UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CAPTION HEALTH, INC.,
Petitioner,

v.

UNIVERSITY OF BRITISH COLUMBIA,
Patent Owner.

IPR2025-01422

Patent No. 10,751,029

DECLARATION OF MILAN SONKA

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

Date: 5/8/2026 By: Milan Sonka

Milan Sonka, Ph.D.

TABLE OF CONTENTS

LISTING OF THE CHALLENGED CLAIMS

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.

I, Milan Sonka, hereby declare as follows:

I. INTRODUCTION

1. I have been retained by counsel for Patent Owner University of British Columbia, ("Patent Owner" or "UBC") as an independent expert consultant in this proceeding in connection with inter partes review (IPR) proceeding IPR2025-01422 concerning U.S. Patent 10,751,029 ("'029 patent") (EX1001), pending before the U.S. Patent and Trademark Office, Patent Trial and Appeal Board ("Board").

2. I understand that the '029 patent has been assigned to University of British Columbia.

3. I have been asked to opine on whether the Challenged Claims of the '029 Patent are anticipated or rendered obvious by the prior art. Along with my years of education, research, and experience, my opinions are based on investigation and study of relevant materials. The materials that I evaluated in support of this Declaration include all exhibits cited in this Declaration and in the Petition.

4. I may rely upon these materials, my knowledge and experience, and/or additional materials to rebut arguments raised by the Petitioner. Further, I may also consider additional documents and information in forming any necessary opinions, including documents that may not yet have been provided to me.

5. My analysis of the materials in this proceeding is ongoing, and I will continue to review any new material as it is provided. This Declaration represents

only those opinions I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions herein based on new information and my continuing analysis of the materials already provided.

6. I am being compensated for consulting services including time spent testifying at any hearing that may be held. I am also reimbursed for reasonable and customary expenses associated with my work in this case. I receive no other forms of compensation related to this case. My compensation does not depend on the outcome of this post-grant review or the co-pending district court litigation, and I have no other financial interest in this post-grant review.

II. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE

7. I have summarized in this section my educational background, career history, publications, and other relevant qualifications.

8. In general, I have a broad knowledge of image processing, medical image analysis, ultrasound image analysis, a solid grounding in the specific technologies employed by imaging systems, and a historical perspective based on active personal participation in the medical image processing industry. I can develop application-relevant image analysis methods, approaches, and systems in 2D, 3D, 4D, and generally n-D images.

A. Education

9. I earned a Ph.D. degree in Technical Cybernetics, with a specialty in

Digital Image Analysis, from Czech Technical University of Prague, Czechoslovakia in 1983 and a Master of Science in Electrical Engineering with a specialty in Technical Cybernetics from the same University in 1979.

B. Relevant Work Experience

10. I am a Professor of Electrical & Computer Engineering, a Professor of Ophthalmology & Visual Sciences, and a Professor of Radiation Oncology – all at the University of Iowa. I am an IEEE Fellow, an AIMBE Fellow, a MICCAI Fellow, Fellow of the National Academy of Inventors, and Fulbright Specialist.

11. I have been a faculty member at the University of Iowa since 1990. I was the Founding Co-Director of the Iowa Institute for Biomedical Imaging and I have maintained that position since 2007. I have been serving as the Institute's Director from 2010 to 2016. I currently serve as co-director of this institute.

12. I have been Director of the Iowa Initiative for Artificial Intelligence since 2019. I continue serving in that role.

C. Publications

13. My research interests include medical imaging and knowledge-based image analysis with emphasis on cardiovascular, pulmonary, orthopedic, dermatology, cancer, and ophthalmic image analysis.

14. I am the first author of four editions of "Image Processing, Analysis and Machine Vision" book (1993, 1998, 2008, and 2014). I am co-editor of "Medical

Image Analysis" book (2024). I co-authored or co-edited 21 books/proceedings. I have published more than 245 journal papers and over 510 other publications.

15. I am past Editor-in-Chief of the IEEE Transactions on Medical Imaging, past member of the Editorial Board of the Medical Image Analysis journal, and past member of the Editorial Board of the International Journal of Cardiovascular Imaging.

16. I am a co-inventor on 20 patents, most of which relate to medical image processing and analysis.

17. I have received more than $40 million in research funds as principal investigator, most from the National Institutes of Health to support my research on medical image analysis. My scholarship and leadership in machine learning and medical image analysis are well established.

18. To bring results of this research work to clinical practice, I have co-founded two medical imaging companies—Medical Imaging Applications LLC, and VIDA Diagnostics Inc.

D. Experience with Ultrasound Image Analysis in Healthcare

19. Most relevant to this case, I have extended and deep experience with research and clinical use of ultrasound medical imaging devices in cardiovascular applications. Ultrasound image analysis was one of my long-lasting research focus areas and my first ultrasound image analysis journal paper was published in 1995.

In 1999, I co-founded a medical image analysis company "Medical Imaging Applications, LLC" that focuses on cardiovascular ultrasound image analysis. The company exists to date, holds an almost complete market share in tools for brachial and carotid image analysis research, and offers FDA cleared products for cardiovascular clinical care research, and clinical trials.

E. Curriculum Vitae

20. A copy of my curriculum vitae is attached as Ex2050 to this declaration.

III. MATERIALS CONSIDERED

21. My opinions included in this declaration are based on my education and experience as an engineer, as well as the documents and materials identified in this declaration, including the '029 patent, its prosecution history, the prior art references and background materials discussed in this declaration, and the other references specifically identified in this declaration. I have considered these materials in their entirety, even if only portions are discussed here.

22. In forming my opinion expressed in this declaration, I reviewed the following materials:

Paper/Exhibit No.	Description
1	Petition (Aug. 15, 2025)
6	Petitioner's Sotera Stipulation
9	Patent Owner's Brief for Discretionary Denial (Oct. 20, 2025)

Paper/Exhibit No.	Description
10	Patent Owner’s Preliminary Response (Nov. 20, 2025)
11	Petitioner’s Opposition to Patent Owner’s Request for Discretionary Denial (Nov. 20, 2025)
12	Petitioner’s Supplemental Opposition to Patent Owner’s Request for Discretionary Denial (Nov. 28, 2025)
13	Patent Owner’s Supplemental Brief for Discretionary Denial (Dec. 5, 2025)
14	Director Discretionary Decision: Refer (Dec. 18, 2025)
15	Director Discretionary Decision: Refer (Dec. 18, 2025)
17	Institution Decision: Grant (Feb. 3, 2025)
1001	U.S. Patent No. 10,751,029 (“the Patent”)
1002	Declaration of Dr. Rahul Deo
1003	Dr. Deo Curriculum Vitae
1004	Prosecution History File of the Patent (Application No. 16/557,261)
1005	U.S. Patent Application Publication No. 2005/0251013 (“Krishnan”)
1006	U.S. Patent Application Publication No. 2019/0076127 (“Aase”)
1007	U.S. Patent No. 10,013,640 (“Angelova”)
1008	International Patent Application Publication No. WO2016/189313 (“Paterson”)
1009	Chen, “Automatic Fetal Ultrasound Standard Plane Detection Using Knowledge Transferred Recurrent Neural Networks,” Medical Image Computing and Computer-Assisted Intervention – MICCAI 2015: 507-514 (November 18, 2015), https://doi.org/10.1007/978-3-319-24553-9_62 (“Chen”)

Paper/Exhibit No.	Description
1010	Wu, "FUIQA: Fetal Ultrasound Image Quality Assessment With Deep Convolutional Networks," IEEE Transactions on Cybernetics, 47(5):1336-1349 (May 2017), doi: 10.1109/TCYB.2017.2671898 ("Wu")
1011	First Amended Complaint, *University of British Columbia v. Caption Health, Inc.*, Case No. 5:24-cv-03200-EKL, Dkt. 46, Dec. 20, 2024.
1012	Itchhaporia, "Artificial Neural Networks: Current Status in Cardiovascular Medicine," JACC 28(2): 515-521 (August 1996) ("Itchhaporia")
1013	Chen, "Iterative Multi-domain Regularized Deep Learning for Anatomical Structure Detection and Segmentation from Ultrasound Images," Medical Image Computing and Computer-Assisted Intervention–MICCAI 2016: 487-495 (October 2, 2016)
1014	Kong, "Recognizing End-Diastole and End-Systole Frames via Deep Temporal Regression Network," Medical Image Computing and Computer-Assisted Intervention—MICCAI 2016: 264-272 (2016), DOI:10.1007/978-3-319-46726-9_31
1015	Joint Claim Construction and Prehearing Statement, University of *British Columbia v. Caption Health, Inc.*, Case No. 5:24-cv-03200-EKL, Dkt. 68, May 30, 2025.
1016	Chen, "Standard plane localization in fetal ultrasound via domain transferred deep neural networks," IEEE Journal of Biomedical and Health Informatics, 19(5): 1627-1636 (September 2015), DOI:10.1109/JBHI.2015.2425041 ("Chen I")
1017	Miller et al., "Review of neural network applications in medical imaging and signal processing," Medical &

Paper/Exhibit No.	Description
	Biological Engineering & Computing (30):449-464 (September 1992) ("Miller")
1018	U.S. Patent Application Publication No. 2017/0262982 ("Pagoulatos")
1019	Reserved
1020	González et al., "Echocardiogram Image Recognition Using Neural Networks in Recent Advances on Hybrid Approaches for Designing Intelligent Systems," Studies in Computational Intelligence 547:427-435 (March 2014) ("González")
1021	Donahue et al., "Long-term Recurrent Convolutional Networks for Visual Recognition and Description," arXiv:1411.4389v1 [cs.CV] (November 2014) ("Donahue")
1022	Caruana, "Multitask Learning: A Knowledge-Based Source of Inductive Bias," Proceedings of the 10th International Conference on Machine Learning, ML-93, University of Massachusetts, Amherst, 1993, pp. 41-48.
1023	U.S. Patent No. 5,906,578 ("Rajan")
1024	U.S. Patent Application Publication No. 2009/0074280 ("Lu")
1025	U.S. Patent Application Publication No. 2007/0055153 ("Simopoulos")
1026	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
1027	LeCun et al., "Handwritten Digit Recognition with a Back-Propagation Network," Neural Computation. 1 (4): 541–551. doi:10.1162/neco.1989.1.4.541. ISSN 0899-7667. S2CID 41312633 ("LeCun")

Paper/Exhibit No.	Description
1028	A. Bouzerdoum, et al., "Image quality assessment using a neural network approach," Proceedings of the Fourth IEEE International Symposium on Signal Processing and Information Technology, 2004., Rome, Italy, 2004, pp. 330-333, doi: 10.1109/ISSPIT.2004.1433751 ("Bouzerdoum")
1029	A. Krizhevsky, et al., "ImageNet classification with deep convolutional neural networks," Communications of the ACM, Volume 60, Issue 6, pp. 84-90 doi: 10.1145/3065386 (June 2017) ("Krizhevsky")
1032	Complaint, University of British Columbia v. Caption Health, Inc., GE Healthcare Technologies Inc. Case No. 3:24-cv-3200-PBS, Dkt. 1, May 28, 2024
1033	Order Granting Plaintiff's Motion for Leave to Amend Infringement Contentions, Dkt. 74, July 2, 2025
1034	Case Management & Scheduling Order, ECF No. 39, Oct. 11, 2024
1035	Scheduling Order, ECF No. 82, Aug. 13, 2025
1036	Order Denying Motion to Stay, *University of British Columbia v. Caption Health, Inc.*, Case No. 5:24-cv-03200-EKL, Dkt. 80, Aug. 6, 2025
1037	Caption Health, Inc. v. University of British Columbia, IPR2025-01066, Paper 13 (October 10, 2025)
1038	UBC's First Supplemental Objections and Response to Defendant's First Set of Interrogatories (Nos. 1-3), March 7, 2025
1039	Ex. C to Joint Amended and Supplemented Claim Construction and Prehearing Statement, Univ. of British Columbia v. Caption Health, Inc., No. 24-cv-03200 (N.D. Cal. Oct. 10, 2025), ECF No. 87-3

