]) corresponds to a processor and implements a view identification module 104 and a quality assessment module 105. Thus, Krishnan also discloses at least one processor configured to perform the functions recited in claim 27 rendering claim 27 anticipated.

167. More specifically, claim 27, like claim 9, adds the additional limitation that the processor be configured to "input the one or more extracted

feature representations into a quality assessment value specific neural network" and to "input the one or more extracted feature representations into an image property specific neural network." As I explained regarding claim 9, beyond anticipating the independent claim, it is my opinion that Krishnan also anticipates claim 27 because it discloses a "set of classifiers," which can be neural networks, for performing the described functions of quality assessment and view identification.

168. As I explained in Section IX.A.6.c, Krishnan discloses a "feature analysis module (102) … 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 decision support modules (103, 104 and/or 105)." Ex1005, [0016]. The view identification module 104 "use[s] the extracted features/parameters to automatically identify the view of acquired image." *Id.*, [0019]. The quality assessment module 105 "use[s] the extracted features/parameters to assess a level of diagnostic quality of an acquired image data set." *Id.*, [0020].

169. Krishnan further explains that "the various modules (103) (104), and (105) can implement classification methods that utilize [a] classification module (108)." Ex1005, [0023]. The classification module 108 maintains "one or more trained classification models," also referred to as a "bank of classifiers" or a "set of

classifiers" (*id.*, [0043]), which Krishnan states can be "built using neural networks" (*id.*, [0044]). "The classifiers are implemented by the various decision support modules (102-105) for performing their respective functions." *Id.*, [0023]. In one example, Krishnan states that "[t]hese classifiers would use the set of features as an input, and classify the image as belonging to a particular anatomy, view, or level of quality." *Id.*, [0043].

170. It is my opinion that the bank of neural network classifiers for performing the respective functions of quality assessment and view identification disclosed in Krishnan disclose all the elements of and therefore anticipate claim 27.

9. Claim 29: "[W]herein the at least one processor is configured to produce signals for causing a representation of the quality assessment value and a representation of the image property to be displayed by at least one display in association with the set of ultrasound images."

171. Claim 29 depends from claim 22, which depends from claim 21, which as I explained in Sections IX.A.6-7, are anticipated by Krishnan. It is my opinion that Krishnan also discloses the additional limitations of claim 29.

172. Claim 29 is substantially the same as claim 11, which is addressed in Section IX.A.5, above, except, whereas claim 11 is a method claim, claim 29 is a system claim that depends from claim 22 and recites "wherein the at least one processor is configured to" perform the same function recited in claim 11. Krishnan anticipates claim 22 for the reasons already addressed above.

Additionally, Krishnan discloses the functions recited in claim 29 for the same reasons already discussed with respect to claim 11 in Section IX.A.5.

173. Generally, as addressed with respect to claim 21 in Sections IX.A.6, above, the data processing module/system 101 in Krishnan corresponds to a processor and Krishnan states that "[t]he data processing system (101) and image rendering and visualization system (111) may be implemented as a single application" or alternatively "may be independent tools that are distributed over a computer network" for "transmitting image data over the network." Ex1005, [0026]. Thus, Krishnan also discloses at least one processor configured to perform the functions recited in claim 29 rendering claim 29 anticipated.

174. More specifically, claim 29 adds the additional claim element of the processor being configured to "produce signals for causing a representation of the quality assessment value and a representation of the image property to be displayed by at least one display in association with the set of ultrasound images." Krishnan discloses this functionality. Referring to Figure 1, Krishnan discloses "an image rendering and visualization system (111) to process digital image data (10) of an acquired image dataset (or a portion thereof) and generate and <u>display 2D and/or 3D images on a computer monitor</u>." Ex1005, [0025]. Additionally, as I explain below, Krishnan discloses displaying the image dataset with its quality assessment value and view category to provide real-time feedback during image acquisition.

175. Krishnan states that "[t]he image dataset will be labeled … based on the processing results obtained."Ex1005, [0036]. For example, "a medical image will be labeled with the appropriate … view identification" and "a quality score." *Id*.; *see also Id.* [0024] ("The processing results … can be rendered as overlays on the associated image data."). Krishnan also generally explains that "automatic anatomy and view identification and image quality assessment are powerful tools that provide substantial assistance … in medical imaging acquisition." *Id*., [0027]. For example, during a stress echocardiography examination, "the sonographer has a very limited time … to acquire images from four different views." *Id*., [0028]. The "automated view identification methods according to [Krishnan] could provide significant workflow enhancement" by "automatically identifying the views." *Id*. Indeed, Krishnan explains that "automated anatomy identification, view identification, and image quality assessment are performed in real-time during image acquisition, wherein the results of image quality assessment are presented to a user in real-time during image acquisition." *Id*., [0009].

176. It is my opinion that Krishnan's disclosure of producing signals for causing the quality assessment value and image property (i.e., view category) to be displayed in association with a set of ultrasound images to a user in real time discloses each and every element of claim 29.

10. Claim 30: Claimed Means-Plus-Function System

177. Claim 30 is substantially identical to claim 21, which I have already addressed above except, whereas claim 21 is a system claim comprising "at least one processor configured to" perform a series of functions and describing other specific hardware and software, claim 30 is a system claim drafted in means-plus-function format which I understand describes only "means for" performing the same functions recited in claim 21. I understand that the meaning of "means" is ascribed to specific structure found in the Patent, and my opinions below reflect said meaning (as agreed by the parties) accordingly. As previously explained, in my opinion, claim 21 is anticipated by Krishnan. *See* Section IX.A.6. For similar reasons, as explained below, it is my opinion that Krishnan also anticipates claim 30.

a) "[30(pre)]: "A system for facilitating ultrasonic image analysis, the system comprising:"

178. I understand that [30(pre)] is identical to [21(pre)] except that it does not recite "at least one processor configured to" and instead cites "means for." Accordingly, Krishnan discloses [30(pre)] in the same arrangement for the same reasons already provided for [21(pre)]. *See* Section IX.A.6.a).

b) [30(a)]: "means for receiving signals representing a set of ultrasound images of the subject;"

179. I understand that [30(a)] is drafted in means-plus-function format and recites the same function as [21(a)]. For the reasons already provided with respect

to [21(a)], it is my opinion that Krishnan performs the function recited in [30(a)]. *See* Section IX.A.6.b.

180. Whereas claim 21 recites a "processor configured to: receive signals …," [30(a)] recites a "means for receiving signals …." Consistent with claim 21, the corresponding structure disclosed in the Patent for performing the claimed function is a processor with an I/O (i.e., input/output) interface. *E.g.*, Ex1001, Fig. 2 (100, 112), 7:50-54, 7:61-63, 8:17-22. Krishnan discloses this structure for performing the recited function. Ex1005, [0025]-[0026], Fig. 1 (10, 101, 111), [0017] ("from input medical image data").

181. As I previously explained in the context of claim 21, Krishnan's data processing module/system 101 corresponds to a processor and it receives a set of one or more ultrasound images as input. *See* Sections IX.A.6.a) and IX.A.6.b). Krishnan further explains that the ultrasound image dataset received by the data processing module/system 101 can be received in real-time from a medical imaging system or be "obtained by accessing a previously acquired, and persistently stored image dataset." Ex1005, [0033]. As depicted in Figure 1 (below), the processor (101) has one or more input/output interfaces (not labeled) for receiving/outputting/exchanging data with, for example, a visualization system 111, an image database 106, and a repository 112 for processed results. *Id.*, [0024]-[0025].

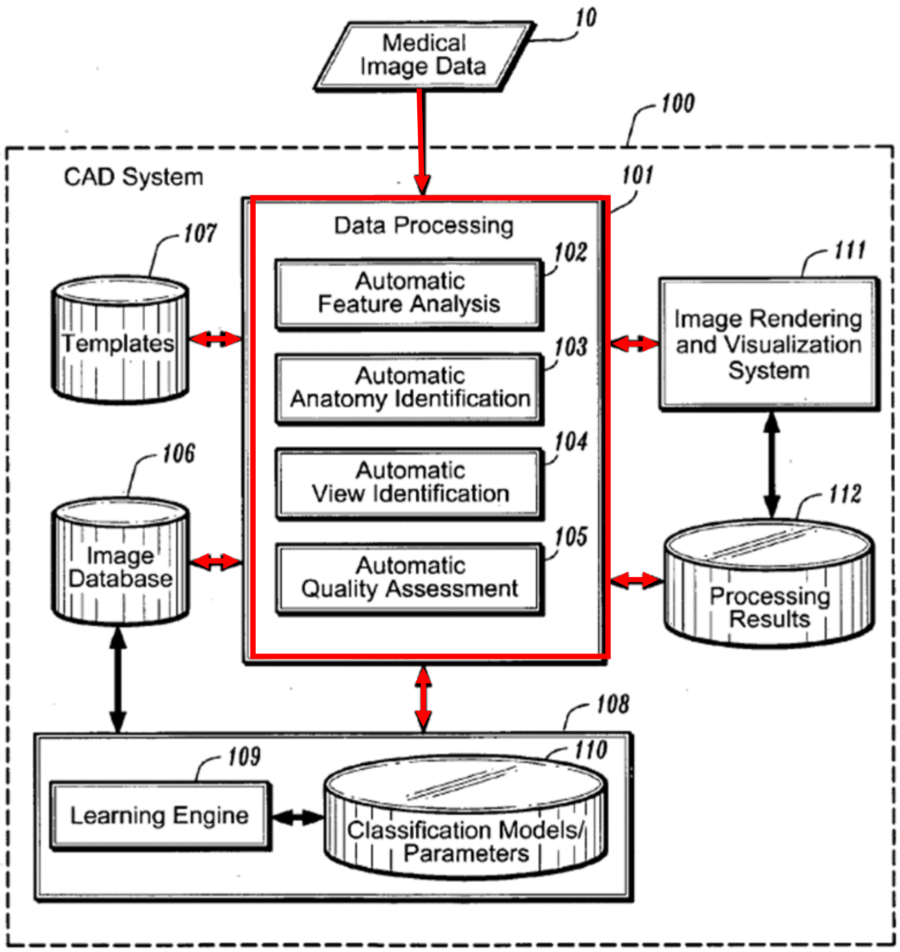


FIG. 1

182. Further, Krishnan explains that the "data processing [module/] system (101)" may be part of a "computer network, wherein known communications protocols such as DICOM, PACs, etc. are used for <u>communicating between</u> the systems <u>and transmitting image data</u> over the network." Ex1005, [0026] (emphasis added).

183. Thus, it is my opinion that Krishnan discloses [30(a)] because it discloses a processor with an input/output interface that performs the function of

"receiving signals representing a set of ultrasound images of the subject" as claimed.

c) [30(b)]: "means for deriving one or more extracted feature representations from the set of ultrasound images;"

184. I understand that [30(b)] is drafted in means-plus-function format and recites the same function as [21(b)]. For the reasons already provided with respect to [21(b)], in my opinion, Krishnan performs the function recited in [30(b)]. *See* Section IX.A.6.c).

185. The corresponding structure/algorithm disclosed in the Patent for performing the claimed function is a processor and memory operating a neural network. *See* Section Ex1001, Fig. 2 (100, 102, 104, 154, 156, 170), 1:55-2:7, 6:35-41, 7:50-52, 8:23-9:3, 9:64-10:2, 10:21-11:60, Fig. 4 (300, 304, 306, 308, 340, 342, 344, 346). It is my opinion that Krishnan discloses this structure/algorithm for performing the recited function from the Patent.

186. As I previously explained concerning [21(b)] above, Krishnan discloses a data processing module/system 101 that corresponds to a processor and includes a feature analysis module 102 that extracts features/parameters from a set of input ultrasound images 10 using known techniques such as segmentation and/or filtering. *See* Section IX.A.6.c). With reference to Figure 1 (below), Krishnan also discloses a classification module/system 108 with a knowledge base 110

corresponding to a memory that "maintains one or more trained classification models" (i.e., "classifiers"). Ex1005, [0021], [0023], [0043]. Krishnan further states that "[t]he classifiers are implemented by the various decision support modules (102-105) for performing their respective functions." *Id.*, [0023] (emphasis added); *see also* [0021] ("[C]lassification system (108) … can be used … by one or more of the various automated decision support modules (102-105) of the data processing system (101) to perform their respective functions.").

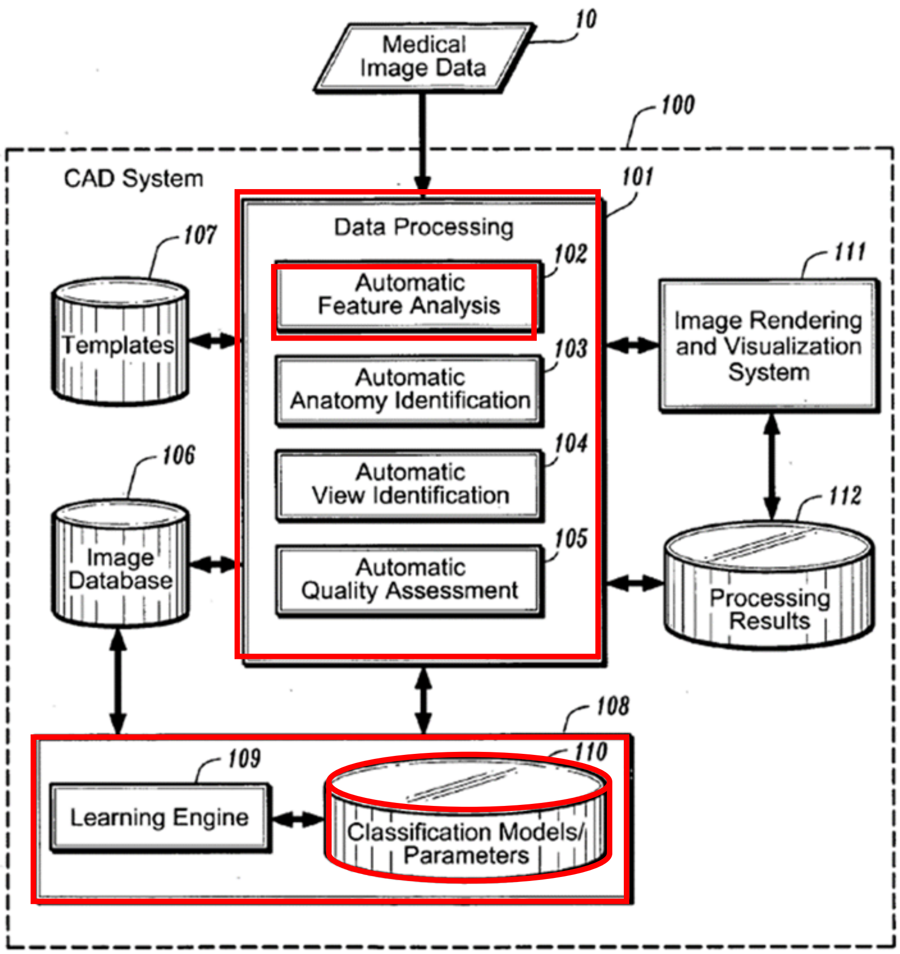


FIG. 1

187. Krishnan also states that the classifiers can be "built using neural networks." *Id*. [0044]. Indeed, as I have explained previously, the use of artificial neural networks to perform feature extraction tasks, including, for example, segmentation or identification objects in medical images was well-known prior to the priority date of the Patent. *See, e.g.*, Ex1007 (Angelova), 4:10-15 ("the feature extraction layers may include one or more convolutional neural network (CNN) layers"); Ex1014, p.267 ("we employ a CNN as the feature extractor").