Paper/Exhibit No.	Description
1042	Lorentzon, M. "Feature Extraction for Image Selection Using Machine Learning," Department of Electrical Engineering, Linköping University, 2017, pp.1-45
1043	Kumar, G. et al. "A Detailed Review of Feature Extraction in Image Processing Systems" 2014 Fourth International Conference on Advanced Computing and Communication Technologies, pp.5-12.
2001	Complaint for Patent Infringement, *Univ. of British Columbia v. Caption Health, Inc.*, No. 5:24-cv-03200-EKL (N.D. Cal. May 28, 2024), ECF No. 1
2002	Decision Referring the Petition to the Board, *Caption Health, Inc. v. Univ. of British Columbia*, IPR2025-01066, Paper 13 (Oct. 10, 2025)
2003	GE HealthCare Techs. Inc. Corporate Structure Tree (July 24, 2025)
2004	GE HealthCare Techs. Inc. Corporate Family Report (July 24, 2025)
2005	Non-Final Rejection, App. No. 16/146770 (June 2, 2020)
2006	Non-Final Rejection, App. No. 17/558271 (June 4, 2024)
2007	Ex. C to Joint Amended and Supplemented Claim Construction and Prehearing Statement, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. Oct. 10, 2025), ECF No. 87-3
2008	Defendants' Notice of Motion and Motion to Stay Case Pending *Inter Partes* Review, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. June 27, 2025), ECF No. 72
2009	Order Denying Motion to Stay and Granting Motion to Seal, Univ. of British Columbia v. Caption Health, Inc. No. 24-cv-

Paper/Exhibit No.	Description
	03200, (N.D. Cal. Aug. 6, 2025)
2010	Order Setting Initial Case Management Conference & ADR Deadlines, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. May 31, 2024), ECF No. 9
2011	Defendants' First Amended Invalidity Contentions, *Univ. of British Columbia v. Caption Health, Inc.*, No. 3:24-cv-03200 (N.D. Cal. Aug. 22, 2025)
2012	Decl. of Dorianne Salmon in Support of UBC's Opp. to Defendants' Motion to Stay Pending *Inter Partes* Review, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. July 11, 2025), ECF No. 77-1
2013	Appendix A to Defendants' First Amended Invalidity Contentions, dated August 22, 2025
2014	Exhibit E to Infringement Contentions
2015	UBC's Objections and Responses to Defendants' Second Set of Requests for Production of Documents and Things (Nos. 64-113), *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. Apr. 21, 2025)
2016	Defendant GE Healthcare's Responses to UBC's Third Set of Requests for Production to Defendant GE Healthcare (Nos. 55-86), *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. May 27, 2025)
2017	Defendant Caption Health's Responses to UBC's Third Set of Requests for Production to Defendant Caption Health (Nos. 30-54), *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. May 27, 2025)
2018	Joint Statement regarding Discovery Dispute Over Plaintiff's Amended Infringement Contentions, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D.

Paper/Exhibit No.	Description
	Cal. Mar. 19, 2025), ECF No. 58
2019	Administrative Motion Regarding Case Schedule and Motion to Stay, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. July 3, 2025), ECF No. 75
2020	Plaintiff UBC's Motion for Leave to Amend Infringement Contentions regarding US Patent Nos. 11,129,591 and 10,751,029, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. May 9, 2025), ECF No. 65
2021	Order Granting Plaintiff's Motion for Leave to Amend Infringement Contentions, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. July 2, 2025), ECF No. 74
2022	Civil Minutes, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. Aug. 6, 2025), ECF No. 81
2023	UBC's list of claim terms, dated April 11, 2025
2024	Defendants' Amended and Supplemented Proposed Claim Terms from U.S. Patent No. 11,129,591 for Construction Pursuant to L.R. 4-1, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. Apr. 11, 2025)
2025	Joint Claim Construction and Prehearing Statement Pursuant to Pat. L.R. 4-3, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. May 30, 2025), ECF No. 68
2026	Scheduling Order, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. Aug. 13, 2025), ECF No. 82
2027	UBC's Additional Proposed Terms for Construction, dated Sept. 5, 2025

Paper/Exhibit No.	Description
2028	Defendants' Additional Proposed Terms for Construction, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. Sept. 5, 2025)
2029	UBC's Supplemental Preliminary Claim Constructions, dated Sept. 19, 2025
2030	Defendants' Supplemental Preliminary Claim Constructions Pursuant to L.R. 4-2, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. Sept. 19, 2025)
2031	Amended Supplemental Joint Claim Construction and Prehearing Statement Pursuant to Patent Local Rule 4-3, *Univ. of British Columbia v. Caption Health, Inc.*, No. 24-cv-03200 (N.D. Cal. Oct. 10, 2025), ECF No. 87
2032	U.S. Pub. No. US2019/0266716 ("Rothberg")
2033	U.S. Pub. No. US2009/0088640 ("Park")
2034	'029 Patent Grants Spreadsheet
2035	Krizhevsky, Sutskever, and Hinton, ImageNet classification with deep convolutional neural networks ("AlexNet") (2012)
2036	Zhang, Lipton, Li, and Smola, Dive into Deep Learning, Chapter 8.1 Deep Convolution Neural Networks (AlexNet), https://d2l.ai/chapter_convolutional-modern/alexnet.html
2037	Ghada Zamzmi, et al., *Harnessing Machine Intelligence in Automatic Echocardiogram Analysis: Current Status, Limitations, and Future Directions* (Apr. 27, 2021)
2038	Geoffrey Hinton, The Nobel Prize, https://www.nobelprize.org/prizes/physics/2024/hinton/facts/
2039	Press release, The Nobel Prize (Oct. 8, 2024), https://www.nobelprize.org/prizes/physics/2024/press-

Paper/Exhibit No.	Description
	release/
2040	U.S. Patent No. 10,878,311
2041	App. No. 16/146,770 Non-Final Rejection dated June 2, 2020
2042	U.S. Patent No. 12,369,883
2043	App. No. 18/431,566 Non-Final Rejection dated May 10, 2024
2044	Japanese Patent No. 7,284,298
2045	Japanese Patent App. No. 2021 to 572915 Notice of Reasons for Refusal dated Nov. 24, 2022 (English translation)
2036	November 25, 2025 Email from Tina Williams
2047	Plaintiff UBC's Opening Claim Construction Brief, Redacted Version (Dkt. 92)
2048	Defendants' Claim Construction Brief (Dkt. 94)
2050	Curriculum vitae of Dr. Milan Sonka
2051	Deposition Transcript of Dr. Rahul Deo (Session I) (April 17, 2026)
2052	Deposition Transcript of Dr. Rahul Deo (Session II) (April 17, 2026)
2053	*Caption Health v. Univ. of British Columbia*, IPR2025-01066, Paper 15 (Institution Decision) (Dec. 19, 2025)
2054	Zhang L, Wahle A, Chen Z, Lopez JJ, Kovarnik T, Sonka, *Predicting Locations of High-Risk Plaques in Coronary Arteries in Patients Receiving Statin Therapy*, M.IEEE Trans Med Imaging (Jan. 2018)

Paper/Exhibit No.	Description
2055	Zhang H, Abiose AK, Gupta D, Campbell DN, Martins JB, Sonka M, Wahle A., *Novel indices for left-ventricular dyssynchrony characterization based on highly automated segmentation from real-time 3-d echocardiography*, Ultrasound Med Biol. (Jan. 2013)
2056	Sonka M, Downe RW, Garvin JW, Lopez J, Kovarnik T, Wahle A., *IVUS-based assessment of 3D morphology and virtual histology: prediction of atherosclerotic plaque status and changes*, Annu Int Conf IEEE Eng Med Biol Soc. (Sept. 2011)
2057	Wahle A, Lopez JJ, Olszewski ME, Vigmostad SC, Chandran KB, Rossen JD, Sonka M., *Plaque development, vessel curvature, and wall shear stress in coronary arteries assessed by X-ray angiography and intravascular ultrasound*, Med Image Anal. (Aug. 2006)
2058	Bosch JG, Nijland F, Mitchell SC, Lelieveldt BP, Kamp O, Reiber JH, Sonka M., *Computer-aided diagnosis via model-based shape analysis: automated classification of wall motion abnormalities in echocardiograms*, Acad Radiol. (Mar. 2005)
2059	Zhang X, McKay CR, Sonka M., *Tissue characterization in intravascular ultrasound images*, IEEE Trans Med Imaging (Dec. 1998)
2060	S. Gummadi. J. Eisenbrey, J. Li, Z. Li, F. Forsberg, A. Lyshchik, J. Liu, *Advances in Modern Clinical Ultrasound* (Aug. 2018)
2061	*ImageNet Large Scale Visual Recognition Competition 2012 (ILSVRC2012)*, https://image-net.org/challenges/LSVRC/2012/results.html.
2062	Frangi, A., Prince, J., Sonka, M., *Medical Image Analysis*,

Paper/Exhibit No.	Description
	Elsevier, London UK (2024).
2063	Ronneberger, O., Fischer, P., Brox, T., *U-Net: Convolutional networks for biomedical image segmentation*, Medical Image Computing and Computer-Assisted Intervention–MICCAI 2015, pp. 234–241. Springer (2015).
2064	F. Milletari, N. Navab, A. Ahmadi, *V-Net: Fully Convolutional Neural Networks for Volumetric Medical Image* Segmentation, arXiv:1606.04797 (June 15, 2016)
2065	Ö. Çiçek, A. Abdulkadir, S. Lienkamp, T. Brox, O. Ronneberger, *3D U-Net: Learning Dense Volumetric Segmentation from Sparse Annotation*, arXiv:1606.06650 (June 21, 2016)
2066	F. Isensee, et. al., *nnU-Net: Self-adapting Framework for U-Net-Based Medical Image Segmentation*, arXiv:1809.10486 (Sept. 72, 2018)
2067	F. Isensee, et. al., *nnU-Net Revisited: A Call for Rigorous Validation in 3D Medical Image Segmentation*, arXiv:2404.09556 (July 25, 2024)

23. I have also relied on my own experience and expertise in medical imaging, medical image processing, medical image analysis, computer vision, ultrasound imaging, and clinical use of medical imaging devices.

IV. SUMMARY OF OPINIONS

24. For the reasons discussed below, the challenged claims of the ’029 patent are not anticipated or rendered obvious by any combination of prior art asserted in the Petition.

V. LEVEL OF ORDINARY SKILL

25. I understand that in analyzing questions of invalidity and infringement, the perspective of a person having ordinary skill in the art is often implicated, and the Court may need assistance in determining that level of skill. I understand that the claims and written description of a patent must be understood from the perspective of a person having ordinary skill in the art.

26. In rendering the opinions set forth in this Declaration, I was asked to consider the claims of the '029 patent and the prior art cited in the Petition through the eyes of a person having ordinary skill in the art at the time of the alleged invention, which I understand to be August 31, 2018. I understand that the factors considered in determining the ordinary level of skill in a field of art (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) the prior-art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the educational level of active workers in the field. I understand that a person having ordinary skill in the art is not a specific, real individual, but rather is a hypothetical individual having the qualities reflecting the factors above. I understand that a person having ordinary skill in the art would also have knowledge from the teachings of the prior art, including the art cited below.