188. Thus, it is my opinion that Krishnan discloses [30(a)] because Krishnan discloses a processor (101, 102) and memory (110) operating a neural network (classifier) that performs the function of "deriving one or more extracted feature representations from the set of ultrasound images" as claimed.

d) [30(c)]: "means for determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images;"

189. I understand that [30(c)] is drafted in means-plus-function format and recites the same function as [21(c)]. For the reasons already provided with respect to [21(c)], in my opinion, Krishnan performs the function recited in [30(c)]. *See* Section IX.A.6.d).

190. The corresponding structure/algorithm disclosed in the Patent for performing the claimed function is a processor and memory operating a neural network. *See* Ex1001, Fig. 2 (100, 102, 104, 142, 144, 158, 170), 2:8-10, 2:14-19,

6:42-48, 7:50-52, 8:23-9:3, 9:64-10:8, Fig. 4 (300, 362, 364, 366), 12:58-13:48. It is my opinion that Krishnan discloses the same structure/algorithm for performing the recited function.

191. As I previously explained in the context of [21(c)], Krishnan discloses a data processing module/system 101 that corresponds to a processor and includes a quality assessment module 105 that determines a quality assessment value for a set of input ultrasound images. *See* Section IX.A.6.d (citing Ex1005, [0020] ("assess a level of diagnostic quality of an acquired image data set")). As explained in Section IX.A.10.c immediately above, Krishnan also discloses a classification module/system 108 with a knowledge base 110 corresponding to a memory that "maintains one or more trained classification models" (i.e., "classifiers"). Ex1005, [0021], [0023], [0043]. Krishnan further states that "[t]he classifiers are implemented by the various decision support modules (102-<u>105</u>) for performing their respective functions." *Id.*, [0023] (emphasis added); *see also* [0021] ("[C]lassification system (108) … can be used … by one or more of the various automated decision support modules (102-<u>105</u>) of the data processing system (101) to perform their respective functions."). Finally, Krishnan states that the classifiers can be "built using neural networks" (*id*. [0044]) and "[t]hese classifiers would use the set of features as an input, and classify the image[s] as belonging to a particular … level of quality" (*id*., [0043]).

192. Thus, in my opinion, Krishnan discloses [30(c)] because it discloses a processor (101, 105) and memory (110) operating a neural network (classifier) that performs the function of "determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images" as claimed.

e) [30(d)]: "means for determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images;"

193. I understand that [30(d)] is drafted in means-plus-function format and recites the same function as [21(d)]. For the reasons already provided with respect to [21(d)], in my opinion, Krishnan performs the function recited in [30(d)]. *See* Section IX.A.6.e).

194. The corresponding structure/algorithm disclosed in the Patent for performing the claimed function is a processor and memory operating a neural network. *See* Ex1001, Fig. 2 (100, 102, 104, 142, 144, 160, 170), 2:11-13, 2:19-23, 6:56-64, 7:50-52, 8:23-9:3, 9:64-10:8, Fig. 4 (300, 372, 374, 376), 13:49-14:53. It is my opinion that Krishnan discloses the same structure/algorithm for performing the recited function.

195. As I previously explained with respect to [21(d)] above, Krishnan discloses a data processing module/system 101 that corresponds to a processor and includes a view identification module 104 that determines a view category

associated with a set of input ultrasound images. *See* Section IX.A.6.e). As I explained in Section IX.A.10.c), Krishnan also discloses a classification module/system 108 with a knowledge base 110 corresponding to a memory that "maintains one or more trained classification models" (i.e., "classifiers"). Ex1005, [0021], [0023], [0043]. Krishnan states that "[t]he classifiers are implemented by the various decision support modules (102-105) for performing their respective functions." *Id*., [0023]; *see also* [0021] ("[C]lassification system (108) … can be used … by one or more of the various automated decision support modules (102-105) of the data processing system (101) to perform their respective functions."). Krishnan also states that the classifiers can be "built using neural networks" (*id*. [0044]) and "[t]hese classifiers would use the set of features as an input, and classify the image[s] as belonging to a particular … view" (*id*., [0043]).

196. Thus, in my opinion, Krishnan discloses [30(d)] because it discloses a processor (101, 104) and memory (110) operating a neural network (classifier) that performs the function of "determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images" as claimed.

f) [30(e)]: "means for producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images."

197. I understand that [30(e)] is drafted in means-plus-function format and recites the same function as [21(e)]. For the reasons already provided with respect to [21(e)], in my opinion, Krishnan performs the function recited in [30(e)]. *See* Section IX.A.6.f).

198. The corresponding structure disclosed in the Patent for performing the claimed function is a processor and memory. *See* Ex1001, Fig. 2 (100, 102, 104, 140, 150, 152, 170), 7:4-14, 7:50-58, 8:23-9:3, 14:54-15:21. It is my opinion that Krishnan discloses the same structure for performing the recited function.

199. As I previously explained with respect to [21(e)], Krishnan discloses a data processing module/system 101 that corresponds to processor and includes a view identification module 104 and an image quality assessment module 105 for producing signals representing the view category and quality assessment value of a set of ultrasound images, respectively. *See* Section IX.A.6.f); Ex1005, [0019] ("the view identification module (104) … label[s] a medical image with respect to what view of the anatomy the medical image contains"), [0036] ("for image quality assessment, the medical images may include a quality score"). Krishnan also states: "The processing results generated by the various modules of the data processing module (101) [i.e., view and quality assessment score] can be persistently stored in a repository (112) in association with the corresponding image dataset." Ex1005, [0024]. The repository 112 corresponds to a memory

where the view and quality value are associated with the ultrasound images.

200. Thus, in my opinion, Krishnan discloses [30(e)] because it discloses a processor (101, 104, 105) and memory (112) that perform the recited function of "producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images" as claimed.

201. Because Krishnan expressly describes, depicts, and discloses every element of claim 30 in the same arrangement, it is my opinion that Krishnan anticipates claim 30.

B. Ground B: Krishnan in view of Chen

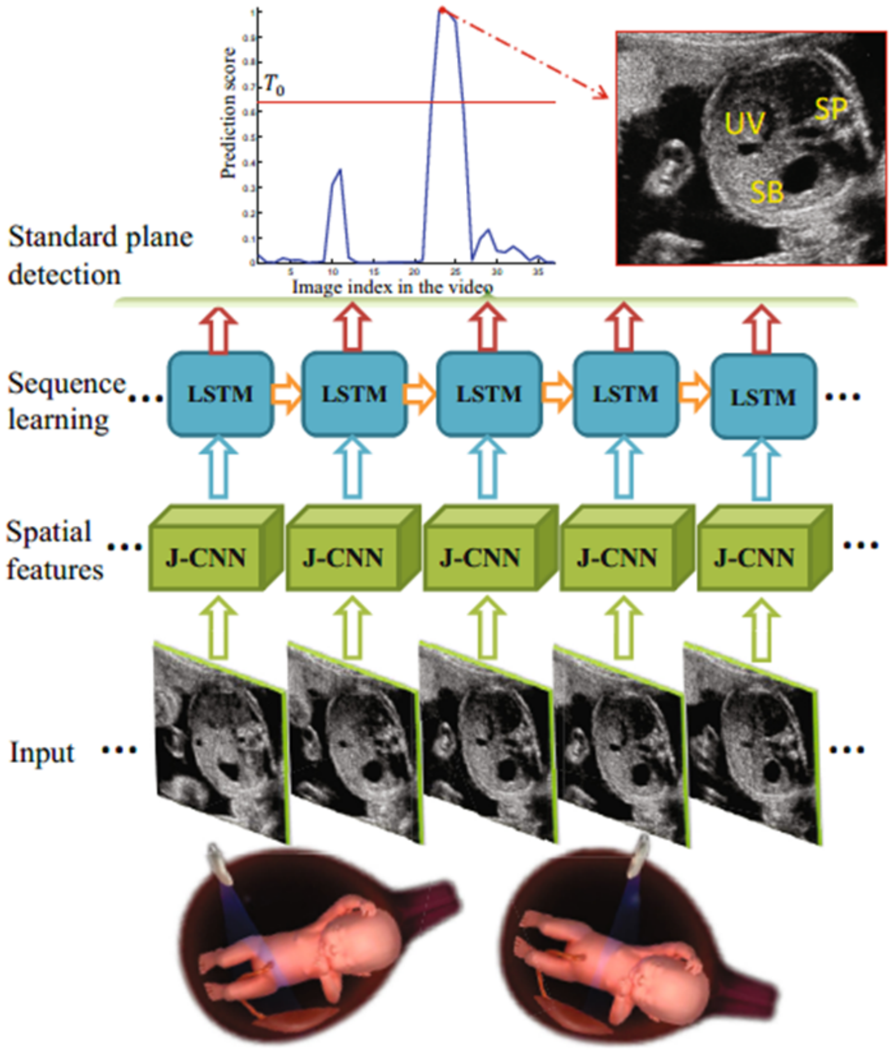
1. Claim 3: "The method of claim 2 wherein deriving the one or more extracted feature representations from the ultrasound images comprises, for each of the ultrasound images, deriving a first feature representation associated with the ultrasound image."

202. As I explained in Section IX.A.3, it is my opinion that Krishnan anticipates Claim 3 of the Patent as well as the claims it depends from, claims 1 and 2. *See* Section IX.A.1-2. I further opine here that additionally or alternatively claim 3 would have been obvious to a POSITA in view of Krishnan in combination with Chen.

203. Claim 3 adds the limitation that the feature extraction additionally comprises "for each of the ultrasound images, deriving a first feature

representation associated with the ultrasound image." It is my opinion that this functionality would have been obvious to a POSITA considering Krishnan in light of Chen. These references disclose the full scope of this claim and a POSITA would have been motivated to combine teachings from both references, as discussed below.

204. Chen states that it "present[s] a general framework to detect standard planes [(*i.e.*, views)] from US [(ultrasound)] videos automatically." Ex1009, Abstract. Referring to Figure 2, the left side of which is reproduced below, Chen discloses a neural network architecture comprising "a hybrid model integrating deep convolutional neural networks (CNN) and recurrent neural networks (LSTM model)" that "considers spatio-temporal feature representations … for the detection of standard planes from US videos." *Id.*, p.509.



205. Still referring to Figure 2, Chen explains that a "classifier is first trained based on … convolutional neural networks (J-CNN) … to locate the most discriminative regions for US standard plane detection" (Ex1009, p.509) and "<u>[f]eatures</u> in the penultimate layer … of the J-CNN model <u>are then extracted from … each frame</u>" (*id*., 511). "Then, the temporal information is explored via the LSTM model based on the <u>features … in consecutive frames</u> extracted from the J-CNN model." *Id*. (emphasis added). In my opinion, a POSITA would understand

this text and figure from Chen to teach a process in which sequential frames of an ultrasound video are input into respective J-CNNs to extract spatial feature representations from individual image frames followed by inputting the extracted features into temporal sequence learning model RNNs (LSTMs) to further analyze the data and train the system. This approach was well-established in Donahue in 2014 and widely used for video analysis thereafter. In my opinion, a POSITA would readily ascertain claim 3's limitation "wherein deriving the one or more extracted feature representations from the ultrasound images comprises, for each of the ultrasound images, deriving a first feature representation associated with the ultrasound image" from Chen.

206. Turning to the combination of the two references, Krishnan and Chen, it is my opinion that express teachings within the references would have motivated a POSITA to combine the references. Krishnan and Chen are in the same field of art, *i.e.*, ultrasonic imaging data analysis using machine learning to automatically determine a view category. Krishnan generally discloses methods for extracting feature data from a sequential set of ultrasound images to, for example, observe "the change in a particular feature across images" (Ex1005, [0034]) while Chen discloses a sample recurrent neural network architecture (T-RNN) that a POSITA would view as appropriate for analyzing sequential ultrasonic imaging data, given that ultrasound imaging data has properties of a typical video. Chen contemplates

the use of its neural network architecture in this manner, stating "[t]emporal information in time-series videos could provide additional contextual clues for the improvement of detection performance" (Ex1009, p.511) and "[c]ompared with other methods, our T-RNN achieved the best performance …, which further highlighted the superiority of exploring spatio-temporal feature learning … in standard plane detection from US videos" (*id.*, p.513). To a POSITA Krishnan-Chen would have presented a routine and obvious combination of an ultrasonic imaging feature extraction method and RNN algorithm architecture from Krishnan and Chen respectively.

207. Chen describes and represents an improvement over an earlier publication, Chen I. Chen I used convolutional neural networks to detect the fetal abdominal standard plane (i.e., view) in ultrasound images but did not consider the temporal aspect of ultrasonic data noting that "only considering spatial features may not be the optimal solution, since temporal information of consecutive sequences in US videos could provide extra contextual clues for better discrimination." Ex1009, p.508. Chen, as set forth above, uses recurrent neural network to extract the same feature from consecutive frames to account for "spatio-temporal feature representations … for the detection of standard planes." *Id.*, pp.509-511.

208. Krishnan, like Chen I, also contemplates the use of neural networks to

identify the view category of ultrasound images. *See*, *e.g.*, Section IX.A.10.e). And, as already stated, Krishnan is also capable of processing one or more sequential ultrasound images, including loops of data (i.e., videos). Therefore, in my opinion, it would have been obvious to a POSITA to improve Krishnan with neural network architecture of Chen in the same way that Chen internally describes these types of improvements over Chen I, *i.e.*, to better extract features from consecutive images in a set, rather than a single image, and thus improve view identification with temporal data.

209. In my opinion, a POSITA would also have had a reasonable expectation of success combining Chen with Krishnan. Krishnan already contemplates using a "bank of classifiers" that perform respective functions. Chen could therefore be implemented in Krishnan by adding the neural network classifier described in Chen, with little to no modification to the bank of classifiers described in Krishnan. As I discussed in Sections IX.A.1.c (claim [1(b)]) and IX.A.4 (claim 9), Krishnan describes using a "bank of classifiers" (Ex1005, [0043]), which can be "built using neural networks" (*id*., [0044]), where "[t]he classifiers are implemented by the various decision support modules (102-105) for performing their respective functions" (*id*., [0023] (emphasis added)). Two of those functions are feature extraction and view identification. Chen discloses neural networks that perform the same functions on the same type of ultrasound

data received by Krishnan, i.e., multiple sequential ultrasound images ("loops of data"). Indeed, Chen is explicit that "the proposed T-RNN is a general framework and can be easily extended to other US standard plane or anatomical structure detection problems." Ex1009, p.509, 514 ("Furthermore, our approach is a general framework and can be extended to the detection of other US standard planes or anatomical structures.").

210. In sum, Krishnan in view of Chen teaches or discloses all the elements in claim 3. And, since, in my opinion, a POSITA would have been motivated to and have had a reasonable expectation of success in combining Krishnan and Chen, the subject matter of claim 3, in my opinion, would have been obvious to a POSITA in light of this combination.

2. Claim 4: "The method of claim 3 wherein deriving the one or more extracted feature representations comprises, for each of the ultrasound images, inputting the ultrasound image into a commonly defined first feature extracting neural subnetwork to generate the first feature representation associated with the ultrasound image."

211. Claim 4 depends from claim 3. As I explained in Section IX.B.1, it is my opinion that Krishnan anticipates Claim 3 and/or renders Claim 3 obvious in further view of Chen. Claim 4 adds: "for each of the ultrasound images, inputting the ultrasound image into a commonly defined first feature extracting neural subnetwork to generate the first feature representation associated with the ultrasound image." It is my opinion that Krishnan in combination with Chen also

renders claim 4 obvious.

212. Chen, with reference to Figure 2, reproduced below, states: "Fig. 2 (left) shows the architecture of the proposed T-RNN [(knowledge transferred recurrent neural network)], which is a hybrid model integrating deep convolutional neural networks (CNN) and recurrent neural networks (LSTM model)." Ex1009, p.509 (emphasis added). Chen refers to and labels the multiple CNNs as "joint learning" convolutional neural networks or "J-CNN" for avoidance of confusion. *Id*.

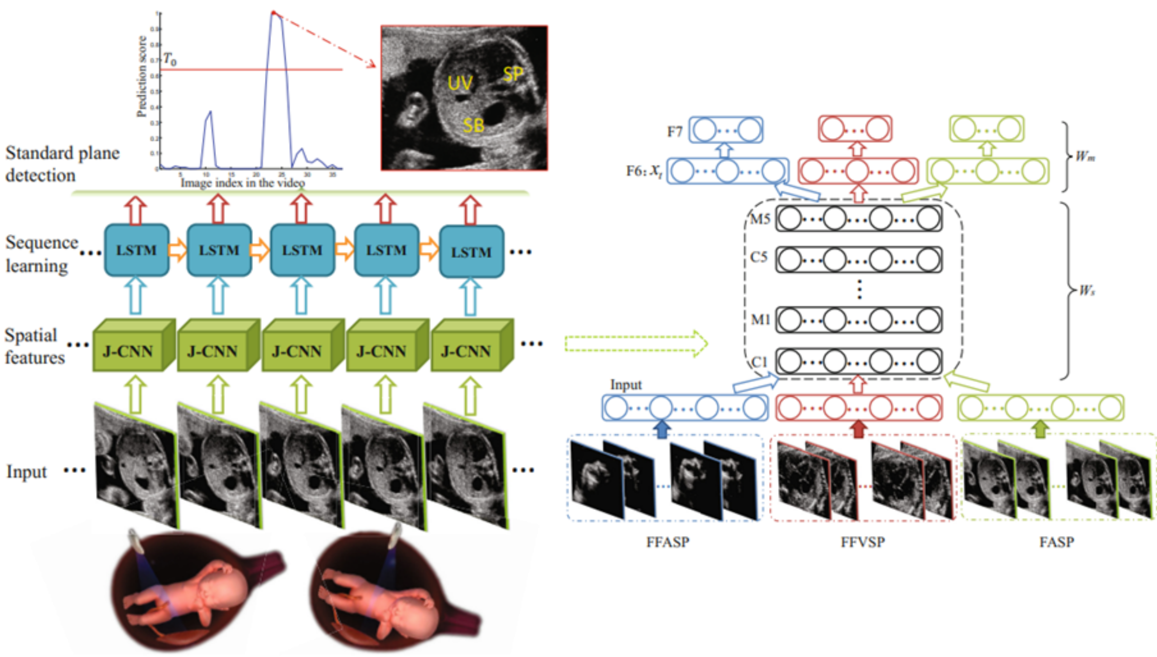


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

213. As I explained at length in Section IX.B.1, and with further reference to Figure 2, Chen extracts features from a set of ultrasound images by first

inputting each consecutive frame of an ultrasound video into a respective J-CNN that extracts spatial features from the frame. Per the figure, each J-CNN is a sub-network within the overall T-RNN (recursive) network, consistent with claim 4. Importantly, with reference to the right side of Fig. 2, each J-CNN is also commonly defined, as claimed. Ex1009, p.509 ("Fig. 2 Left: architecture of the proposed T-RNN; right: the proposed J-CNN"). Accordingly, Chen discloses "for each of the ultrasound images, inputting the ultrasound image into a commonly defined first feature extracting neural subnetwork to generate the first feature representation associated with the ultrasound image" as claimed.

214. A POSITA would have been motivated to combine Krishnan's feature extraction and view identification with the T-RNN (and sub J-CNN) neural network architecture model of Chen as proposed for the same reasons already explained in Section IX.B.1 above.

215. A POSITA would have had a reasonable expectation of success in combining Krishnan and Chen to achieve the claimed subject matter for the same reasons already explained in Section IX.B.1 above. Chen sufficiently teaches a POSITA to apply the neural network architecture such that, with ordinary talent and knowledge, a POSITA would be able to recreate the described techniques without a significant amount of refactoring or experimentation. As discussed above, Krishnan states that "classifiers" can be used to assess the quality of

images, and that these “classifiers” “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]). A POSITA could merely add Chen’s T-RNN to Krishnan’s “bank of classifiers” to perform the same functions already described in Krishnan, which would be a routine change requiring little to know experimentation on the part of the POSITA.

216. In my opinion, Krishnan in view of Chen teaches or discloses all the elements in claim 4. And since a POSITA would have been motivated to and have reasonable expectation of success in combining Krishnan and Chen, the subject matter of claim 4, in my opinion, would have been obvious to a POSITA in light of this combination.

3. Claim 5: “The method of claim 4 wherein deriving the one or more extracted feature representations comprises concurrently inputting each of a plurality of the ultrasound images into a respective implementation of the commonly defined first feature extracting neural network.”

217. Claim 5 depends from claim 4. As I explained in Section IX.B.2, it is my opinion that Krishnan in further view of Chen renders Claim 4 obvious. Claim 5 adds: “concurrently inputting each of a plurality of the ultrasound images into a respective implementation of the commonly defined first feature extracting neural network.” It is my opinion that Krishnan in combination with Chen also renders claim 5 unpatentable as obvious.

218. As I explained in Section IX.B.2, Chen shows in Figure 2 (left) adjacent images from a series (i.e., video) being input to a J-CNN, which is a feature extracting neural network that extracts spatial features from each frame of an ultrasound video, as is claimed in the Patent. Ex1009, p.508-11

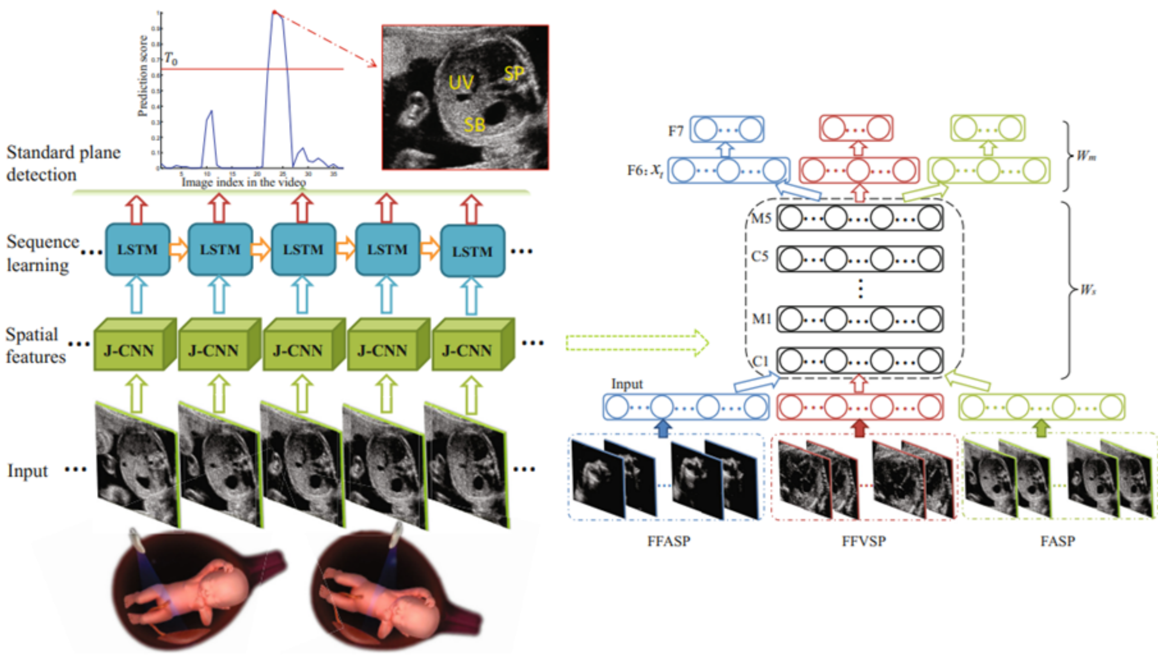


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

219. Furthermore, as I explained in Section IX.B.2, every implementation of a J-CNN shown in Figure 2 of Chen is commonly defined, or put another way, has the same neural network architecture and parameters, just as in the claim. Ex1009, p.508-11. And, as depicted and disclosed in Figure 2 above, each ultrasound image is concurrently input, as claimed, into a respective commonly defined J-CNN for feature extraction. *Id.*

220. In sum, in my opinion, Krishnan in view of Chen teaches or discloses all the elements in claim 5. And for the same reasons I have articulated above (*see* Sections IX.B.1-2), it is my opinion that a POSITA would again have been motivated to and have reasonable expectation of success in combining Krishnan and Chen. It is therefore my opinion that the subject matter of claim 5 would have been obvious to a POSITA in light of this combination.

4. Claim 6: "The method of claim 4, wherein the commonly defined first feature extracting neural network includes a convolutional neural network."

221. Claim 6 depends from claim 4. As I explained in Section IX.B.2, it is my opinion that Krishnan in further view of Chen renders Claim 4 obvious. Claim 6 adds that: "the commonly defined first feature extracting neural network includes a convolutional neural network." It is my opinion that Krishnan in combination with Chen also renders claim 6 unpatentable as obvious.

222. As I explained more fully in Sections IX.B.1-2, Chen is replete with references to and express implementations for convolutional neural networks. Ex1009, p.509. And the "bank of classifiers" from method and system disclosed in Krishnan contemplates that many neural networks of different types may be used to accomplish various functions during the ultrasonic image analysis. Ex1005, [0043-44]. Thus, in my opinion, Krishnan in combination with Chen discloses or teaches all the elements of claim 6.

223. For the same reasons I have articulated with respect to the combination of the processes in Krishnan with the algorithm architecture of Chen (*See*, Sections IX.B.1-2), it is my opinion that a POSITA would again have been motivated to and have reasonable expectation of success in combining Krishnan and Chen. It is therefore my opinion that the subject matter of claim 6 would have been obvious to a POSITA in light of this combination.

5. Claim 7: "The method of claim 4 wherein deriving the one or more extracted feature representations comprises inputting the first feature representations into a second feature extracting neural network to generate respective second feature representations, each associated with one of the ultrasound images and wherein the one or more extracted feature representations include the second feature representations."

224. Claim 7 depends from claim 4. As I explained in Section IX.B.2, it is my opinion that Krishnan in further view of Chen renders Claim 4 obvious. Claim 7 adds that: "inputting the first feature representations into a second feature extracting neural network to generate respective second feature representations, each associated with one of the ultrasound images and wherein the one or more extracted feature representations include the second feature representations." It is my opinion that Krishnan in combination with Chen also renders claim 7 obvious.