27. I understand that Petitioner proposed that as of August 31, 2018, a

person having ordinary skill in the art "would include a person with 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." Petition, 9.

28. I understand that Petitioner proposed the same definition of a person having ordinary skill in the art in the Petition for *inter partes* review of U.S. Patent No. 11,129,591, and that the Board adopted Petitioner's definition in its decision denying institution. *See* Ex2053, Decision Denying Institution, 10-11.

29. For purposes of this *inter* partes review, I have been instructed to apply Petitioner's definition of a person having ordinary skill in the art.

30. Before August 31, 2018, my level of skill in the art was at least that of a person having ordinary skill under the definition proposed by Petitioner. I am qualified to provide opinions concerning what a person having ordinary skill would have known and understood at that time, and my analysis and conclusions herein are from the perspective of a person having ordinary skill in the art as of that date. I have advanced degrees in electrical engineering and Technical Cybernetics – Digital Image Analysis (that is, fields related to computer imaging). As described above and as shown in my CV (Ex2050), I have extensive expertise in the fields of medical imaging, medical image processing, medical image analysis, computer vision, ultrasound imaging, ultrasound image analysis, machine learning, and their

healthcare-related applications in the relevant timeframe. As of August 31, 2018, I had several years of research experience training machine learning models to analyze ultrasound data. *See e.g.*, Ex2050; Ex2054; Ex2055; EX2056; Ex2057; Ex2058; EX2059.

VI. LEGAL STANDARDS

31. I am not an attorney and thus offer no legal opinions. Counsel has notified me of the legal principles for purposes of my analyses and opinions, including those that apply in assessing whether patent claims are obvious and unpatentable. Throughout my work, I have studied and analyzed patents and patent claims from the perspective of a person skilled in the art. I have been asked to apply the following legal principles to my analysis, and I have done so. My understanding of the law is as follows:

32. I have been informed that in *inter partes* review proceedings, the Petitioner bears the burden of proof to prove that the claims that were challenged in the Petition and for which the Board instituted review are unpatentable. It is my understanding that the Petitioner also bears the burden of proving a proposition of unpatentability by a preponderance of the evidence.

33. It is my understanding that based on its filing date, the America Invents Act ("AIA") applies to determination of invalidity of the '029 patent.

A. Priority Date of the Claims

34. I have been informed that a U.S. patent application may claim the benefit of the filing date of an earlier patent application if the earlier patent application disclosed each limitation of the invention claimed in the later-filed U.S. patent application. I have also been informed that priority is determined on a claim-by-claim basis so that certain claims of a patent may be entitled to the priority date of an earlier-filed patent application even if other claims of the same patent are not entitled to that priority date.

35. I have also been informed that a patented claim is invalid if the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention, or the claimed invention was described in an issued patent or a published patent application that was effectively filed before the effective filing date of the claimed invention.

B. Claim Construction Standard

36. I understand that claim terms generally are construed in accordance with the ordinary and customary meaning they would have to a person having ordinary skill in the art at the time of the invention in light of the claim language, the specification, and the prosecution history. I understand that dictionaries and other extrinsic evidence may be considered as well, though such evidence is typically

regarded as less significant than the intrinsic record in determining the meaning of the claim language.

37. In making this Declaration, I have been asked to review the terms in the ’029 patent claims to determine what a person having ordinary skill in the art would have understood those terms to have meant at the time of the alleged invention. In addition, I have been informed that, in an *inter partes* review proceeding, the claim terms under consideration are to be construed using the same claim construction standard used in a civil action under 35 U.S.C. § 282(b), which is articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), and its progeny. I further understand that under the *Phillips* standard, the claim terms are given their ordinary and customary meaning, as would be understood by a person having ordinary skill in the art at the time of the invention, consistent with the specification and the prosecution history. I understand, nevertheless, that a claim’s words may be given a meaning different than their plain and ordinary meaning if: (1) a patentee explicitly and unambiguously defined a term in a different manner as compared to its plain meaning; or (2) a patentee “disclaims” the full scope of a claim term’s plain meaning, such as, by clearly and unambiguously stating during prosecution that a claim term does or does not encompass certain subject matter that may otherwise be encompassed by the plain words of the claim. My opinions regarding the meaning of claim terms of the ’029 patent are based on the construction of the claim terms

using the *Phillips* standard in view of the specification and the prosecution history of the ’029 patent.

C. Anticipation

38. I understand that to be valid, a patent claim must be novel, and that a claim is invalid under § 102 if it is anticipated by a single prior art reference. I further understand that a reference anticipates if it discloses each and every element of the claim and enables a person having ordinary skill in the art to make and use the claimed invention without undue experimentation.

D. Obviousness

39. Patent Owner’s counsel has informed me that a claim may be unpatentable as obvious under § 103 if the subject matter described in the claim as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

40. I have been informed that, prior to considering the prior art, the claims are first analyzed to determine what subject matter the claims cover.

41. I understand that the claims are read from a person having ordinary skill in the art’s perspective at the time of the alleged invention.

42. I have been informed that, after construing the claims, the teachings of the prior art are evaluated. I understand that the information that is used to evaluate

whether an invention is new and not obvious is generally referred to as "prior art" and generally includes patents and printed publications (e.g., books, journal publications, articles on websites, product manuals, etc.).

43. I understand that although the ultimate question of the obviousness analysis is a legal determination, obviousness is based on many factual inquiries, including: the prior art's scope and content, the distinctions between the claimed subject matter and the prior art, the level of ordinary skill in the art at the time of the invention, and any "objective indicia" or "secondary considerations" of non-obviousness, which must all be considered.

44. I have been informed that, in ascertaining the scope and content of the prior art, a prior-art reference is deemed relevant if it falls within the field of the inventor's endeavor, or if it is reasonably pertinent to the particular problem that the inventor was attempting to solve. I understand that a reference is reasonably pertinent if it logically caught an inventor's attention in considering the problem sought to be solved.

45. I have been informed that, to evaluate the differences between the prior art references and the claimed subject matter, the claimed invention must be considered as a whole. I understand that this involves demonstrating that a person having ordinary skill in the art, facing the same problems as the inventor and without

knowledge of the claimed invention, would have recognized the elements in the prior art and combined them in the claimed manner.

46. I understand that there are many rationales for combining prior-art references. For example, I have been informed that it is considered obvious to:

- combine prior-art elements according to known methods to yield predictable results;
- substitute one known element for another to obtain predictable results;
- use the prior-art elements in a predictable way according to their established functions;
- apply a known technique to a known device (method or product) ready for improvement to yield predictable results;
- choose from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- or if there is some teaching, suggestion, or motivation in the prior art that would have led a person having ordinary skill in the art to modify a prior-art reference or combine prior-art teachings to arrive at the claimed invention.

47. I understand, however, that a person having ordinary skill in the art can come to the claimed invention for completely different reasons than the inventors

and therefore does not need to have the same motivations or reasons to combine the prior art as the inventors.

48. I understand that when reviewing the prior art, the prior art cannot be combined or modified with "hindsight." I have been informed that hindsight designates scenarios when the challenged patent is employed as a framework to pick and choose aspects from the prior art to arrive at the claims. I understand that hindsight also occurs when rationales are adopted that are identified by the patent-at-issue, but would not have been recognized by those in the art. Alternatively, I have been informed that the obviousness analysis is evaluated from the perspective of a person having ordinary skill in the art, as of the critical date of the patent-at-issue and with all the prior art before them. I also understand that with this in mind, the analysis includes determining whether the person having ordinary skill in the art would have independently arrived at the claimed invention without the help of the patent-at-issue for guidance.

49. I understand that to evaluate obviousness, "objective indicia" or "secondary considerations" of non-obviousness must also be considered, and include, among a few others, whether: (1) there was a long-felt need for the claimed invention; (2) the claimed invention has attained commercial success; (3) others have copied the claimed invention; (4) others have attempted but failed to create the

alleged invention; (5) there was praise of the invention in the field; and (6) there was skepticism that the claimed invention could be achieved.

50. Additionally, I have been informed that a petition must identify, for any terms with means-plus-function limitations, the particular portions of the specification that describe the structure, material, or acts corresponding to each claimed function. I also understand that a rebuttable presumption exists that without use of the term, "means," a claim term is not interpreted as means-plus-function. However, I have been informed that other nonce words like "component" have been found to satisfy the rebuttable presumption and invoke a means-plus-function claim construction of such a claim term.

51. I have been informed that a petitioner seeking to demonstrate that the prior art discloses a means-plus-function limitation must prove that the corresponding structure—or an equivalent—was present in the prior art and performing the same claimed function.

52. I understand that proving structural equivalence does not require a component-by-component analysis. I have been informed that it is sufficient to show structure, materials, or acts that perform the claimed function in substantially the same way to achieve substantially the same result because the claim limitation is the overall structure corresponding to the claimed function and not individual components.

53. I have been informed that the standard for determining whether the prior art discloses the corresponding structure or an equivalent is whether there are insubstantial differences, which means that if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification, it is equivalent.

54. Lastly, I understand that in *inter partes* review proceedings, the Petitioner must demonstrate the obviousness of a claim by "a preponderance of the evidence." I have been informed that the preponderance of the evidence standard requires that a reasonable factfinder would find a material fact more probable than the nonexistence of that fact. I understand that this standard does not permit speculation concerning particular facts and is rather focused on whether the evidence more likely than not demonstrates the existence or non-existence of particular material facts. I have been informed that "preponderance of the evidence" is a lower standard than "clear and convincing evidence" (which requires a fact to be substantially more likely to be true than untrue) or "beyond a reasonable doubt" (which is an exceedingly high standard that I understand is usually used in criminal matters).

55. Throughout my Declaration, I have applied the "preponderance of the evidence" standard.

VII. BACKGROUND

A. Overview of the Technology

56. At the time of the ’029 patent’s priority date (August 2018), ultrasound imaging in healthcare continued its major reliance on sonographer experience, expertise, and ability to navigate the ultrasound scanning exams using the intimate knowledge of human anatomy. This well-recognized limitation of ultrasound scanning adversely affected the numbers of clinically acceptable ultrasound exams acquired in routine clinical settings. The limitation especially affected scans performed by operators who may have lower levels of experience or may not have been familiar with specific, perhaps rarely performed ultrasound exams. Ultrasound imaging is known to be inherently noisy, with ultrasound signal reflection tissue-associated image speckle sometimes obscuring important anatomy, resulting in less-then-desirable image quality of the obtained ultrasound studies. These limitations, especially those resulting from free-hand sonographer-positioning of the ultrasound probe and thus affecting the spatial positioning of ultrasound imaging planes, yielding imperfect views of the anatomy. They are unique to ultrasound imaging and are not present in other imaging modalities like X-ray computed tomography (CT), magnetic resonance (MR) imaging, positron emission tomography (PET), etc. for which the image acquisition geometry is fixed.

57. The limitations of ultrasound imaging technology, combined with a

generally and broadly recognized value of ultrasound imaging in patient diagnostics, ultrasound-guided interventions, and other applications of ultrasound imaging in healthcare, yielded a well-documented need for further improvements of ultrasound imaging devices. There was an unmet need, across the broad spectrum of ultrasound imaging exam types, to assist the operators with feedback regarding the diagnostic quality of the acquired images, the anatomical views captured on the ultrasound exams, and availability of patient-specific image-based quantitative indices of organ morphology, tissue properties, physiologic function, etc.