225. As I explained in Section IX.C.2, with reference to Figure 2, below, Chen expressly contemplates deriving one or more extracted feature representations from a set of ultrasound images, as claimed, by first extracting

“spatial features” from each image using convolutional neural networks (labelled J-CNN). Ex1009, p.511.

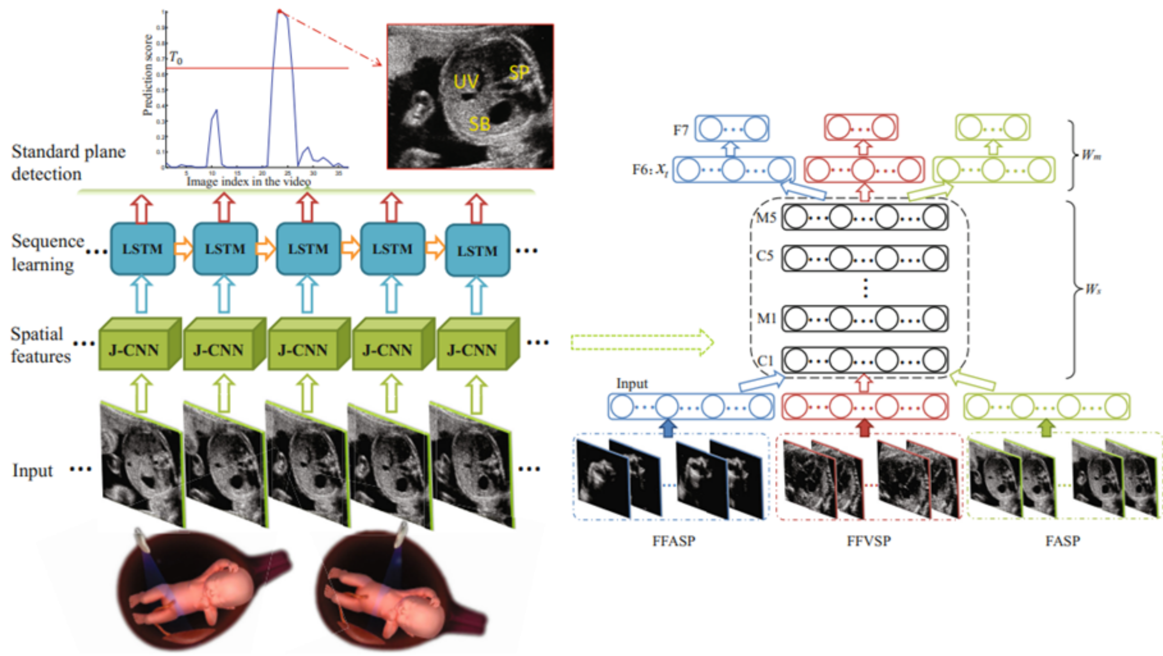


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

226. The extracted spatial feature representations are then input into a second feature extracting neural network (potentially an RNN, labelled the LSTM model), as claimed. *Id.* For example, Chen states: (1) “features …, which have been detected by the J-CNN model, are further explored by the LSTM” (Ex1009, p.511); and (2) “temporal information is explored via the LSTM model based on the features … in consecutive frames extracted from the J-CNN model” (*id.*, p.509). In my opinion, A POSITA would understand that the orange horizontal arrows in Figure 2 between LSTM model and the red vertical arrows represent the

generation and output of respective second feature representations for each image, which are either provided to an adjacent LSTM cell for "sequence learning" or output to an additional layer that performs the view classification task. This is the standard hybrid CNN-RNN architecture first described by Donahue in 2014 for the use of analyzing videos. *See* Ex1021. Thus, it is my opinion that a POSITA would understand Chen to disclose or teach "inputting the first feature representations into a second feature extracting neural network to generate respective second feature representations, each associated with one of the ultrasound images" as claimed.

227. Claim 7 also recites "wherein the one or more extracted feature representations include the second feature representations." Chen identifies the view category of ultrasound images using both spatial features extracted by the J-CNN models and temporal features extracted by the LSTM models. For example, Chen states that it "considers spatio-temporal feature representations … for the detection of standard planes from US videos." Ex1009, p.509. Thus, in my opinion, Chen discloses that "the one or more extracted feature representations include the second feature representations," as claimed.

228. In sum, for the same reasons I have articulated for the combination of the processes in Krishnan with the algorithm architecture of Chen (*See* Sections IX.B.1-2), it is my opinion that a POSITA would have been motivated to and have

had a reasonable expectation of success in combining Krishnan and Chen. It is therefore my opinion that the subject matter of claim 7 would have been obvious to a POSITA in light of this combination.

6. Claim 8: "The method of claim 7 wherein the second feature extracting neural network is a recurrent neural network."

229. Claim 8 depends from claim 7. As I explained in Section IX.B.5, it is my opinion that Krishnan in further view of Chen renders Claim 4 obvious. Claim 8 adds that: "the second feature extracting neural network is a recurrent neural network." It is my opinion that Krishnan in combination with Chen also renders claim 8 obvious.

230. As I explained in Sections IX.C.1, 5, the LSTM models described and depicted in Chen correspond to the claimed "second feature extracting neural network." Because these LSTM models are recurrent neural networks (Ex1009, p.509 ("recurrent neural networks (LSTM model)"), in my opinion, Krishnan in view of Chen discloses "the second feature extracting neural network is a recurrent neural network" as claimed.

231. And for the same reasons I have articulated for claim 7 and for the combination of the processes in Krishnan with the algorithm architecture of Chen, (*See*, Sections IX.B.1-2, 5), it is my opinion that a POSITA would have been motivated to and have reasonable expectation of success in combining Krishnan

and Chen. It is therefore my opinion that subject matter of claim 8 would have been obvious to a POSITA in light of this combination.

7. Claim 23: "The system of claim 22 wherein the at least one processor is configured to, for each of the ultrasound images, input the ultrasound image into a commonly defined first feature extracting neural subnetwork to generate a first feature representation associated with the ultrasound image."

232. Claim 23 depends from claim 22, which is anticipated by Krishnan. *See* Section IX.A.7. The additional limitations recited in claim 23 appear substantially identical to limitations recited in claim 4 (Section IX.B.2) except, whereas claim 4 is a method claim, reciting functions, claim 23 is a system claim that recites "the at least one processor is configured to" perform said corresponding functions recited in claim 4. As I explained in Section IX.B.2, above, it is my opinion that Chen discloses the function limitations recited in claim 4. It is my opinion that Chen also discloses and recites all the structural limitations of claim 23 in that its computer-implemented process is performed by a processor (e.g., "a 2.50 GHz Intel(R) Xeon(R) E5-2609 CPU"). Ex1009, p.513. For the reasons explained in Section IX.B.1-2, in my opinion, it would have been obvious to a POSITA to combine Krishnan with Chen. Krishnan already utilizes a "bank of classifiers" to perform respective functions, including extracting features from a set of ultrasound images for view identification (Ex1005, [0034, 0043-0044]), and Chen discloses an improved neural network classifier architecture for feature

extraction and view identification that inputs each ultrasound image within a set into a commonly defined feature extracting neural subnetwork, as claimed (Ex1009, p.509, 511, 513). In my opinion, a POSITA would have been motivated to combine, and had a reasonable expectation of success combining, Krishnan and Chen to arrive at the subject matter claim in claim 23 simply by using neural network classifiers like those described by Chen in Krishnan's "bank of classifiers."

233. In sum, in my opinion, Krishnan in view of Chen teaches or discloses all the elements in claim 23. And since a POSITA would have been motivated to and have had reasonable expectation of success in combining Krishnan and Chen, the subject matter of claim 23, in my opinion, would have been obvious to a POSITA in light of this combination.

8. Claim 24: "The system of claim 23 wherein the at least one processor is configured to, for each of the ultrasound images, input the ultrasound image into a commonly defined first feature extracting neural subnetwork to generate the first feature representation associated with the ultrasound image."

234. Claim 24 depends from claim 23 and repeats, nearly identically, the limitations recited in claim 23. It is my opinion, therefore, that claim 24 does not add any additional limitations to claim 23 and is unpatentable for the same reasons provided in Section IX.B.7 above.

235. At bottom, for the same reasoning as with Claim 23—the subject

matter of claim 24 was obvious to a POSITA in light of this combination.

9. Claim 25: "The system of claim 24 wherein the at least one processor is configured to concurrently input each of a plurality of the ultrasound images into a respective implementation of the commonly defined first feature extracting neural network."

236. Claim 25 depends from claim 24, which I have opined is rendered obvious over Krishnan in view of Chen. *See* Section IX.A.7-8. The additional limitations recited in claim 25 appear substantially identical to limitations recited in claim 5 (Section IX.B.3) except, whereas claim 5 is a method claim, reciting functions, claim 25 is a system claim that recites "the at least one processor is configured to" perform said corresponding functions recited in claim 5. And, as I explained in Section IX.B.3, Chen discloses the function recited in in claim 5. Specifically, Chen uses feature-extracting J-CNN that are commonly defined by the same neural network parameters. Ex.1009, p.508-11. As I further explained in Section IX.C.7, Chen also states that its computer-implemented process is performed by a processor (e.g., "a 2.50 GHz Intel(R) Xeon(R) E5-2609 CPU"). Ex1009, p.513. For the reasons explained in Section IX.B.1-3, it would have been obvious to a POSITA to combine, and they would have a reasonable expectation of success combining, Krishnan and Chen to arrive at the subject matter in claim 25 using structured neural network classifiers like those described by Chen in Krishnan's "bank of classifiers."

237. In sum, in my opinion, Krishnan in view of Chen teaches or discloses all the elements in claim 25. And since, in my opinion, a POSITA would have been motivated to and have reasonable expectation of success in combining Krishnan and Chen, the subject matter of claim 25, in my opinion, would have been obvious to a POSITA in light of this combination.

10. Claim 26: "The system of claim 24 wherein the at least one processor is configured to input the first feature representations into a second feature extracting neural network to generate respective second feature representations, each associated with one of the ultrasound images and wherein the one or more extracted feature representations include the second feature representations."

238. Claim 26 depends from claim 24. As discussed above, it is my opinion that claim 24 is obvious over Krishnan in view of Chen. *See* Section IX.A.7-8. The additional limitations recited in claim 26 appear substantially identical to limitations recited in claim 7 (Section IX.B.5) except, whereas claim 7 is a method claim, reciting functions, claim 25 is a system claim that recites "the at least one processor is configured to" perform said corresponding functions recited in claim 7. Specifically, as I explained above, Chen discloses use of LSTM/RNN for temporal information exploration, sequence learning, and consideration of spatio-temporal feature representations from the ultrasonic image data. Ex.1009, p.509, 511. As explained in Section IX.C.7, above, Chen also states that its computer-implemented process is performed by a processor (e.g., "a 2.50 GHz Intel(R)

Xeon(R) E5-2609 CPU"). *Id.*, p.513. For the reasons explained in Section IX.B.1-3, it is my opinion that it would have been obvious to a POSITA to combine, and they would have had a reasonable expectation of success combining, Krishnan and Chen to arrive at the subject matter claim in claim 25 by using structured neural network classifiers like those described by Chen in Krishnan's "bank of classifiers."

239. In sum, it is my opinion that Krishnan in view of Chen teaches or discloses all the elements in claim 26. And, since a POSITA would have been motivated to and have had a reasonable expectation of success in combining Krishnan and Chen, the subject matter of claim 26, in my opinion, would have been obvious to a POSITA in light of this combination.

C. Ground C: Krishnan in view of Aase

1. Claims 9 and 27: A "Quality Assessment Value Specific Neural Network and an "Image Property Specific Neural Network"

240. It is my opinion, set forth in Sections IX.A.4 and IX.A.8, that Claims 9 and 27 are anticipated by Krishnan. These claims depend from claims 2 and 22, that, in my opinion, are also anticipated by Krishnan. *See* Sections IX.A.2 and IX.A.7. I have grouped my analysis of Claims 9 and 27 together because they are substantially the same, save that claim 9 recites functional method steps and claim 27 recites structure, such as a processor, which is configured to perform the

corresponding functions recited in claim 9. As set forth below, it is my opinion that additionally or in the alternative, claims 9 and 27 would have been viewed by a POSITA obvious over Krishnan in view of Aase.

241. As I explained in Section IX.A.4, Krishnan performs the respective functions of quality assessment and view identification using extracted features as input into a set of machine learning classifiers. A view identification module 104 "use[s] the extracted features/parameters to automatically identify the view of an acquired image." Ex1005, [0019]. A quality assessment module 105 "use[s] the extracted features/parameters to assess a level of diagnostic quality of an acquired image data set." *Id.*, [0020]. The modules 104 and 105 utilize a "bank of classifiers" or a "set of classifiers" (*id.*, [0043]), which Krishnan states can be "built using neural networks" (*id.*, [0044]). "The classifiers are implemented by the various decision support modules (102-105) for performing their respective functions." *Id.*, [0023] (emphasis added). For example, "[t]hese classifiers would use the set of features as an input, and classify the image as belonging to a particular anatomy, view, or level of quality." *Id.*, [0043] (emphasis added).

242. In my opinion, as discussed above, Krishnan discloses that its quality assessment module 105 inputs extracted feature representations "into a quality assessment value specific neural network" to determine a quality assessment value, and the view identification module 104 inputs extracted feature representations

"into an image property [(i.e., view)] specific neural network" to identify the view category, as claimed. Nevertheless, if Krishnan were found not to anticipate claims 9 and 27 because it does not explicitly refer to a quality assessment value specific neural network and/or a view category specific neural network, it is my opinion that Krishnan-Aase discloses or teaches such functionality. In my opinion, implementation of separate view-category-specific neural networks and quality assessment neural networks would have been obvious to a POSITA upon combining the teachings Krishnan and Aase.