58. At the time of the invention, it was broadly recognized that inexperienced ultrasound operators may have a great deal of difficulty using the full capabilities of the complex, state-of-the-art ultrasound imaging systems to provide the clinically acceptable imaging exams, especially if under time pressure to complete exams within a short time window dictated by the nature of the exam, or in cases with challenging patient anatomy. Such less experienced sonographers may not only have difficulty to acquire the correct images, they may also have problems to identify and/or correct the potential imperfections and incorrect acquisitions in already-performed exams and thus can fail to capture diagnostically relevant ultrasound images.

59. The above-described need to improve clinical ultrasound imaging workflow and quality control resulted in a number of attempts to do so. *See* Ex2060.

Yet, success of these attempts was either limited in their functionality, not providing the desired performance, or was available only for a very narrow set of ultrasound examinations. *See* Ex1009.

60. The insufficient impact of the proposed solutions to address the well-recognized ultrasound imaging and clinical relevance problems of routine clinical ultrasound exams was mainly caused by the lack of sufficient medical image analysis technology capable of addressing the difficult task at hand. Approaches proposed and even patented prior to the priority date of the ’029 patent relied on state-of-the-art image analysis techniques of that time, techniques that are now considered as methods from the “conventional” computer vision toolbox. While continuous and incremental progress was certainly made throughout the years, these improvements were evolutionary in principle and did not enable inventing full solutions to the well-recognized and well-documented challenges affecting clinical use of ultrasound imaging.

61. In 2012, a much-needed technological revolution came to the fields of computer vision and medical image analysis. At that time, the novel concept of deep convolutional neural networks (CNN) demonstrated a markedly improved performance over the conventional computer vision approaches. At that time, a CNN model called AlexNet was introduced, by the University of Toronto SuperVision team. *See* Ex2035; Ex2061; Ex1029. Further advances of this revolutionary

approach have affected all fields of computer vision and medical image analysis. The general approach introduced by AlexNet has been carried to these days, and years of subsequent architectural and model training improvements continue until today.

62. It can thus be observed, that medical image analysis approaches published prior to the year of 2012 invariably followed the conventional methodology design strategies. A person having ordinary skill in the art at the pre-2012 time could not be aware of deep-learning (DL)-based image analysis approaches as such approaches did not exist. Deep learning for medical image analysis did not emerge as a practical methodology until years later.

1. Conventional approaches to solving ultrasound analysis and image-based ultrasound scanning guidance needs

63. Prior to the ’029 patent priority date, the methods proposed to solve the task of ultrasound image analysis and image-based ultrasound scanning guidance relied on conventional image analysis and computer vision approaches. Most frequent methods employed for that task required organs or regions of interest to be segmented. Numerous image segmentation techniques existed at that time. Examples include thresholding, region growing, edge-based segmentation, watershed segmentation, template matching, deformable models, active contours (snakes), graph cut segmentations, etc. Conventional image segmentation techniques

are covered in their breadth and depth in an authoritative text published in 4 editions in 1993, 1998, 2007, and 2015. *See* Ex2050, 4 (listing books authored); Sonka, M., Hlavac, V. Boyle, R., *Image Processing, Analysis, and Machine Vision. Chapman and Hall Publishers*, London – New York, 555 p., 1993 ("*Image Processing, Analysis, and Machine Vision* 1st Ed."); Sonka, M., Hlavac, V. Boyle, R., *Image Processing, Analysis, and Machine Vision* - 2nd Ed., PWS, Pacific Grove, CA, 800 p., 1998 ("*Image Processing, Analysis, and Machine Vision* 2nd Ed."); Sonka, M., Hlavac, V. Boyle, R., *Image Processing, Analysis, and Machine Vision* - 3rd Ed., Thomson Engineering, Toronto, Canada, 850 p., 2008 ("*Image Processing, Analysis, and Machine Vision* 3rd Ed."); Processing, Analysis, and Machine Vision - 4th Ed., Cengage Learning, New York, 890 p., 2014 ("*Image Processing, Analysis, and Machine Vision* 4th Ed."). The evolutionary character of segmentation methodology progress throughout those years can be clearly seen when comparing the contents of the respective *Image Segmentation* chapters.

64. The use of machine learning (ML) was already researched prior to the time of deep learning discovery and adoption to improve performance of the conventional segmentation techniques. The employed ML techniques of that time were not based on deep learning and focused on learning-based improvement or optimization of segmentation method parameter values for the otherwise fixed segmentation parameters. ML of that time allowed to optimize the segmentation

method parameter values based on the availability of a provided training set but did not allow designing new parameters (features) that would be employed by the segmentation algorithms. The segmentation methods of that time relied on expert-designed (hand-designed) parameters/features, the design of which was based on experience and expertise of humans, who designed each specific segmentation method and its parameters for each specific segmentation task. A functionality of learning the desired features from sets of examples only became available after the revolutionary introduction of deep convolutional network models for image segmentation.

65. Similarly, methods for image quality assessment existed prior to the deep learning era, but were mainly based on analytical determination of general image properties like signal-to-noise ratio, rather than assessments of clinical or diagnostic usability. Such subjective medical image quality studies were mainly performed by trained humans as part of image perception research. The functionality of learning the desired task-specific ultrasound image-based features for assessing diagnostic or clinical image quality from sets of example images only became available after the revolutionary introduction of deep convolutional network models for image segmentation.

66. The Krishnan patent application US 2005/0251013-Al, that the party requesting the IPR substantially relies on, invariably utilizes the conventional

approaches to solving problems in medical imaging that were known at the time of its priority date in March 2005. Ex1005. At that time, none of the deep learning approaches that ’029 patent is teaching were known.

67. As an author of the 4 editions of the comprehensive *Image Processing, Analysis, and Machine Vision* text referenced above, as the SPIE International Symposium on Medical Imaging conference chair in 2001-2008, and as the Editor in Chief of “the” premier medical imaging journal *IEEE Transactions on Medical Imaging* in 2009-2014, I am deeply familiar with the medical image analysis approaches and methods that are now considered “conventional,” well versed in DL-based medical image analysis approaches, and well-aware of the level of knowledge of a person having ordinary skill in the art throughout the years. *See* Ex2050, 4 (listing books authored), 8 (listing professional activities); *Image Processing, Analysis, and Machine Vision* 1st Ed.; *Image Processing, Analysis, and Machine Vision* 2nd Ed.; *Image Processing, Analysis, and Machine Vision* 3rd Ed.; *Image Processing, Analysis, and Machine Vision* 4th Ed.

2. Deep learning approaches to image analysis

68. Following AlexNet superior performance in the ImageNet competition of 2012, a true revolution arrived in the fields of computer vision and medical image analysis in the years that followed. *See* Ex2060. This revolution was not immediately recognized as such. As described in the 2017 paper of the team that brought AlexNet

to the world: "Four years ago, a paper by Yann LeCun and his collaborators was rejected by the leading computer vision conference on the grounds that it used neural networks and therefore provided no insight into how to design a vision system. At the time, most computer vision researchers believed that a vision system needed to be carefully hand-designed using a detailed understanding of the nature of the task." Ex1029, 1.

69. Following the introduction and demonstrated superior performance of the AlexNet, the advantages of deep convolutional neural network segmentation models were gradually recognized, and conventional approaches were replaced with deep learning approaches.

70. Deep learning computer vision and medical image analysis approaches are overviewed in their breadth and depth in a recent comprehensive text Medical Image Analysis, 2024: "The term *deep neural network* loosely refers to neural networks with three or more stacked hidden layers. . . Deep neural networks have been used extensively across several domains in recent years, including healthcare, to address real-world problems involving tasks in signal processing, computer vision, and natural language processing, amongst others. Medical image analysis has benefited greatly with the advent of deep learning too, allowing researchers in the community to tackle increasingly complex and clinically interesting and meaningful tasks." *See* Ex2062, 415.

71. DL for image analysis – as described above – dates back to 2012. At that time, CNNs were only able to process 2D images while most medical data used in clinical practice consist of 3D volumes. The foundational fully convolutional deep neural network U-Net, introduced in 2015, was only applicable to 2D (microscopy) image analysis. *See* Ex2063, 234-36. In 2016 (June 15, 2016), a 3D CNN was introduced and called the V-Net, a fully convolutional, end-to-end trained deep neural network suitable for analyses of 3D medical image data. *See* Ex2064, 1. Just a week later (June 21, 2016), 3D U-Net model was introduced. *See* Ex2065, 1. 3D U-Net and its later-developed variants nnU-Net (2018) and nnU-Net-v2 are broadly used as the CNN models of choice for medical image analysis. *See* Ex2066; Ex2067.

72. As another new, previously unavailable, and thus revolutionary capability, deep CNNs facilitate direct feature derivation from training data. This is in contrary to the past need to separately hand- or expert-design each and every feature or parameter of the image analysis and/or image segmentation approach. This capability is critical for CNN-based deep learning approaches as the hand-design of analysis or segmentation parameters can be fully bypassed, and raw image data can thus be used on the CNN input. This is in contrast to the past conventional approaches, that typically require image data processing, initial segmentation, individual expert/hand-design of each quantitative characteristic (feature) to be used for a given task, then calculating values of these hand-designed features, and feeding

these quantitative feature indices to a classifier to learn producing desired classification outputs (e.g., labels of view, quality property). The unquestionable advantage of hand-designed features is their humanly understandable meaning and clinical relevance (like determining left-ventricular ejection fraction).

73. Feature derivation in deep learning is an automated process during which a training set of images together with known labels of desired output (e.g., labels of view, quality, property) is provided to an end-to-end CNN and the CNN is trained to perform the task at hand. While hand-designed features are typically designed individually, one-by-one, without direct consideration of mutual feature context; DL-based approaches design the entire feature representations jointly during the DL model training processes. Such derived feature representations are sets of features derived to be most distinguishing from a decision-making standpoint and are frequently better than hand-designed features for a particular analysis task at hand, as their derivation is considering the provided training set of examples and their desired labels. At the same time, these machine-derived features may not have an immediately human-understandable meaning and frequently lack clinical relevance. A separate branch of AI/ML called Explainable AI is addressing the questions of how AI decisions can be explained and communicated to the humans.

3. Major differences between conventional and DL-based image analysis models

74. Conventional approaches require features to be hand/expert designed, then (automatically) computed for each image, and used as a numerical features/descriptors (called feature vectors) as input to conventional ML processes. The DL-CNN approaches directly use the original images as inputs to the respective decision-making processes in what is called end-to-end decision-making models.

75. Incidentally, both the Krishnan patent and the ’029 patent use the identical wording “deriv[ing]” the features but these words refer to fundamentally different approaches. In Krishnan “to derive” features is equated with “to extract” features. *See e.g.*, Ex1005, ¶¶22, 43, claim 1. Feature derivation is defined as “extracting feature data from the image data.” *Id.*, claim 1. This, in the context of the state of the art in 2005, is describing the conventional image analysis approach as summarized above. These feature data (feature vectors, each from a single image), in agreement with the above description, serve as inputs to a classifier, e.g., “determining the diagnostic quality is performed by processing the extracted feature data using a classifier …” *Id.*, claim 4.

76. In the ’029 patent, the wording “deriving features” refers to a fundamentally different functionality: “deriving one or more extracted feature representations from the set of ultrasound images” and “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." Ex1001, claims 1 and 12. This description corresponds to fundamental functionality of DL-based approaches, in which the full training set of image data is used as the input (not a single-image feature vector) and the features (descriptors) are automatically derived in the deep learning process (features are not hand designed).

77. Therefore, extracting features in conventional ML approaches follows hand/expert design of those features while deriving features in DL approaches is a fully automated process of machine-design of useful features from the training sets of images. Thus, these two processes are fundamentally different.