243. Like Krishnan, Aase is directed to systems for automatically identifying the view and quality of sets of ultrasound images (i.e., loops). Referring to Figure 2, below, the processor 132 in Aase includes a separate quality assessment value specific neural network 170 and a view category assignment specific neural network 160 (labelled as modules).

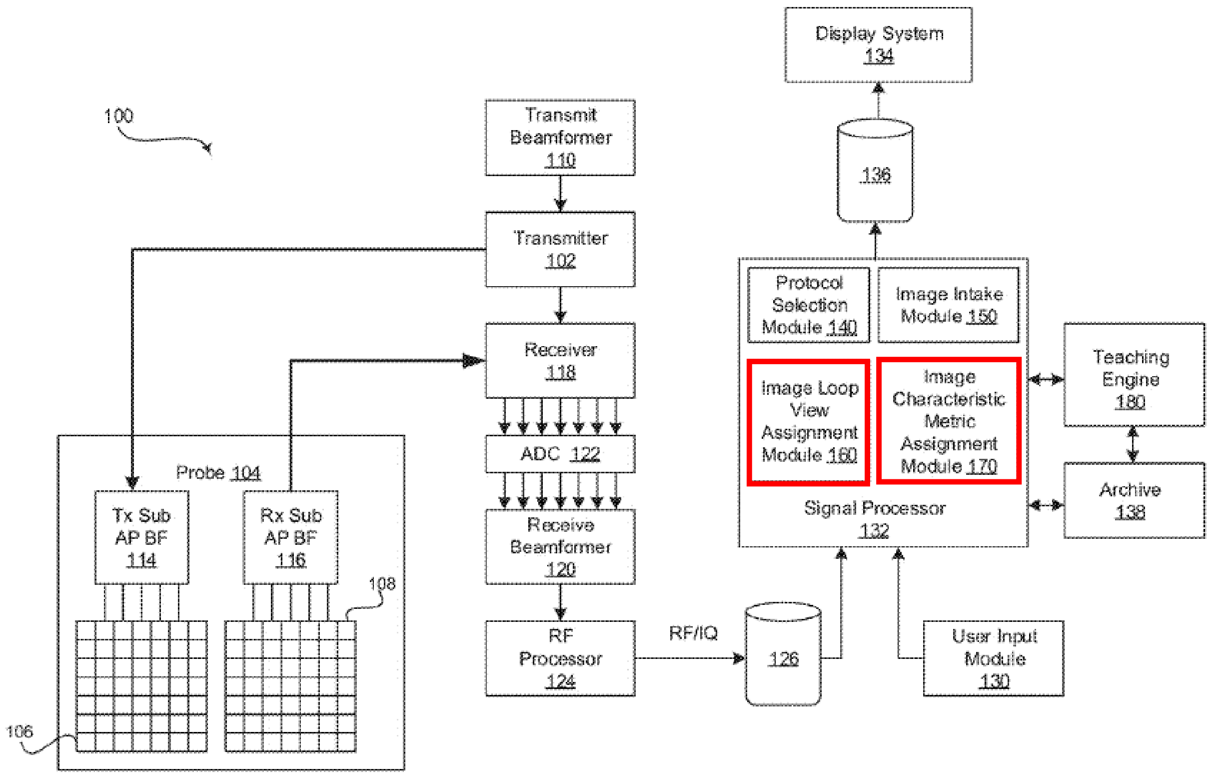


FIG. 2

244. Aase states that the "signal processor 132 may include an image loop view assignment module 160 … operable to automatically assign an image view type" (Ex1006, [0032]) and "the image loop view assignment module 160 may include one or more deep neural networks" (*id.*, [0033]). Likewise, Aase states that the "signal processor 132 may include an image characteristic metric assignment module 170" (*id.*, [0034]) and "the image characteristic metric assignment module 170 may include one or more deep neural networks" that "provide an image quality score" (*id.*, [0035]).

245. Krishnan extracts features from a set of ultrasound images and inputs

the extracted features into a bank of classifiers that perform the function of view identification and quality assessment, while Aase explicitly includes a view category specific neural network classifier and a quality assessment value specific neural network classifier for handling these tasks.

246. Regarding the combination of Krishnan and Aase, the motivation to implement view category specific neural network and a quality assessment specific neural network, like those in Aase, into the system or method of Krishnan is supplied by the teachings of references themselves. Krishnan explicitly teaches a "bank" or "set" of classifiers to perform a variety of functions, including view identification and quality assessment, where classifiers can be neural networks. Ex1005, [0044]. A POSITA would recognize that a simple and elegant implementation of Krishnan's disclosure is to implement separate, function-specific classifier modules to perform each function contemplated for the "bank of classifiers." A POSITA would understand this implementation as a well-modeled solution (such as in Krishnan) of employing separate classifiers to perform separate functions important in ultrasonic image analysis—for example, determining a view category or performing a quality assessment. Aase takes the express teachings and suggestions of Krishnan, i.e., a quality assessment specific neural network can be used to assess quality, and a view assignment specific neural network can be used to identify the view category and further details their

implementation.

247. Additionally, a POSITA would immediately recognize that Krishnan and Aase are both directed to systems for automatically identifying the view and quality of sets of ultrasound images (i.e., loops) and would thus have a reasonable expectation of success in their compatibility. Combining these aspects of Krishnan and Aase would not require any material modification or experimentation on the part of the POSITA and the result would render claims 9 and 27 obvious.

248. In sum, in my opinion, Krishnan in view of Aase teaches or suggests all elements of claims 9 and 27.

2. Claims 10 and 28: Inputting corresponding data into "a commonly defined quality assessment value specific neural subnetwork" and "a commonly defined image property specific neural network."

249. Claims 10 and 28 depend from claims 9 and 27. As identified above, it is my opinion that a POSITA would understand both claims 9 and 27 to be obvious over Krishnan in view of Aase. *See* Section IX.C.1. As with the previous section, I have grouped my analysis of Claims 10 and 28 together because they are substantially the same save that claim 10 recites functional method steps and claim 28 recites structure, such as a processor, which is configured to perform the corresponding functions recited in claim 10. As set forth below, it is my opinion that a POSITA would view claims 10 and 28 to be obvious over Krishnan in view of Aase.

250. Claims 10 and 28 add the additional limitations of: (i) "inputting[/input] each of the one or more extracted feature representations into an implementation of a commonly defined quality assessment value specific neural subnetwork"; and (ii) "inputting[/input] each of the one or more extracted feature representations into an implementation of a commonly defined image property specific neural network."

251. In contrast to claims 5 and 25, claims 10 and 28 do not require "concurrently" inputting into a "respective" implementation of a commonly defined neural network. I understand from conversations with counsel, that Patent Owner in the California Litigation alleges that a product having a single convolutional neural network with a single input layer where ultrasound image frames are input one at a time in series, one after another, for evaluation by the same neural network layers, infringes claims 10 and 28. A POSITA would be well-versed in the architecture, implementation, and training differences for separate multi-layered neural networks versus a single multi-layered, multi-function neural network.

252. As I explained in Section IX.C.1, the combination of Krishnan and Aase teaches and suggests inputting the extracted features from a set of ultrasound images into separate quality assessment and view identification specific neural network classifiers, as claimed. *See*, Ex.1006, [0032-0035] (teaching view specific

and image property specific neural networks). As I also explained in Section IX.A.1.c, Krishnan states that "the image dataset will be processed to … extract relevant feature data from the image dataset" where "[t]hese features could include any kind of characteristic" and "can be obtained across images, such as motion of a particular point, or the change in a particular feature across images." Ex1005, [0034] (emphasis added). Thus, Krishnan evaluates each of the extracted feature representations from respective images within the data set. *See also*, Ex1005, [0020] ("using the extracted features/parameters to assess a level of diagnostic quality of an acquired image data set").

253. Krishnan extracts features from each image in a set of ultrasound images (e.g., to track changes). In combination, Krishnan-Aase thus further teaches and suggests inputting extracted features into respective quality assessment and view identification specific neural networks. A POSITA would therefore find that Krishnan in view of Aase renders claims 10 and 28 obvious.

254. In sum, in my opinion, Krishnan in view of Aase teaches or suggests all elements of claims 10 and 28. And for the same reasons I expound in Section IX.C.1, it is my opinion that a POSITA would have been motivated to and have had reasonable expectation of success in combining Krishnan and Aase.

D. Ground D: Krishnan in view of Chen and Wu

255. Independent claim 12 and dependent claims 13 through 20 generally

cover "computer-implemented method of training (rather than implementing) one or more neural networks to facilitate ultrasonic image analysis." I find no instance in the Patent, however, where a novel or nuanced technique for training neural networks is disclosed or implied.

256. Rather, in my opinion, the "training claims" employ an industry-standard technique comprising (i) using pre-labeled training images as input, and (ii) adjusting the neural network parameters (e.g., weights and biases) to predict—with minimal error—the training labels at the neural network output which was well known in the art before the Patent was even filed. *See*, e.g., Ex1012, p.516 (Itchaporia) (describing "Training methods for artificial neural networks"); Ex1017, p.450 (Miller) (explaining "Supervised learning") ("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."); Ex1018, [0037], [0040]-[0041], [0046], [0084] (Pagoulatos) ("common method of training artificial neural networks"), [0046] ("The neural network may be trained by providing training images to the input layer."). Such training methods were well-established for both categorical and continuous outputs, and the Patent does not propose anything beyond industry-standard. The methods described in the Patent for updating of weights and biases, namely backpropagation and gradient

computation, were routinely described in the literature for training neural networks.

257. It is my opinion that Krishnan's neural network classifiers perform the same functions recited in the claims (i.e., quality assessment and view category assignment for a set of ultrasound images). Combined with the POSITA's industry-standard and common knowledge on training such networks, it is my opinion that that the Patent's "training" claims would have been obvious to a POSITA. Additionally, or in the alternative, the teachings of Chen and Wu explicitly teach CNN and RNN training for view category or plane identification as well as quality assessment.

1. Claim 12:

258. It is my opinion that a POSITA would have understood that independent claim 12 was obvious over Krishnan in view of Chen and Wu. As I explained above, *see e.g.*, Sections IX.A.1 and IX.A.4 above, Krishnan contemplates ultrasonic image analysis using a bank of neural network classifiers to determine a view category and quality assessment of the images. Chen and Wu describe methods for training a view category neural network classifier neural network and a quality assessment neural network classifier neural network, respectively.

259. Krishnan, Chen, and Wu are all directed to the same field of

ultrasonic image analysis using machine learning techniques. Accordingly, in my opinion, a POSITA would be motivated to and readily capable of combining these references given explicit teachings and motivations expressed in the references themselves.

260. Krishnan discloses classification modules that perform view identification and quality assessment. Ex1005, [0019] ("view identification module"), [0020] ("quality assessment module"), [0023] ("one or more classifiers"). "The classifiers can be implemented using machine learning methods" (Ex1005, [0006], [0023]), including "neural networks." *Id.*, [0042]-[0044]. Chen and Wu disclose various sample neural network architectures (in some cases both convolutional and recurrent) for extracting feature data from a sequential set of ultrasound images and performing the same functions of view identification and quality assessment. *E.g.*, Ex1009, p. 512; Ex1010 p. 1339, 41.

261. In my opinion, it would have been intuitive to a POSITA to use recurrent neural networks—like those disclosed in Chen and Wu—to improve view identification and quality assessment in Krishnan as these represented the industry-standard for video analysis. It would likewise be intuitive, and a POSITA would be motivated, to use the "training" techniques disclosed in Chen and Wu, which, in turn, were well-described in Donahue and supplemented by the multi-task learning approach described in Caruana. Further, Krishnan's "machine

learning" neural network classifiers need to be trained. See Ex1005, [0023] ("learning engine (109) includes methods for training/building one or more classifiers using training data … of previously … labeled cases"). Chen and Wu describe techniques for training (and multi-network training) such classifiers as they relate to view category and quality assessment. *See, e.g.*, Ex1009, 507, 509-10, 513 (contemplating "joint learning and knowledge transfer" across multiple domains in which annotated and labeled image data is input into various convolutional and recurrent networks and the output of same is input into other networks for further supervised learning); Ex1010, p. 1337-1341 (pdf pp. 2-6). In my opinion, a POSITA would naturally look to neural networks disclosed in Chen and Wu to improve sequential data processing, and a POSITA would have been further motivated to implement the training methods described in Chen and Wu, with Krishnan, for their intended purpose (i.e., ultrasound view identification and quality assessment, respectively).

262. Krishnan, Chen, and Wu all relate to the use of machine learning to improving ultrasonic image analysis. In my opinion, a POSITA would have had a reasonable expectation of success combining the teaching of these references for this purpose. Ex1005, [0023] ("training/building … classifiers using train data … of previously diagnosed/labeled cases"); Ex1009, p.512 ("For training the … classifier …, training samples … were generated" and "manually annotated by an

experiences obstetrician."); Ex1010, p.1341 (pdf p.6) ("The annotation of all training data for the [convolutional neural networks] was initially done by a graduate student."). Chen even expressly states that it discloses "a general framework and can be easily extended to other [ultrasound] standard plane or anatomical structure detection problems." Ex1009, p.509. Likewise, Wu also states that its "proposed [quality assessment] scheme can be easily generalized to other types of fetal [ultrasound] views." Ex1010, p.1338 (pdf p.2).

263. As set forth more fully below, Krishnan in view of Chen and Wu teaches or suggests all elements of claims 12. And, in my opinion, a POSITA would again have been motivated to and have had a reasonable expectation of success in combining Krishnan, Chen, and Wu.

a) [12(pre)]: "A computer-implemented method of training one or more neural networks to facilitate ultrasonic image analysis, the method comprising:"

264. It is my opinion that Krishnan discloses [12(pre)] to the extent it is a limitation. *See*, *e.g.*, Ex1005, Fig. 1 ("Learning Engine 109"), [0023] ("The learning engine (109) includes <u>methods for training</u>/building one or more classifiers using training data that is learned from the database (106) of previously diagnosed/labelled cases.") (emphasis added), [0044] ("classifiers are built using neural networks"), [0016] ("methods for analyzing medical image data … (e.g., ultrasound image data)"). Chen and Wu are likewise directed to

computer-implemented methods of training neural networks for ultrasound image analysis. Ex1009, p.513 ("The … method generally took less than 1 minute to detect the standard planes from a video containing 40 frames using a workstation equipped with a … CPU."), p.509 ("classifier is first trained based on the joint learning of convolutional neural networks … for [ultrasound] standard plane detection"), p.510 (describing the training of common (C1 to M5) and view-specific (F6 and F7) neural network layers); Ex1010, Abstract ("The proposed [fetal ultrasound image quality assessment] is realized with two deep convolutional neural network models, which are denoted as L-CNN and C-CNN, respectively."), p.1341 (pdf p. 6)(describing the training of L-CNN and C-CNN).

b) [12(a)]: "receiving signals representing a plurality of sets of ultrasound training images;"

265. It is my opinion that Krishnan discloses [12(a)], "receiving signals representing a plurality of sets of ultrasound training images." Ex1005, [0016]-[0017] ("ultrasound image data"). With reference to Figure 1, reproduced below, Krishnan states: "The database (106) may comprise a plurality of labeled/diagnosed medical images … which are indexed … based on relevant features/parameters." Ex1005, [0021].

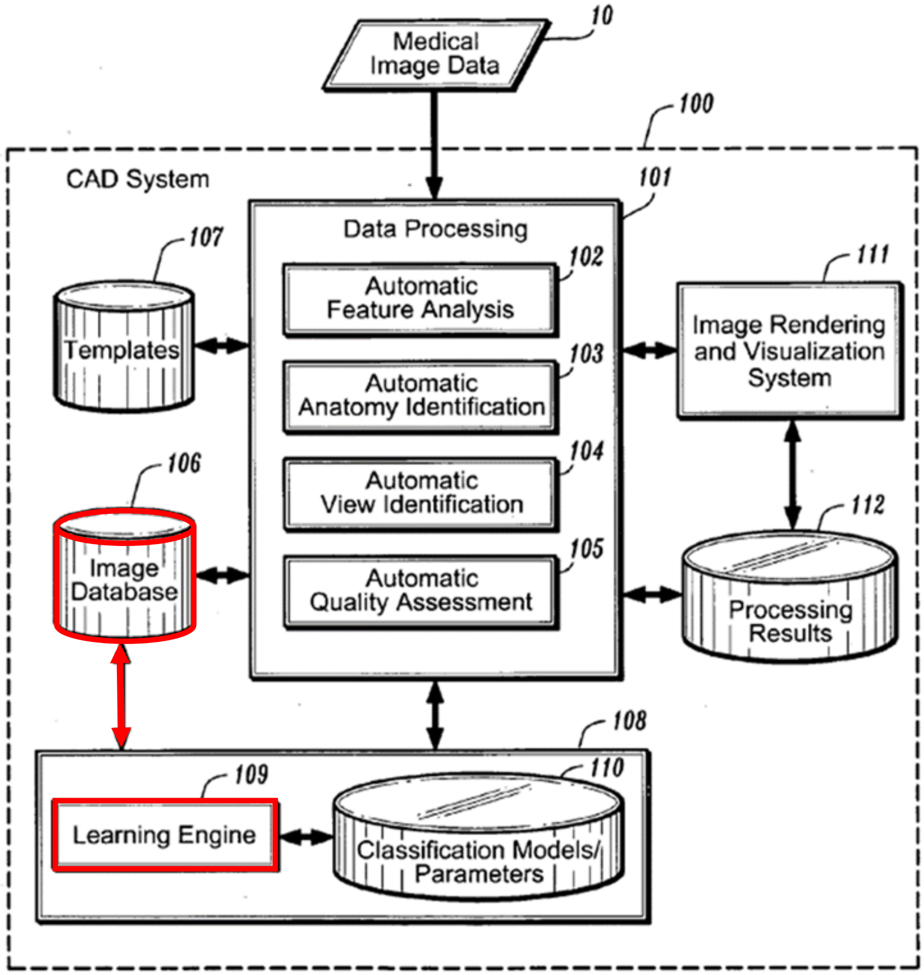


FIG. 1

"The learning engine (109) includes methods for training/building one or more classifiers using training data that is learned from the database (106) of previously diagnosed/labelled cases." *Id.*, [0023] (emphasis added).

c) [12(b)]: "receiving signals representing quality assessment values, each of the quality assessment values associated with one of the sets of ultrasound training images and representing a quality assessment of the associated set of ultrasound training images;"

266. It is my opinion that Krishnan and/or Wu teach or suggests [12(b)]

"receiving signals representing quality assessment values, each of the quality assessment values associated with one of the sets of ultrasound training images and representing a quality assessment of the associated set of ultrasound training images" to a POSITA including reception signals representing quality assessment values. Ex1010, p.1338-39 (pdf pp.3-4).

267. The learning process in Krishnan involves "using training data … from the database (106) of previously diagnosed/labeled cases." Ex1005, [0023]. Krishnan further teaches that one or more of the trained classifiers is implemented to "determine[e] a quality measure within a predefined range of values to provide an indication as [to] the quality level of the acquired images." *Id.*, [0020], [0036] ("the medical images may include a quality score"). In my opinion, a POSITA would have a working knowledge of the training of machine learning algorithms, including neural networks, thus the process for training these classifiers. A POSITA would be familiar with the use of training neural network parameters with pre-labeled images —the standard method already known in the art. *See* Ex1017, 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."); In my opinion, a POSITA with this working knowledge would understand that if the desired output from the classifier module in Krishnan is a

quality assessment value (as taught by Krishnan), then the training input to the classifier would include images labeled with quality assessment values. A POSITA would understand that the particular logistic regression classifier described in the Patent for quality assessment would represent one such classifier that could be used to derive a quality assessment value. The POSITA would recognize that such a classifier could be trained by assigning a 0 and 1 label to each image and training the model to minimize a classification loss. The output of such a trained model could either be continuous score (such as a numeric value between 0 and 1 or scaled to be between 0 and 100) or, if a hard threshold is applied to the continuous score, a binary output (0 or 1).

268. Wu is consistent with the above-described knowledge of a POSITA and teaches the use of "training sample" ultrasound images to train neural network classifiers to provide quality assessment values. Ex1010, p.1341 (pdf p.6). Wu further explains that the training samples include thousands of images in each quality class (1-4) and that "annotation of all training data … was done by a graduate student…." *Id.* Thus, Wu's "training" disclosures support this function.

d) [12(c)]: "receiving signals representing image properties, each of the image properties associated with one of the sets of ultrasound training images; and"

269. It is my opinion that Krishnan teaches or suggests [12(c)], "receiving signals representing image properties, each of the image properties associated with

one of the sets of ultrasound training images" to a POSITA. But, to the extent Krishnan does not explicitly state that it receives signals representing image properties—each associated with a set of ultrasound training images, then, in my opinion, Chen discloses this feature.

270. The Patent states that "image properties" may be a "view category." Ex1001, 1:50, 17:1-2. Krishnan implements one or more trained classifiers to "automatically identify the view of an acquired image." *Id.*, [0019], [0023] ("The classifiers are implemented by the various decision support modules (102-105) for performing their respective functions."). Krishnan trains the one or more classifiers "using training data … from the database (106) of previously diagnosed/labeled cases." Ex1005, [0023]. A POSITA would have a working knowledge of neural network classifier training and therefore would know that to train a neural network classifier to determine the view, as described in Krishnan, the training input to the classifier would include images labeled by their view category. *E.g.*, Ex1017, p. 450. View classification represents a multi-label classification task, which was well described in the neural network literature, both for static images (Ex1029 ("Krizhevsky" describing ImageNet 2012 classification) and videos (Donahue; Ex1021).

271. Chen is consistent with the above-described knowledge of a POSITA and describes training its "ROI classifier under the framework of J-CNN" using

"training samples" 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, where the training images "were manually annotated by an experienced obstetrician." Ex1009, p. 512.

e) [12(d)]: "training a neural network, the training comprising, for each set of the plurality of sets of ultrasound training images, using the set of ultrasound training images as an input to the neural network and using the quality assessment values and the image properties associated with the set of ultrasound training images as desired outputs of the neural network."

272. Krishnan teaches or suggests [12(d)] to a POSITA, "training a neural network, the training comprising, for each set of the plurality of sets of ultrasound training images, using the set of ultrasound training images as an input to the neural network and using the quality assessment values and the image properties associated with the set of ultrasound training images as desired outputs of the neural network."

273. Krishnan trains one or more neural network classifiers to perform view identification and quality assessment "using training data … from the database (106) of previously diagnosed/labeled cases." Ex1005, [0023], [0044]. This "training data" is used in conjunction with "a learning engine (109)" that "includes methods for training/building one more classifiers using training data that is learned from database (106)." *Id.* A POSITA would have a working

knowledge on training neural networks and know, therefore, that the "training data" would include "previously diagnosed/labeled" images labeled with associated "quality assessment" or "image property" data, as discussed above with respect to [12(a)], [12(b)], and [12(c)]. *Supra* Section IX.D.1(b), (c), (d). A POSITA would likewise understand that training would entail using the training images as input to the neural network and adjusting the neural network parameters based on the training labels associated with the images being the "desired output of the neural network." Ex1018, [0037], [0040]-[0041] (describing the training of neural networks using training images as input and a back-propagation algorithm to minimize "the difference between the input and output values").

2. Claim 13: "The method of claim 12, wherein the image property is a view category."

274. Claim 13 depends from claim 12, which, as I explained in Section IX.D.1, is rendered obvious by Krishnan-Chen-Wu. It is my opinion that this combination further renders claim 13 obvious because the image property determined by Krishnan is a view category associated with a set of ultrasound images. Ex1005, [0023], *See also,* Sections IX.A.1, 7. Moreover, I find that Chen likewise determines the standard views of sets of ultrasound images. Ex1009, p. 512. I again opine that the specifics of training these neural networks could be accomplished by using well-known and standard techniques that would be obvious and routine to the POSITA.

275. Therefore, in my opinion, Krishnan in view of Chen and Wu teaches or suggests all elements of claim 13. And, since a POSITA would again have been motivated to and have had a reasonable expectation of success in combining Krishnan, Chen and Wu, the subject matter of claim 13 would have been obvious to a POSITA in light of this combination.

3. Claim 14: A Feature Extracting Neural Network, Image Property Specific Neural Network, and Quality Assessment Value Specific Neural Network.

276. Claim 14 depends from claim 13, which, as I explained in Section IX.D.2, is rendered obvious by Krishnan-Chen-Wu. It is my opinion that this combination further renders claim 14 obvious because the bank of classifiers disclosed in Krishnan contemplates use of neural networks for various functions including, but not limited to, feature extraction, image property extraction, and quality assessment value determination. Ex1005, [0043], *See* also, Sections IX.A.2, IX.C.2.

277. In my opinion, Krishnan-Chen-Wu renders claim 14 obvious because Krishnan discloses a "set of classifiers," specifically giving examples of neural networks implemented and trained to accomplish feature extraction, quality assessment, and view identification. A "feature analysis module (102) … automatically extract[s] one or more types of features/parameters from input medical image data and combin[es] the extracted features/parameters in a manner

that is suitable for processing by the decision support modules (103, 104 and/or 105)." Ex1005, [0016]. A view identification module 104 "use[s] the extracted features/parameters to automatically identify the view of acquired image." *Id*., [0019]. And finally, a quality assessment module 105 "use[s] the extracted features/parameters to assess a level of diagnostic quality of an acquired image data set." *Id*., [0020].

278. Krishnan further discloses that the various modules (102-105) utilize "one or more trained classification models," also referred to as a "bank of classifiers" or a "set of classifiers" (*id*., [0043]), which Krishnan explains can be "built using neural networks" (*id*., [0044]). "The classifiers are implemented by the various decision support modules (102-105) for performing their respective functions." *Id*., [0023] (emphasis added). For example, "[t]hese classifiers would use the set of features as an input, and classify the image as belonging to a particular anatomy, view, or level of quality." *Id*., [0043] (emphasis added). Thus, it is my opinion that a POSITA would understand Krishnan to teach a bank of classifiers with multiple, distinct neural networks designated and trained to accomplish various functions.

279. Accordingly, in my opinion, a POSITA would understand that Krishnan discloses the "feature extracting neural network," "image property specific neural network," and "quality assessment value specific neural network,"

as claimed. Additionally, A POSITA would further understand more broadly that Krishnan discloses a neural network image processing pipeline in which the image property neural network takes extracted feature representations as input and outputs an image property (view), as claimed, and that the quality assessment neural network takes the extracted features as input and outputs a quality assessment value, as claimed. In my opinion, Krishnan also teaches a POSITA that these classifiers are trained based on training data comprising previously labeled images to accomplish their respective functions (Ex1005, [0023]) such that the feature extracting neural network is configured to take training images as input and output extracted feature representations, as claimed.

280. Therefore, in my opinion, Krishnan in view of Chen and Wu teaches or suggests all elements of claim 14, rendering it obvious. And since a POSITA would again have been motivated to and have had a reasonable expectation of success in combining Krishnan, Chen and Wu, as I have explained above, in my opinion, the subject matter of claim 14 would have been obvious to a POSITA in light of this combination.

4. Claim 15: "The method of claim 14, wherein the feature extracting neural network is configured to, for each of the ultrasound training images included in the input set of ultrasound training images, derive a first feature representation associated with the ultrasound image."

281. Claim 15 depends from claim 14, which, as I explained in Section

IX.D.3, is rendered obvious Krishnan-Chen-Wu. It is my opinion that this combination further renders claim 15 obvious because Krishnan discloses feature extraction as claimed, *See also*, Sections IX.A.2.