78. The chart below summarizes additional differences between the conventional and DL approaches:

Characteristic	**Conventional**	**DL - CNN**
Performance		Typically outperform conventional approaches
Training set of examples and desired labels	Not required, not used	Required
Feature design	Hand/Expert based	Automated, part of CNN model training
Feature design	Features designed one by one, individually. Features extracted from	Feature representations (sets of features) derived simultaneously from the

	images using the hand-based design formula or algorithm	set of training images
Feature relevance	Features are humanly understandable but may not be useful for a decision-making task at hand	Features may not be understandable to humans but are model-training optimized as a set to be maximally useful for a decision-making task at hand
Decision making process	Features extracted from an image, extracted features serve as input to a trained ML model	Images are directly input to a trained CNN model, DL facilitates end-to-end decision-making
Year of introduction	Gradually evolved since 1940's	Concept introduced in 2012, practical adoption years later[1]

B. The '029 Patent

1. Specification

79. The '029 patent discloses systems and methods for analyzing ultrasound images with a neural network and for training the neural network. Regarding analyzing the images, the '029 patent discloses an exemplary analyzer 14 in Figure 1.

[1] *See* Ex1029, Ex2035, Ex2036.

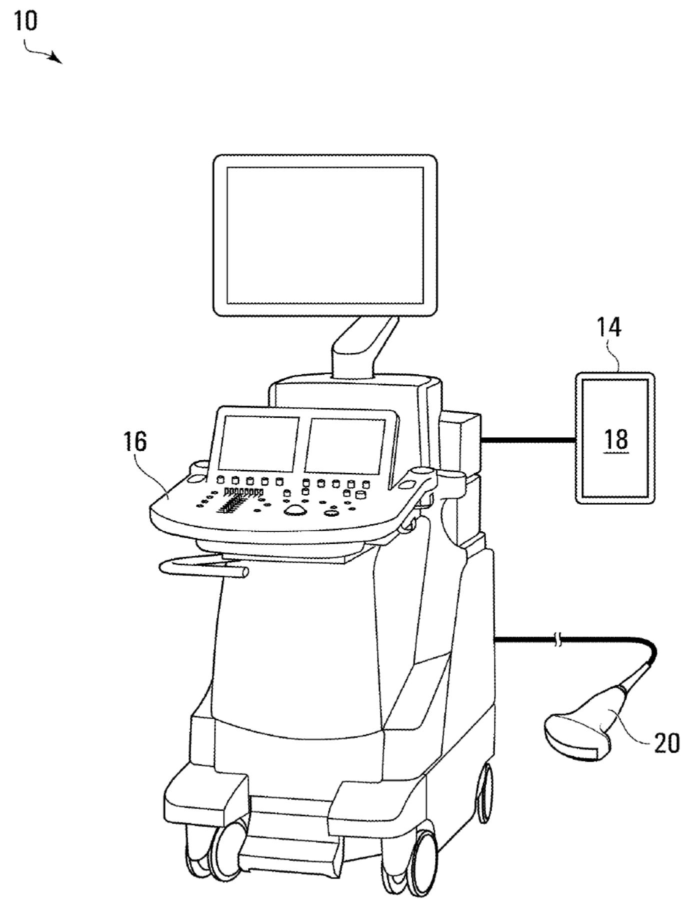

FIG. 1

Ex1001, Fig. 1.

80. The ’029 patent explains that “the analyzer 14 may receive signals representing a set of ultrasound images of the subject.” *Id.*, 6:23-25. “The analyzer 14 may then derive one or more extracted feature representations from the received set of ultrasound images” (*id.*, 6:35-37) and “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” (*id.*, 6:42-45). “The analyzer 14

may also determine, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images." *Id.*, 6:56-58. An exemplary image property is view category. *Id.*, 6:58-60; *see also, e.g., id.*, 20:41-59 (disclosing that, with respect to echocardiography, examples of image properties include the view category, left ventricular ejection fraction, and left atrial ejection fraction).

81. "The analyzer 14 may then 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." *Id.*, 7:4-7. Then, in some embodiments, "the analyzer 14 may produce signals for causing a representation of the quality assessment value and a representation of the view category to be displayed by the display 18 in association with the set of ultrasound images." *Id.*, 7:7-11.

82. In this way, the disclosed invention may allow for "near real-time or real-time feedback to the operator," which "may help the operator improve their skills and/or improve image quality for subsequently captured images." *Id.*, 7:15-18; *see also id.*, 7:18-32.

83. Regarding training the neural network for image analysis, Figure 11 shows a schematic view of neural network trainer 502, which may be included in system 10 shown in Figure 1. *Id.*, 15:37-41.

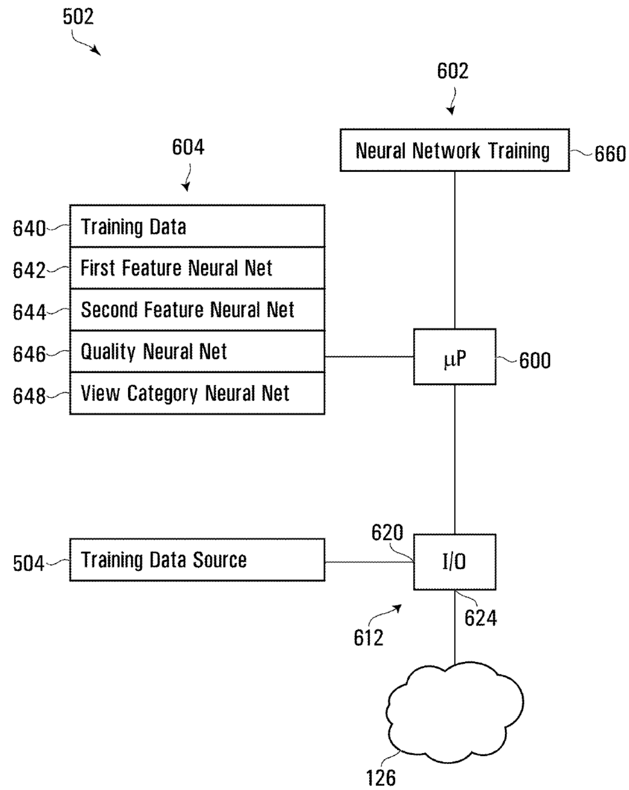

FIG. 11

Ex1001, Fig. 11.

84. Figure 12 depicts a flowchart for directing the trainer processor 600 shown in Figure 11 to perform neural network training. *Id.*, 16:14-21. Trainer processor 600 receives signals representing ultrasound training images (702), signals representing quality assessment values (704), and signals representing image properties (706). *Id.*, 16:23-17:26.

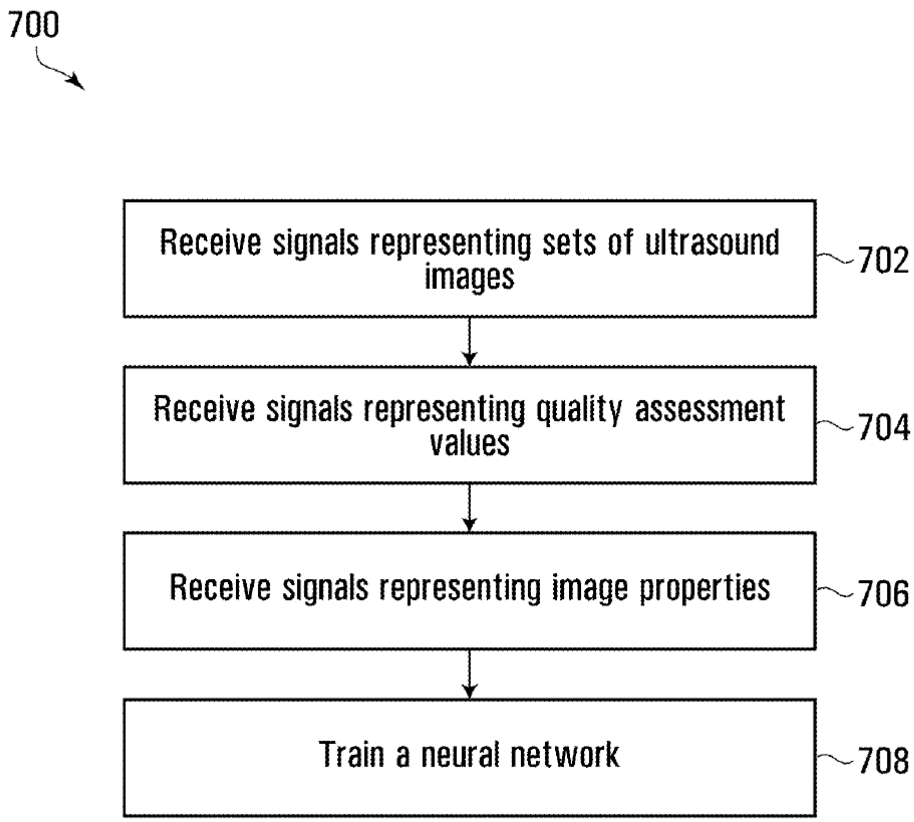

FIG. 12

Ex1001, Fig. 12.

85. In block 708, the neural network is trained "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."[2] *Id.*, 17:27-33; *see also id.*, 17:33-44 (describing training the neural network 300 shown in Figure 4).

86. Accordingly, the '029 patent discloses that the neural network is trained using ultrasound images as inputs, rather than features (descriptors) separately defined and extracted from the ultrasound images prior to the neural network training.

2. Prosecution History

87. The application leading to the issuance of the '029 patent was filed August 30, 2019 and claimed priority, through a continuation application, to provisional application no. 62/725,913 (filed Aug. 31, 2018). EX1001, (22), (63), (60).

88. On January 8, 2020, the Examiner issued a non-final office action rejecting then-pending claims 1-30. EX1004, 265-79. The Examiner rejected all claims as anticipated by Abolmaesumi et al. (U.S. 2019/0125298). *Id.*, 271. I understand that U.S. 2019/0125298 is the publication of an application that later issued as U.S. Patent No. 11,129,591, which Petitioner challenged in a separate IPR (IPR2025-01066).

89. On March 19, 2020, the applicants responded to the Office Action and

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[2] All emphases are added in this declaration unless otherwise noted.

explained that U.S. 2019/0125298 did not qualify as prior art because both the ’029 patent application and the published application U.S. 2019/0125298 were subject to an obligation of assignment to the University of British Columbia. EX1004, 298.

90. Also on March 19, 2020, the Applicant submitted the Krishnan publication in an information disclosure statement (U.S. Patent Application Publication No. 2005/0251013 (EX1005)). EX1004, 302.

91. On June 18, 2020, the Examiner signed the information disclosure statement to indicate that the Krishnan publication has been considered. EX1004, 398, 416.

92. On June 25, 2020, the Examiner issued a notice of allowance. EX1004, 345-56. The Examiner stated that the anticipation rejection was withdrawn. *Id.*, 350.

93. The Examiner provided the following statement of reasons for allowance:

> The closest prior art of Rothberg et al. (U.S. patent pub. 2019/0130554 A1) discloses during ultrasound imaging the quality of the set of images obtained is obtained and to updated the set of images and calculate a new quality measurement on the updated set of [i]mages. 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 quality assessment value and the image property to be associated with the set of ultrasound images," these, in combination with the other claim limitations.

EX1004, 353-54.

> Regarding claim 12, none of the prior art of record teaches the features of "receiving signals representing image properties, each of the image properties associated with one of the sets of ultrasound training images; and 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," these, in combination with the other claim limitations.

EX1004, 354.