282. As I previously explained in Section IX.A.1.b), above, the medical image dataset obtained by Krishnan can include one or more ultrasound images. And, as I also explained in Section IX.A.1.c), "the image dataset will be processed to … extract relevant feature data from the image dataset" where "[t]hese features could include any kind of characteristic" and "<u>can be obtained across images, such as motion of a particular point, or the change in a particular feature across images</u>." Ex1005, [0034] (emphasis added). Accordingly, it is my opinion that a POSITA would read from Krishnan a description of extracting features from a dataset for tracking said feature across different images in the set, thus it discloses deriving a first feature representation for each image within the dataset, as claimed.

283. Therefore, in my opinion, Krishnan in view of Chen and Wu teaches or suggests all elements of claim 15.

5. Claim 16: "The method of claim 15, wherein the feature extracting neural network includes, for each of the ultrasound images included in the input set of ultrasound training images, a commonly defined first feature extracting neural network configured to take as an input the ultrasound training image and to output a respective one of the first feature representations."

284. Claim 16 depends from claim 15. As I explained in Section IX.D.4,

claim 15 is rendered obvious by Krishnan-Chen-Wu. It is my opinion that this combination further renders claim 16 obvious to a POSITA because Krishnan and Chen disclose at least one commonly defined first feature extracting neural ingests an ultrasound training image in order to output a respective one of the first feature representations extraction as claimed.

285. As described above, a POSITA would recognize that Krishnan contemplates classification methods which may be implemented via neural networks, including a "feature extracting neural network." Ex1005, [0016], [0019], [0020], [0023], [0043]-[0044]. A POSITA would further understand that these neural networks as capable of analyzing "a set of ultrasound training images," as claimed, given the POSITA's innate knowledge of training (for which the use of labeled ultrasound images were remarkably common in the art). With reference to Figure 2 (below), Krishnan states: "Initially, a physician, clinician, radiologist, etc., will obtain a medical image <u>dataset comprising one or more medical images</u> of a region of interest of a subject patient (step 200)." Ex1005, [0033].

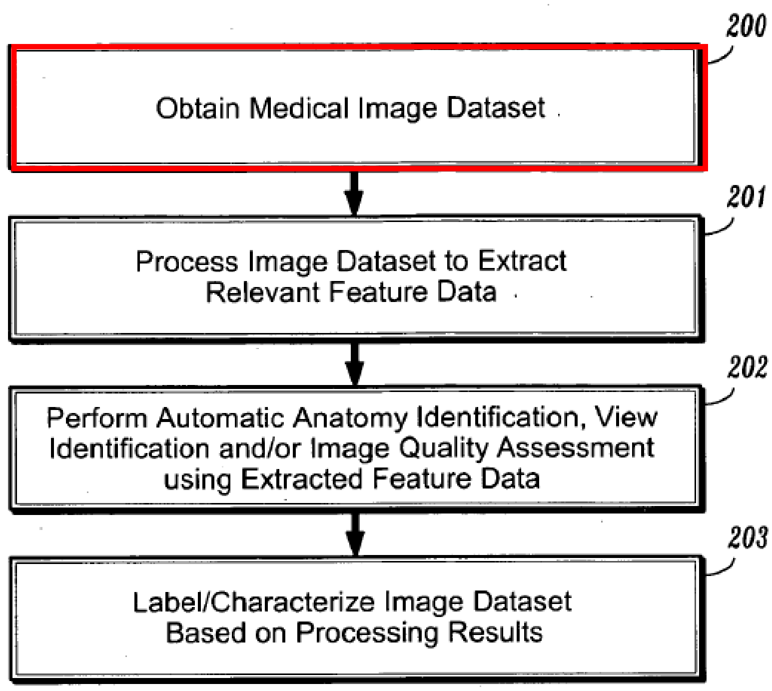


FIG. 2

286. "The image dataset may be obtained using a medical imaging system for real-time acquisition and processing" or "the image dataset may be obtained by accessing a previously acquired, and persistently stored image dataset." Ex1005, [0033]. Additionally, Krishnan states that "[t]he digital image data (10) may comprise one or more 2D slices," or "multiple views of a beating heart acquired with a 3D Ultrasound probe." *Id.*; *see also* [0032] (describing providing automatic quality checks for "loops of data" obtained by a sonographer "where each loop represents a heart cycle.") Thus, Krishnan discloses receiving "a set of ultrasound training," as claimed.

287. It is my opinion POSITA would find it obvious to adapt the teachings

of Chen regarding specific neural network architecture in Krishnan's proposed workflow. Again, Krishnan discloses that its classification methods may be implemented via trained neural networks, including a feature extracting neural network. Ex1005, [0016], [0019], [0020], [0023], [0043]-[0044]. Chen discloses a particular neural network structure that extracts spatial feature representations from a sequence of ultrasound images by inputting each consecutive frame of an ultrasound video into a respective J-CNN that is commonly defined by the same neural network parameters. Ex1009, p.509 ("Fig. 2 Left: architecture of the proposed T-RNN; right: <u>the</u> proposed J-CNN").

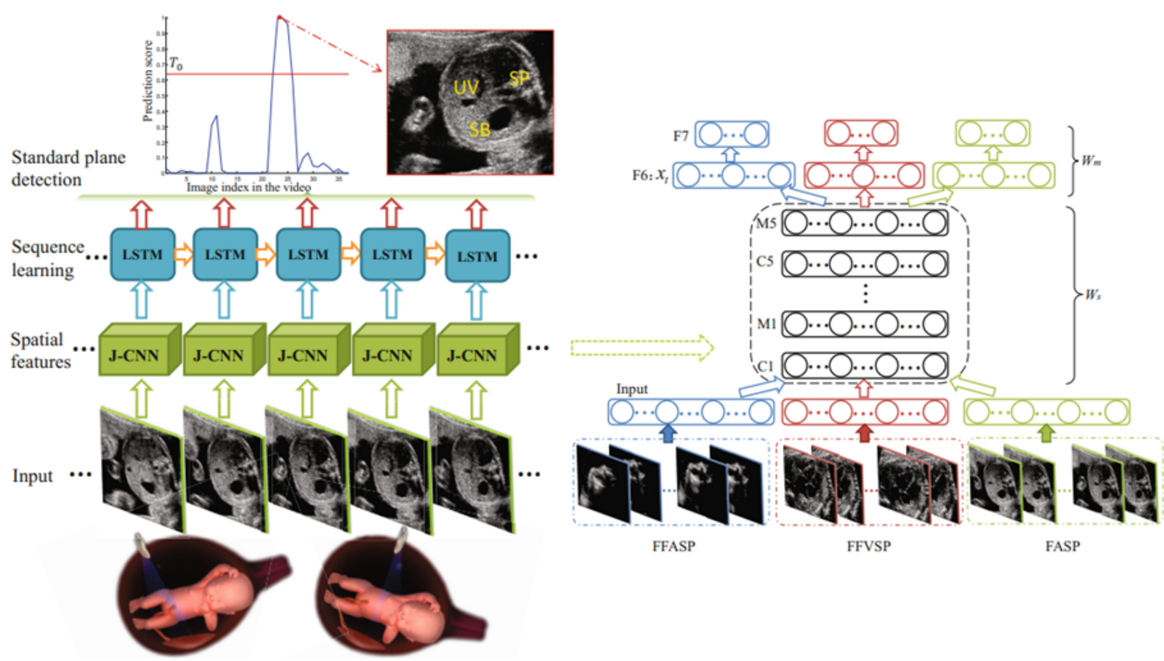


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

288. Chen also discloses a method for training the feature extracting

J-CNN using training images. Ex1009, p.509-510 ("a joint learning model for effective spatial feature learning across multi-tasks is presented") ("A ROI classifier is first trained based on the joint learning of convolutional neural networks (J-CNN) across multi-tasks to locate the most discriminative regions for US standard plane detection.") (describing the training to determine the parameters in W_s and W_m of the J-CNN depicted in Figure 2).

289. As already explained in Section IX.D.1, in my opinion, it would have been natural and obvious for a POSITA to use the neural network structure and training methods described in Chen to perform the same feature extracting function described in Krishnan.

290. Therefore, in my opinion, Krishnan in view of Chen and Wu teaches or suggests all elements of claim 16, rendering it unpatentable as obvious.

6. Claim 17: "The method of claim 16 wherein more than one implementation of the commonly defined first feature extracting neural networks are configured to concurrently generate the first feature representations."

291. Claim 17 depends from claim 16. As I explained in Section IX.D.5, claim 16 is rendered obvious Krishnan-Chen-Wu. It is my opinion that this combination further renders claim 17 obvious to a POSITA because, as I already explained in Section IX.D.3, Krishnan discloses neural networks including those used for feature extraction and Chen contemplates concurrent use of more than one neural network for feature extraction.

292. As discussed in previous sections, a POSITA would understand that Krishnan contemplates that its classification methods may be implemented via neural networks, including a "feature extracting neural network" capable of analyzing "a set of ultrasound training images." Ex1005, [0016], [0019], [0020], [0023], [0043]-[0044]. As also discussed above, in my opinion, it would have been obvious to a POSITA to implement Krishnan's feature extraction using the neural network structure and training methods disclosed in Chen. With reference to Figure 2, below, Chen "concurrently" extracts features from a set of ultrasound images by inputting each consecutive frame of an ultrasound video into a respective, common-defined J-CNN that extracts spatial features from the frame.

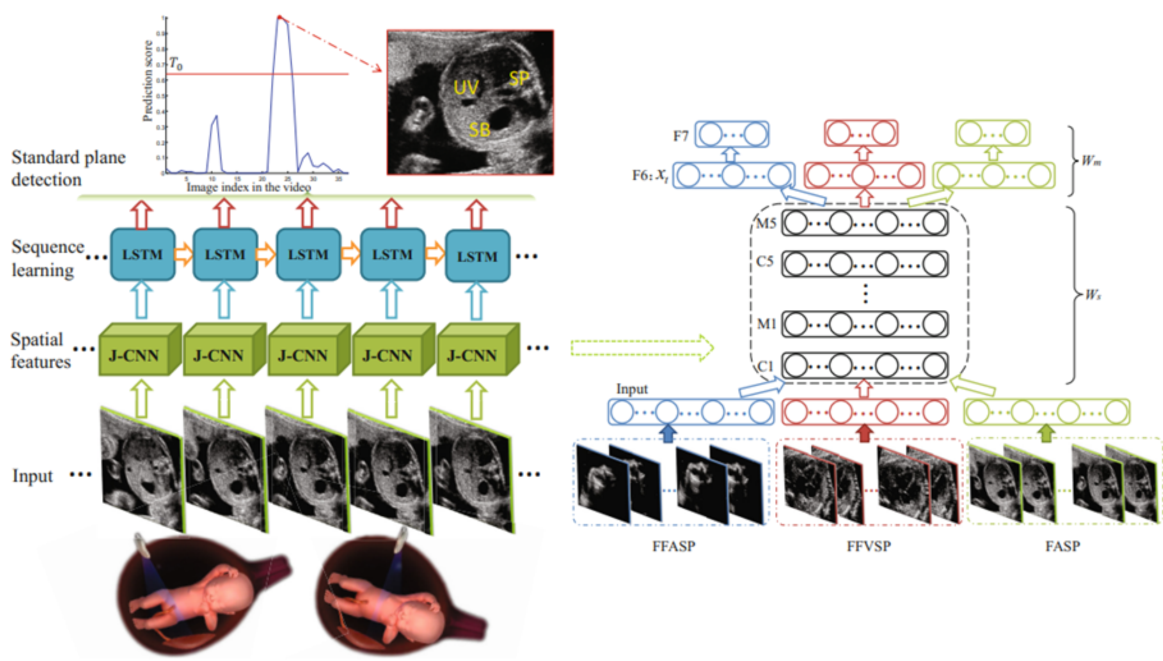


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

293. Further, every implementation of a J-CNN shown in Figure 2 of Chen is commonly defined, or put another way, has the same neural network architecture and parameters, just as in the claim. Ex1009, p.508-11.

294. Therefore, in my opinion, Krishnan in view of Chen and Wu teaches or suggests all elements of claim 17, rendering it obvious.

7. Claim 18: "The method of claim 16 wherein the commonly defined first feature extracting neural network is a convolutional neural network."

295. Claim 18 depends from claim 16. As I explained in Section IX.D.3, it is my opinion that claim 16 is rendered obvious by Krishnan-Chen-Wu. Chen discloses a "J-CNN" (Joint-Convolutional Neural Network) as a sub-network implemented in an overarching T-RNN network. Ex1009, p.509. Each J-CNN is commonly defined, as claimed. *Id.*

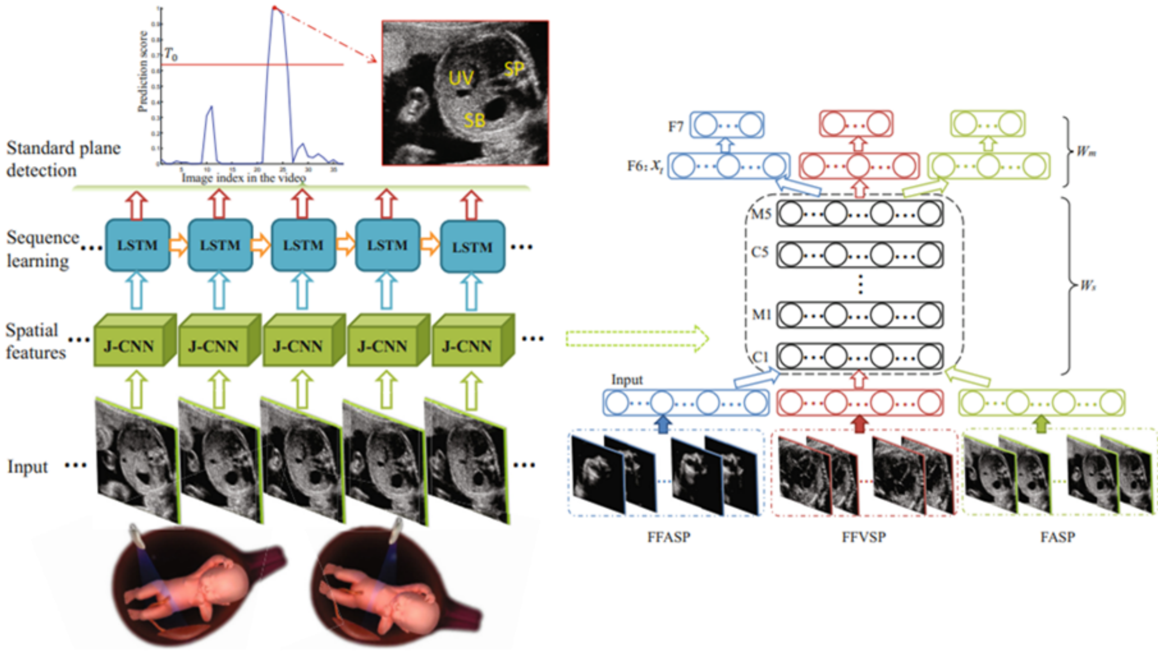


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

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

296. Therefore, in my opinion, Krishnan in view of Chen and Wu teaches or suggests all elements of claim 18.

8. Claim 19: Second Feature Extracting Neural Network

297. Claim 19 depends from claim 16, which, as I explained in Section IX.D.3, is rendered obvious by Krishnan-Chen-Wu. It is my opinion that a first and second feature extracting neural networks are disclosed in Chen, as I've described in previous sections (*See*, *e.g.*, sections IX.B.5).