> Regarding claim 21, none of the prior art of record teaches the features of "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; determine, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images; and produce signals representing the quality assessment value and the image property for causing the quality assessment value and the image property be associated with the set of ultrasound images," these, in combination with the other claim limitations. Regarding claim 30, none

> of the prior art of record teaches the features of "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; means for determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images; and 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," these, in combination with the other claim limitations.

EX1004, 354-55.

> Regarding claims 2-11, 13-20, and 22-29 these claims are allowed since they are directly or indirectly dependent from allowed independent claims 1, 12, and 21, respectively.

EX1004, 355.

VIII. CLAIM CONSTRUCTION

A. "Extracted Feature Representations" (Independent Claims 1, 21, and 30 and Dependent Claims 3-5, 7, 9-10, 14, 19, and 26-28)

94. As explained below, in my opinion, the Petition applies an overbroad interpretation of "extracted feature representations," for example, when analyzing limitations 1(b), 21(b), and 30(b) and certain dependent claims. I understand that UBC asserts that "extracted feature representations" should be construed as "feature

representations that are learned using a neural network," which is the construction UBC has proposed in parallel litigation. *See* Ex2007, 7.

95. As discussed below, it is my opinion that a person having ordinary skill in the art would have read the claims in view of the specification and concluded that "extracted feature representations" were "feature representations that are learned by a neural network."

96. It is my opinion that when "extracted feature representations" is appropriately read in the context of the claim language requiring "deriv[ing]" the features and the '029 patent specification, the term plainly requires "feature representations that are learned using a neural network." And as I explain below, when the term is properly construed, the prior art does not disclose at least limitations 1(b), 21(b), and 30(b).

97. I understand that when a patent repeatedly and consistently characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization. And in my opinion, a person having ordinary skill in the art would have understood that the "extracted feature representations" are feature representations learned using a neural network. This is because the claim language itself refers to "deriv[ing]" the features, the '029 patent specification repeatedly and consistently characterizes the "extracted feature representations" as feature representations that are learned using a neural network,

and a person having ordinary skill in the art would have thus understood that learning extracted features using a neural network was central to the claimed invention of the ’029 patent.

98. As a preliminary matter, the ’029 patent describes “feature representations” as encodings of image patterns of one or more images. *See, e.g.*:

- Ex1001, 11:30-35 (“[T]he commonly defined first feature extracting neural networks (e.g. 304, 306, and 308 shown in FIG. 4) may be each configured to <u>extract features that are encodings of image patterns</u> of a single echo frame which are correlated with the image quality and view category of the single input echo frame.”).
- *Id.*, 11:35-39 (“In some embodiments these <u>features (encodings or mappings)</u> may be in the form of a vector of real-valued numbers (after the flatten operation), and each number may be considered as the level of presence of a specific spatial pattern in the input echo frame.”);
- *Id.*, 12:28-31 (“As a result, in some embodiments, the <u>features</u> extracted by the LSTM networks <u>may be encodings of both spatial and temporal patterns</u> of a multitude of echo frames.”).

99. The ’029 patent’s figures and corresponding descriptions uniformly disclose that these extracted feature representations (i.e., encodings of image patterns) are learned using a neural network. *See, e.g.*:

- Ex1001, 8:43-45 (disclosing that Figure 2 depicts storage memory 104, which includes a plurality of storage locations, including "location 154 for storing first feature extracting neural network parameter data, location 156 for storing second feature extracting neural network parameter data").

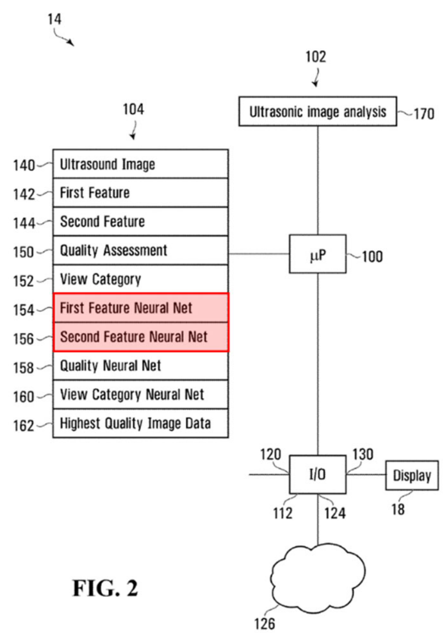

FIG. 2

Ex1001, Fig. 2

(depicting locations 154/156 for storing feature extracting neural network parameter data)

- Ex1001, 11:30-32 (disclosing that Figure 4 depicts feature extractor neural networks 304, 306, and 308).

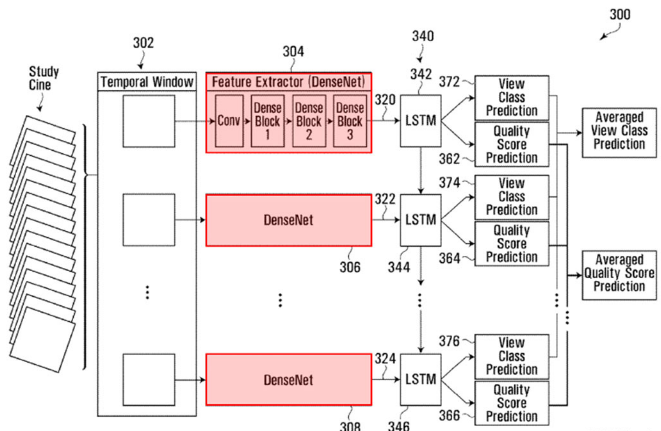

FIG. 4

Ex1001, Fig. 4

(depicting feature extractor neural networks 304, 306, and 308).

- Ex1001, 11:28-29 (disclosing that Figures 5, 6, and 7 depict feature extractor neural networks 310, 312, and 314).

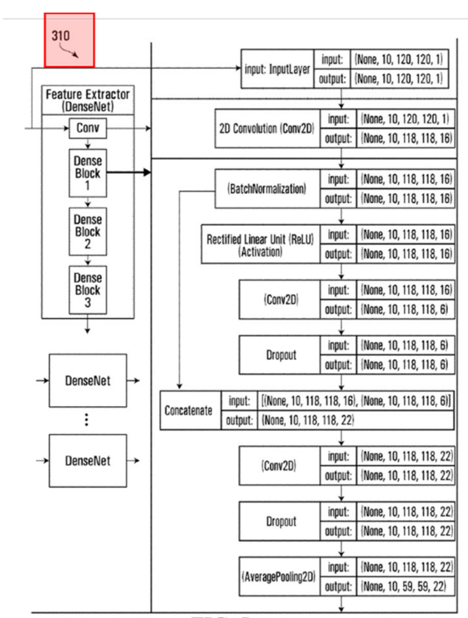

FIG. 5

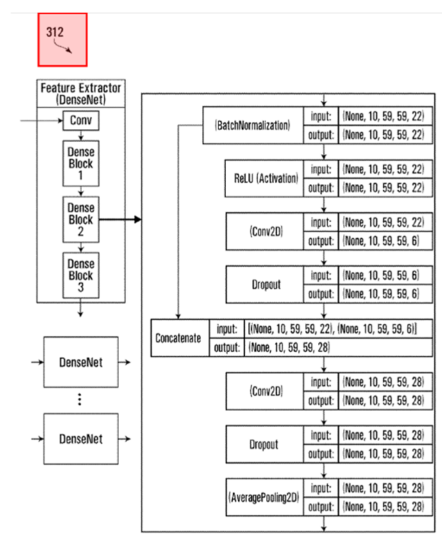

FIG. 6

Ex1001, Fig. 5

Ex1001, Fig. 6

(depicting feature extractor neural network 310) (depicting feature extractor neural network 312)

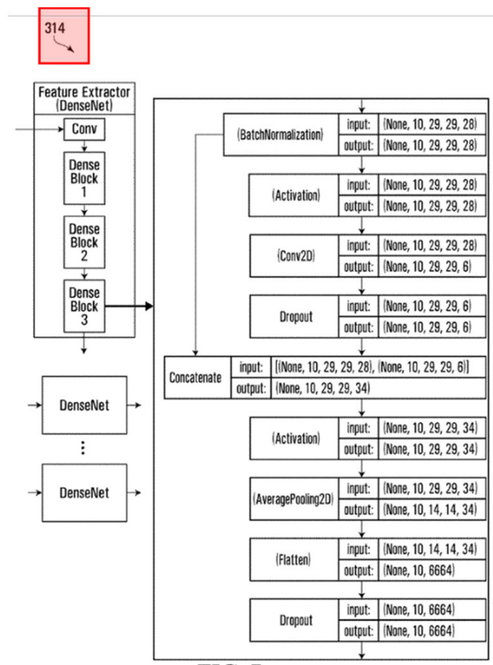

FIG. 7

Ex1001, Fig. 7

(depicting feature extractor neural network 314)

- Ex1001, 16:3-5 (disclosing that Fig. 11 depicts storage memory 604 and "location 642 for storing first feature extracting neural network data, location 644 for storing second feature extracting neural network")

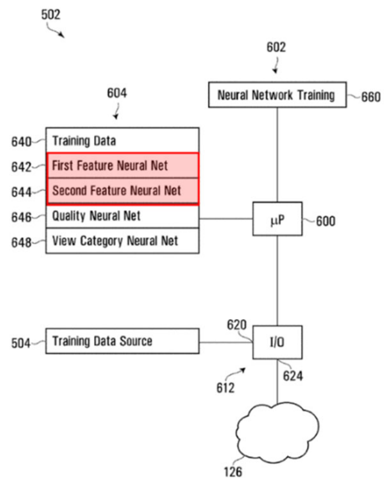

FIG. 11

Ex1001, Fig. 11

(depicting locations 642/644 for storing feature extracting neural network data)

- Ex1001, 22:24-34 (disclosing that Fig. 13 depicts "three first feature extracting neural network or CNN threads" 752, 754, and 756).

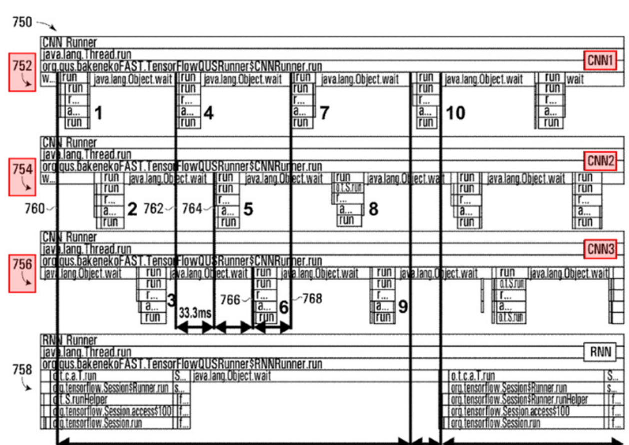

FIG. 13

Ex1001, Fig. 13

(depicting three first feature extracting neural network threads 752/754/756, which are implemented as convolutional neural networks)

100. Further, whenever the specification mentions "deriving extracted feature representations," it explains this is performed using a neural network. *See e.g.*:

- Ex1001, 6:35-41 ("The analyzer 14 may then <u>derive one or more extracted feature representations</u> from the received set of ultrasound images. In some embodiments, the analyzer 14 <u>may implement a neural network</u> including a feature extracting neural network and the analyzer 14 may input the set of ultrasound images into the feature extracting neural network in order to derive the one or more extracted feature representations").
- Ex1001, 10:9-31 (explaining with respect to Figure 3 that "block 204 directs the analyzer processor 100 to <u>derive one or more extracted feature representations</u> from the set of ultrasound images received at block 202" and that the extracted feature representations are learned upon inputting images into various neural networks)
- Ex1001, 10:32-12:51 (describing further details about implementing neural networks for deriving extracted feature representations).