298. In my opinion, Krishnan-Chen-Wu also discloses or teaches the functionality of Claim 19.

299. As discussed in previous sections, a POSITA would understand that

Krishnan contemplates that its classification methods may be implemented via neural networks, including a "feature extracting neural network" capable of analyzing "a set of ultrasound training images." Ex1005, [0016], [0019], [0020], [0023], [0043]-[0044]. As also discussed above, in my opinion, it would have been obvious to a POSITA to implement Krishnan's feature extraction using the neural network structure and training methods disclosed in Chen.

300. Claim 19 discloses functionality of a "second feature extracting neural network." Chen discloses "a second feature extracting neural network." With reference to Figure 2 (below), Chen derives one or more extracted feature representations from a set of ultrasound images, as claimed, by first extracting "spatial features" from each image using convolutional neural networks. Ex1009, p.511.

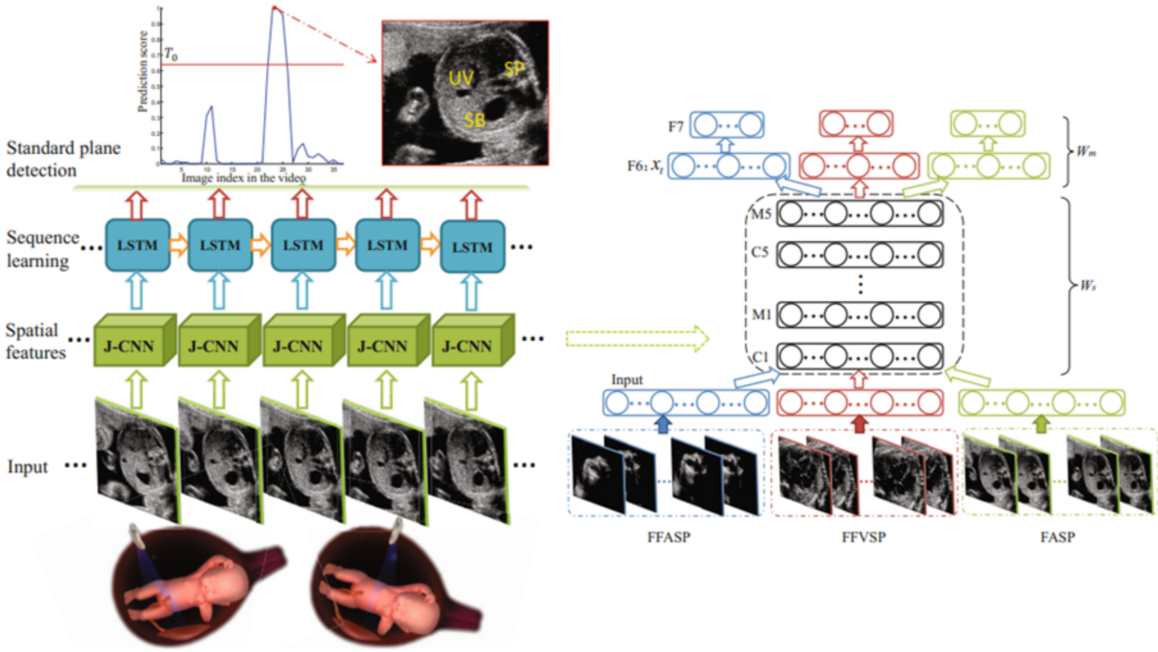


Fig. 2. Left: architecture of the proposed T-RNN; right: the proposed J-CNN.

301. Chen states: (1) "features …, which have been detected by the J-CNN model, are further explored by the LSTM" (Ex1009, p.511); and (2) "temporal information is explored via the LSTM model based on the features … in consecutive frames extracted from the J-CNN model" (*id.*, p.509). In my opinion, a POSITA would understand Figure 2's depiction as to how its LSTM operates to teach generation of respective second feature representations for each image, which are provided to an adjacent LSTM cell for "sequence learning." Thus, it is my opinion that Chen discloses, as claimed, inputting the first feature representations into a second feature extracting neural network to generate

respective second feature representations, each associated with one of the ultrasound images.

302. Therefore, in my opinion, Krishnan in view of Chen and Wu teaches or suggests all elements of claim 19.

9. Claim 20: "The method of claim 19 wherein the second feature extracting neural network is a recurrent neural network."

303. Claim 20 depends from claim 19. As I explained in Section IX.D.8, claim 19 is rendered obvious Krishnan-Chen-Wu. In my opinion, Krishnan-Chen-Wu also discloses or teaches the functionality of claim 20.

304. As I explained in Section IX.B.5 and IX.D.8, the LSTM models described and depicted in Chen correspond to the claimed "second feature extracting neural network" implemented using a T-RNN. Specifically, in my opinion, a POSITA would understand that these T-RNNs/LSTMs are a recursive solution for the necessary sequence and temporal learning in machine learning ultrasonic image analysis. Ex1009, p.509 ("recurrent neural networks (LSTM model)").

305. Therefore, Krishnan in view of Chen and Wu teaches or suggests all elements of claim 20.

*   *   *

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: 8/14/2025

/Rahul C. Deo/

Dr. Rahul C. Deo.

ATTACHMENT A

CLAIMS APPENDIX

Limitation	Claim Language
Claim 1	
[1(pre)]	1. A computer-implemented method of facilitating ultrasonic image analysis of a subject, the method comprising:
[1(a)]	receiving signals representing a set of ultrasound images of the subject;
[1(b)]	deriving one or more extracted feature representations from the set of ultrasound images;
[1(c)]	determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images;
[1(d)]	determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images; and
[1(e)]	producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images.
Claim 2	
[2]	The method of claim 1 wherein the image property is a view category.
Claim 3	
[3]	The method of claim 2 wherein deriving the one or more extracted feature representations from the ultrasound images comprises, for each of the ultrasound images, deriving a first feature representation associated with the ultrasound image.
Claim 4	
[4]	The method of claim 3 wherein deriving the one or more extracted feature representations comprises, for each of the ultrasound images, inputting the ultrasound image into a commonly defined first feature extracting neural subnetwork to generate the first feature representation associated with the ultrasound image.
Claim 5	
[5]	The method of claim 4 wherein deriving the one or more extracted feature representations comprises concurrently inputting each of a plurality of the ultrasound images into a respective implementation of the commonly defined first feature extracting neural network.

Claim 6	
[6]	The method of claim 4 wherein the commonly defined first feature extracting neural network includes a convolutional neural network.
Claim 7	
[7]	The method of claim 4 wherein deriving the one or more extracted feature representations comprises inputting the first feature representations into a second feature extracting neural network to generate respective second feature representations, each associated with one of the ultrasound images and wherein the one or more extracted feature representations include the second feature representations.
Claim 8	
[8]	The method of claim 7 wherein the second feature extracting neural network is a recurrent neural network.
Claim 9	
[9]	The method of claim 2 wherein determining the quality assessment value comprises inputting the one or more extracted feature representations into a quality assessment value specific neural network and wherein determining the image property comprises inputting the one or more extracted feature representations into an image property specific neural network.
Claim 10	
[10]	The method of claim 9 wherein inputting the one or more extracted feature representations into the quality assessment value specific neural network comprises inputting each of the one or more extracted feature representations into an implementation of a commonly defined quality assessment value specific neural subnetwork and wherein inputting the one or more extracted feature representations into the image property determining neural network comprises inputting each of the one or more extracted feature representations into an implementation of a commonly defined image property specific neural network.
Claim 11	
[11]	The method of claim 2 wherein producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images comprises producing signals for causing a representation of the quality assessment value and a representation of the image property to be displayed by at least one

	display in association with the set of ultrasound images.
Claim 12	
[12(pre)]	A computer-implemented method of training one or more neural networks to facilitate ultrasonic image analysis, the method comprising:
[12(a)]	receiving signals representing a plurality of sets of ultrasound training images;
[12(b)]	receiving signals representing quality assessment values, each of the quality assessment values associated with one of the sets of ultrasound training images and representing a quality assessment of the associated set of ultrasound training images;
[12(c)]	receiving signals representing image properties, each of the image properties associated with one of the sets of ultrasound training images; and
[12(d)]	training a neural network, the training comprising, for each set of the plurality of sets of ultrasound training images, using the set of ultrasound training images as an input to the neural network and using the quality assessment values and the image properties associated with the set of ultrasound training images as desired outputs of the neural network.
Claim 13	
[13]	The method of claim 12 wherein each of the image properties is a view category.
Claim 14	
[14(pre)]	The method of claim 13 wherein the neural network includes a feature extracting neural network, an image property specific neural network, and a quality assessment value specific neural network and wherein:
[14(a)]	the feature extracting neural network is configured to take an input set of the plurality of sets of ultrasound training images as an input and to output one or more extracted feature representations;
[14(b)]	the image property specific neural network is configured to take the one or more extracted feature representations as an input and to output a representation of an image property associated with the input set of ultrasound training images; and
[14(c)]	the quality assessment specific neural network is configured to take the one or more extracted feature representations as an input and to output a quality assessment value associated with the input set of ultrasound training images.

Claim 15	
[15]	The method of claim 14 wherein the feature extracting neural network is configured to, for each of the ultrasound training images included in the input set of ultrasound training images, derive a first feature representation associated with the ultrasound image.
Claim 16	
[16]	The method of claim 15 wherein the feature extracting neural network includes, for each of the ultrasound images included in the input set of ultrasound training images, a commonly defined first feature extracting neural network configured to take as an input the ultrasound training image and to output a respective one of the first feature representations.
Claim 17	
[17]	The method of claim 16 wherein more than one implementation of the commonly defined first feature extracting neural networks are configured to concurrently generate the first feature representations.
Claim 18	
[18]	The method of claim 16 wherein the commonly defined first feature extracting neural network is a convolutional neural network.
Claim 19	
[19]	The method of claim 16 wherein the feature extracting neural network includes a second feature extracting neural network configured to take as an input the first feature representations and to output respective second feature representations, each associated with one of the ultrasound images included in the input set of ultrasound training images and wherein the one or more extracted feature representations include the second feature representations.
Claim 20	
[20]	The method of claim 19 wherein the second feature extracting neural network is a recurrent neural network.
Claim 21	
[21(pre)]	A system for facilitating ultrasonic image analysis comprising at least one processor configured to:
[21(a)]	receive signals representing a set of ultrasound images of the subject;
[21(b)]	derive one or more extracted feature representations from the set of ultrasound images;
[21(c)]	determine, based on the derived one or more extracted feature representations, a quality assessment value representing a quality

	assessment of the set of ultrasound images;
[21(d)]	determine, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images; and
[21(e)]	produce signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images.
Claim 22	
[22]	The system of claim 21 wherein the image property is a view category.
Claim 23	
[23]	The system of claim 22 wherein the at least one processor is configured to, for each of the ultrasound images, input the ultrasound image into a commonly defined first feature extracting neural subnetwork to generate a first feature representation associated with the ultrasound image.
Claim 24	
[24]	The system of claim 23 wherein the at least one processor is configured to, for each of the ultrasound images, input the ultrasound image into a commonly defined first feature extracting neural subnetwork to generate the first feature representation associated with the ultrasound image.
Claim 25	
[25]	The system of claim 24 wherein the at least one processor is configured to concurrently input each of a plurality of the ultrasound images into a respective implementation of the commonly defined first feature extracting neural network.
Claim 26	
[26]	The system of claim 24 wherein the at least one processor is configured to input the first feature representations into a second feature extracting neural network to generate respective second feature representations, each associated with one of the ultrasound images and wherein the one or more extracted feature representations include the second feature representations.
Claim 27	
[27]	The system of claim 22 wherein the at least one processor is configured to input the one or more extracted feature representations into a quality assessment value specific neural network and to input the one or more extracted feature representations into an image

	property specific neural network.
Claim 28	
[28]	The system of claim 27 wherein the at least one processor is configured to input each of the one or more extracted feature representations into an implementation of a commonly defined quality assessment value specific neural subnetwork and to input each of the one or more extracted feature representations into an implementation of a commonly defined image property specific neural network.
Claim 29	
[29]	The system of claim 22 wherein the at least one processor is configured to produce signals for causing a representation of the quality assessment value and a representation of the image property to be displayed by at least one display in association with the set of ultrasound images.
Claim 30	
[30(pre)]	A system for facilitating ultrasonic image analysis, the system comprising:
[30(a)]	means for receiving signals representing a set of ultrasound images of the subject;
[30(b)]	means for deriving one or more extracted feature representations from the set of ultrasound images;
[30(c)]	means for determining, based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images;
[30(d)]	means for determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images; and
[30(e)]	means for producing signals representing the quality assessment value and the image property for causing the quality assessment value and the image property to be associated with the set of ultrasound images.