101. The '029 patent's description of Figure 3 further supports my opinion. Figure 3 is a "flowchart depicting blocks of code for directing the analyzer processor 100 shown in FIG. 2 to perform ultrasonic image analysis functions in accordance

with various embodiments...” Ex1001, 9:9-13.

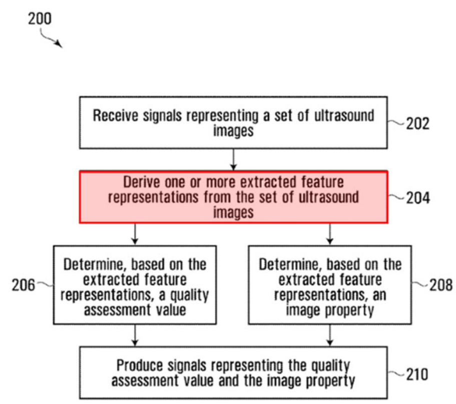

FIG. 3

Ex1001, Fig. 3.

102. The ’029 patent discloses that the flowchart 200 depicted in Fig. 3 “begins with block 202 which directs the analyzer processor 100 shown in FIG. 2 to receive signals representing a set of ultrasound images of a subject.” Ex1001, 9:16-19. Then, the ’029 patent discloses that “[i]n various embodiments, execution of blocks 204, 206 and 208 of the flowchart 200 may result in the analyzer processor 100 being directed to input the received set of ultrasound images into a neural network 300 shown in FIG. 4, to generate an output of a quality assessment value and an image property, which in some embodiments may be a view category.” *Id.*, 9:65-10:4.

103. The ’029 patent specification then explains that the images are input into a neural network in block 204 in order to “derive” extracted feature

representations.

> Referring to FIG. 3, block 204 directs the analyzer processor 100 to derive one or more extracted feature representations from the set of ultrasound images received at block 202. In some embodiments, deriving the one or more extracted feature representations may involve deriving a first feature representation and then deriving a second feature representation based on the first feature representation for each ultrasound image.
>
> In various embodiments, block 204 may direct the analyzer processor to, for each of the set of ultrasound images stored in the location 140 of the storage memory 104, derive a first feature representation associated with the ultrasound image. In some embodiments, block 204 may direct the analyzer processor 100 to derive the first feature representations by inputting each image of the set of ultrasound images (shown at 302 in FIG. 4) into a commonly defined first feature extracting neural network, instances of which are shown at 304, 306, and 308 of the neural network 300 shown in FIG. 4, for example. In some embodiments, block 204 may direct the analyzer processor 100 to input each of the ten ultrasound images stored in the location 140 of the storage memory 104 into one of the commonly defined first feature extracting neural networks 304, 306, and 308.

Ex1001, 10:9-31.

104. As I noted previously, I have reviewed the declaration and deposition transcript of Dr. Deo. Dr. Deo opines in his declaration that the ’029 patent

"discloses and claims an echocardiographic image analysis workflow shown in Figure 3." Ex1002, ¶62. I agree with Dr. Deo that claims of the '029 patent are directed to the general process flow depicted in Figure 3.

105. Dr. Deo also opined that the workflow in Figure 3 uses a neural network in block 204, which is the feature extraction step. *See* Ex1002, ¶62 ("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.").

106. Dr. Deo also testified at deposition that there are no specific alternative embodiments in the '029 patent that do not use a neural network for block 204. *See* Ex2051 (Deo Tr., Session I), 44:8-45:4 (explaining that the specification does not describe any alternatives to employing a neural network for block 204).

107. Dr. Deo's opinion thus further supports my opinion that a person having ordinary skill in the art would have read the '029 patent to be disclosing and claiming a neural network for learning extracted features from images.

108. It is also my opinion that construing "extracted feature representations" to mean "feature representations that are learned using a neural network" does not result in any dependent claims being redundant. Specifically, certain dependent claims specify the type of neural network involved in extracting features, e.g., a

"commonly defined first feature extracting neural subnetwork," whereas claims 1 and 21 are broader in that they only require that the extracted features be learned using a neural network. *See*:

Claim 1 Dependent Claims:

> 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 <u>commonly defined first feature extracting neural subnetwork</u> to generate the first feature representation associated with the ultrasound image.

Ex1001, Claim 4.

> 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 <u>commonly defined first feature extracting neural network</u>.

Ex1001, Claim 5.

> Claim 6. The method of claim 4 wherein the <u>commonly defined first feature extracting neural network includes a convolutional neural network</u>.

Ex1001, Claim 6.

> Claim 7. The method of claim 4 wherein deriving the one or more extracted feature representations comprises inputting the first feature representations into a <u>second feature extracting neural network to</u>

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.

Ex1001, Claim 7.

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

Ex1001, Claim 8.

Claim 21 Dependent Claims:

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.

Ex1001, Claim 23.

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.

Ex1001, Claim 24.

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 <u>commonly defined first feature extracting neural network.</u>

Ex1001, Claim 25.

> Claim 26. The system of claim 24 wherein the at least one processor is configured to input the first feature representations into a <u>second feature extracting neural network</u> 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.

Ex1001, Claim 26.

B. "Quality Assessment Value" (Independent Claims 1, 12, 21, and 30 and Dependent Claims 9, 10, 11, 14, and 27-29)

109. I understand that UBC does not propose a construction for "quality assessment value." I have not been asked to provide my opinion on the construction of the term, and I have no opinion on the proper construction of this term.

110. Nevertheless, I understand that Petitioner is bound in the current proceeding to apply the construction "score of diagnostic image quality" for this term (*see* Paper 15, below). Therefore, I have applied this construction when assessing the invalidity grounds in this proceeding.

> Under *Revvo*, a petitioner must explain any inconsistent claim construction positions. While it is not entirely clear whether Petitioner

> sought to advance an inconsistent claim construction position in this proceeding, the Office accepts Petitioner's "consent" as a stipulation to construe "quality assessment value" herein— and in any other proceeding before the Office that involves Petitioner and the same claim term—as "score of diagnostic image quality," as Petitioner proposed in district court. Petitioner's stipulation, therefore, resolves any potential inconsistency in claim construction positions between forums and does not require further explanation under *Revvo*.

Paper 15, 3.

C. Means-Plus-Function (Claim 30)

111. Regarding claim 30, I note that Petitioner identifies several §112(f) constructions that the parties have agreed to in the parallel litigation. Petition, 10-12.

[30(a)]: "means for receiving signals representing a set of ultrasound images of the subject"	Function: receiving signals representing a set of ultrasound images of the subject Corresponding structure: a processor with I/O interface
[30(b)]: "means for deriving one or more extracted feature representations from the set of ultrasound images"	Function: deriving one or more extracted feature representations from the set of ultrasound images

	Corresponding structure: a processor and memory operating a neural network
[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"	Function: 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 Corresponding structure: a processor and memory operating a neural network
[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"	Function: determining, based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images Corresponding structure: a processor and memory operating a neural network
[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"	Function: 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

	Corresponding structure: a processor and memory

Ex2031, §I.A; Petition, 10-12.

112. I have applied these constructions in the analysis below. Notably, the corresponding structure for limitation 30(b) is: "a processor and memory operating a neural network." Petition, 10. Petitioner further states that the corresponding structure for 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" identified in the specification is "a processor and memory operating a neural network." *Id.*, 11.

113. Under these agreed constructions, it is my opinion that Krishnan does not anticipate claim 30.

IX. ASSERTED PRIOR ART REFERENCES

A. Krishnan (Ex1005)

114. Krishnan is directed to providing decision support for medical imaging and describes "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].

115. Krishnan's Figure 1 depicts a high-level block diagram of Krishnan's system 100 for providing automated decision support for medical imaging. *Id.*,

[0016]. The system includes a data processing module 101, which comprises an automatic feature analysis module 102, an anatomy identification module 103, a view identification module 104, and an image quality assessment module 105. *Id.*

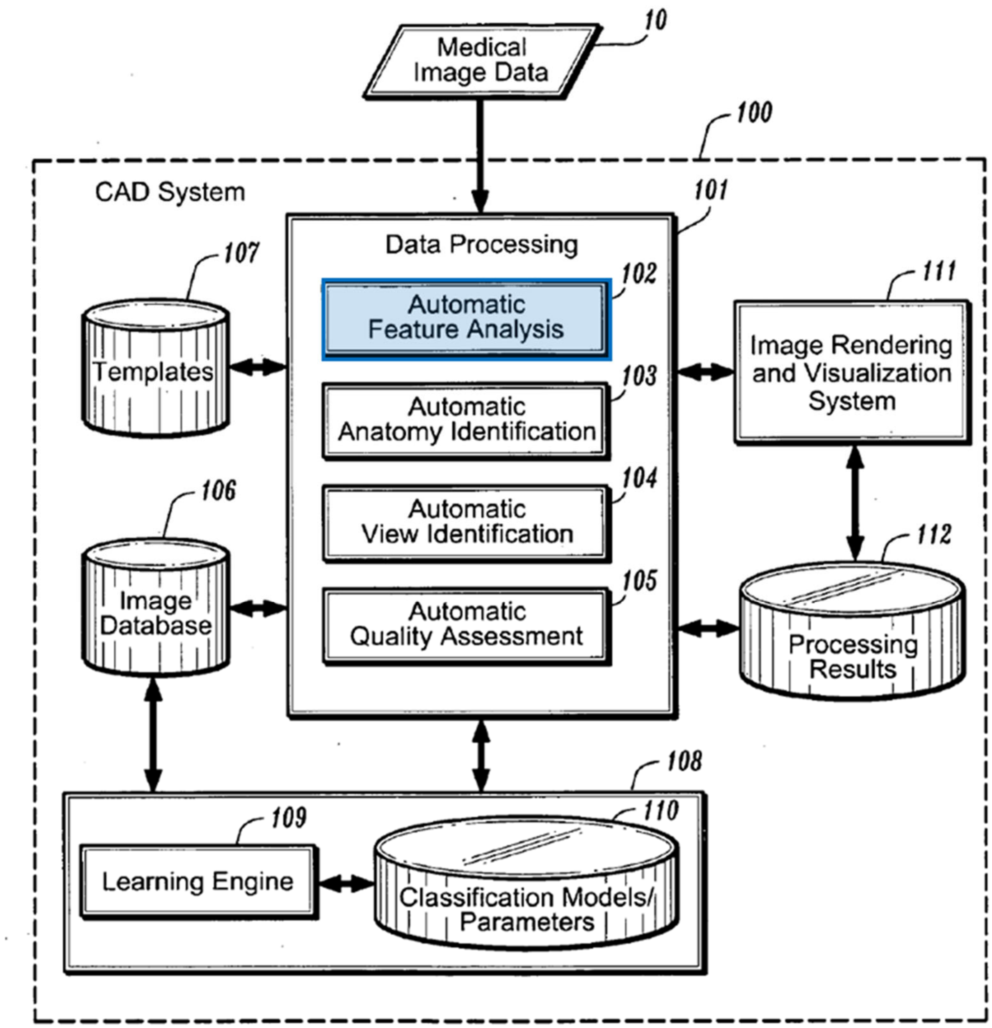

FIG. 1

Ex1005, Fig. 1.[3]

> FIG. 1 illustrates a high-level block diagram of a system (100) for providing automated decision support for medical imaging, according to an exemplary embodiment of the invention. In general, the exemplary system (100) comprises a data processing module (101) that implements various methods for analyzing medical image data (10) in one or more imaging modalities (e.g., ultrasound image data, MRI data, nuclear medicine data, etc.) to automatically extract and process relevant information from the medical image data to provide various decision support function(s) for evaluating the medical images. In the exemplary embodiment, the data processing module (101) comprises an automatic feature analysis module (102), an anatomy identification module (103), a view identification module (104) and an image quality assessment module (105).

Ex1005, [0016].

116. 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].

[3] All color annotations added.

> 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). The system (100) can process digital image data (10) in the form of raw image data, 2D-reconstructed data (e.g., axial slices), or 3D-reconstructed data (volumetric image data or multiplanar reformats), 4D-reconstructed data, or other image modalities/formats. It is to be understood that methods implemented by the feature extraction module (102) will vary depending on the imaging modalities and/or automated decision support methods that are supported by the CAD system (100), as well as the type(s) of anatomical structures under consideration.

Ex1005, [0017].

117. The anatomy identification module 103 "implements methods for using the extracted features/parameters to automatically identify anatomical objects." *Id.*, [0018].

> The anatomy identification module (102) implements methods for using the extracted features/parameters to automatically identify anatomical objects (heart chambers, kidneys, etc[.]) in the image dataset and label the image(s) with the appropriate anatomy identification. In another exemplary embodiment, the anatomy identification module (102) implements methods for determining (for each anatomy/view ID label) a confidence or likelihood measure that

> the identified anatomy/view is properly labeled. The results of anatomy identification for a medical image can be used by other automated methods such as the view identification and quality assessment methods, or other application that provide automated diagnosis, therapy planning, etc.

Ex1005, [0018].

118. I note that paragraph 18 of Krishnan refers to the anatomy identification module as module 102, which is a typographical error because Figure 1 illustrates that the anatomy identification module is module 103.

119. The view identification module 104 "implements methods for using the extracted features/parameters to automatically identify the view of an acquired image." Ex1005, [0019].

> The view identification module (103) implements methods for using the extracted features/parameters to automatically identify the view of an acquired image. In other words, the view identification module (104) implements methods for pose estimation and label a medical image with respect to what view of the anatomy the medical image contains. 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), the parasternal short axis view (PSAX). Ultrasound

> images of the heart can be taken from various angles, but efficient analysis of cardiac ultrasound images requires recognizing the position of the imaged heart (view) to enable identification of important cardiac structures. In accordance with an exemplary embodiment of the invention, view identification module (103) implements methods for identifying an unknown cardiac image as one of the standard views. In addition, the view identification module (103) may implements methods for determining (for each view label) a confidence or likelihood measure that the identified view is properly labeled.

Ex1005, [0019].

120. I note that paragraph 19 of Krishnan refers to the view identification module as module 103, which is a typographical error because Figure 1 illustrates the view identification module as module 104.

121. 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." Ex1005, [0020].

> The quality assessment module (105) <u>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</u>. In other exemplary embodiments of the invention, the results of anatomy and/or view identification may be used for quality assessment. Moreover, methods

> can be implemented for providing real-time feedback during image acquisition regarding the diagnostic quality of the acquired images, allowing for changes in the image acquisition. In addition, methods can be implemented for determining a quality measure within a predefined range of values to provide an indication as the quality level of the acquired images based on some specified criteria.

Ex1005, [0020].

122. Thus, feature analysis module 102 is the only module that receives images (*id.*, [0017]), whereas modules 103, 104, and 105 "use[] the extracted features/parameters" output by module 102 as an input, not the images themselves (*id.*, [0018]-[0020]). Krishnan discloses three alternative embodiments for implementing modules 103-105: database querying methods, template-based methods, and classification methods. Ex1005, [0021]-[0023].

> The system (100) further comprises a database (106) of previously diagnosed/labeled medical images, a template database (107) and a classification system (108), which can be used singularly, or in combination, by one or more of the various automated decision support modules (102˜105) of the data processing system (101) to perform their respective functions. <u>For example, in one exemplary embodiment, the various modules (103), (104) and (105) implement database querying methods to use extracted feature data to search for similar labeled cases in the database (106)</u>. The database (106) may comprise a plurality of labeled/diagnosed medical images for various

clinical domains, which are indexed using a multi-dimensional indexing scheme based on relevant features/parameters. In such instance, the features/parameters extracted from an image dataset under consideration can be compared to the feature data of known cases in the database (106) according to some metrics or criteria identify the particular anatomy or view, or help identify the quality of the image extracted.

Ex1005, [0021].

In another exemplary embodiment, the various modules (103), (104) and (105) can implement template-based methods to use extracted feature data to search for similar templates in template database (107). In particular, various templates can be constructed using information obtained from the database of cases (106). For example, feature data over a plurality of known cases for a given identity and view can be processed using statistical techniques to derive feature data for a template representative over the set of related cases. In this instance, the features/parameters extracted from an image dataset under consideration can be compared to the feature data for templates in the database (107) according to some metrics or criteria identify the particular anatomy or view, or help identify the quality of the image extracted.

Ex1005, [0022].

In another exemplary embodiment, the various modules (103), (104) and (105) can implement classification methods that utilize the

> classification module (108) to process extracted feature data to classify the image dataset under consideration. In the exemplary embodiment of FIG. 1, the classification module (108) comprises a learning engine (109) and knowledge base (110) to implement a principle (machine) learning classification system. 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/labeled cases. The classifiers are implemented by the various decision support modules (102~105) for performing their respective functions.

Ex1005, [0023].

123. When describing the "classifier" embodiment, Krishnan discloses that "the various modules (103), (104) and (105) can implement classification methods that utilize the classification module (108) to process extracted feature data to classify the image dataset under consideration." Ex1005, [0023]. Krishnan further discloses that "classification module (108) comprises a learning engine (109) and knowledge base (110) to implement a principle (machine) learning classification system," and that "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/labeled cases." *Id.* "The classifiers are implemented by the various decision support modules (102~105) for performing their respective functions." *Id.* In my opinion, Krishnan discloses that only modules 103, 104, and 105 may be implemented using classification methods (and further, these modules

only use classification methods if implemented according to the classification method alternative embodiment, which is described in more detail as to Figure 5). The generic reference to "102~105" at the conclusion of paragraph 23 is a typographical error, which is clear because the first sentence of the paragraph explicitly lists only modules 103, 104, and 105 as implementing "classification methods" according to one of the alternative embodiments.

124. Krishnan's process is described in more detail with respect to Figure 2.

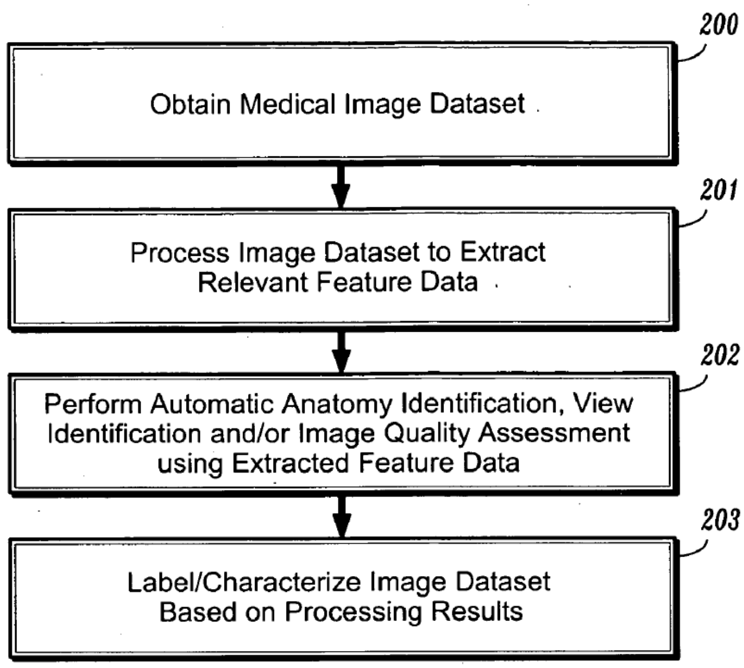

FIG. 2

EX1005, Fig. 2.

125. In step 200, the process obtains the medical image dataset. In step 201,

the process processes the image dataset to extract relevant feature data. Step 201 is performed by the automatic feature analysis module 102. Specifically, Krishnan describes performing feature extraction according to "known" methods such as "segmentation" or "filtering"—not learning the extracted features using a neural network. Ex1005, [0034]. In step 202, the process performs automatic anatomy identification, view identification and/or image quality assessment using extracted feature data as an input (which was output from the automatic feature analysis module 102). Step 202 is performed by modules 103 (automatic anatomy identification), 104 (automatic view identification), and 105 (automatic quality assessment). In step 203, the process labels/characterizes the image dataset based on processing results.

> Referring now to FIG. 2, a flow diagram illustrates methods for providing automated decision support for medical imaging, according to exemplary embodiments of the invention. For purposes of illustration, exemplary methods for automated decision support will be described with reference to the exemplary system of FIG. 1. <u>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)</u>. The image dataset may be obtained using a medical imaging system for real-time acquisition and processing of raw image data, such as raw CT data (radon data) which is acquired during a CT scan or raw data that is acquired using other imaging

> modalities. Alternatively, the image dataset may be obtained by accessing a previously acquired, and persistently stored image dataset. The digital image data (10) may comprise one or more 2D slices or three-dimensional volumetric images, which are reconstructed from the raw image data and persistently stored. As noted above, an exemplary CAD process can support one or more imaging modalities such as MRI, PET, etc. Image data can be 2D (e.g. X-ray Mammography images), 3D (e.g. CT, MRI, PET), 4D (Dynamic 3D MRI, multiple views of a beating heart acquired with a 3D Ultrasound probe), etc.

Ex1005, [0033].

> Next, the image dataset will be processed to determine or otherwise 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). As noted above, the relevant features/parameters that are extracted/determined from the image dataset will vary depending on the imaging modality, the supported clinical domains, and the methods implemented for providing automated decision support, and one of ordinary skill in the art can readily envision various types of feature data or parameters that can be extracted or determined from medical image data for use with automated anatomy and view identification methods and image quality assessment methods according to exemplary embodiments of the invention. For example, various parameters related to optical density and contrast can be extracted 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. These features could include any kind of characteristic that could be extracted from the image, such as a particular shape or texture. Further, various types of feature data can be obtained across images, such as motion of a particular point, or the change in a particular feature across images. In other embodiments, feature data may include gradient feature data that is computed from image data along various axes (x, y, z), distributions of pixel intensities, or other statistical features, or combinations of different features.

Ex1005, [0034].

> The image dataset will be labeled or otherwise classified based on the processing results obtained (step 203). For instance, for anatomy and view identification, a medical image will be labeled with the appropriate anatomy and view identification. In addition, for each anatomy/view ID label, a confidence or likelihood measure that the identified anatomy/view is properly labeled. Moreover, for image quality assessment, the medical images may include a quality score (within a predefined range) that provides an indication a diagnostic quality level of the medical images.

Ex1005, [0036].

126. Krishnan illustrates the alternative approaches for step 202 (that is, for the steps performed by modules 103, 104, and 105) in Figures 3, 4, and 5. Ex1005, [0035]. Figure 3 corresponds to the database querying approach, Figure 4 corresponds to the template processing approach, and Figure 5 corresponds to the classifier approach. As to each approach, Krishnan discloses the modules "utilize the extracted features to provide automated decision support functions." *Id.*;.

> Methods for automatic anatomy identification, automatic view identification and 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 to provide automated decision support functions.

Ex1005, [0035].

127. As to database querying methods (Fig. 3), Krishnan discloses that the "methods of FIG. 3 may be implemented by modules (103), (104), and/or (105) of FIG. 1 and in step 202 of FIG. 2."

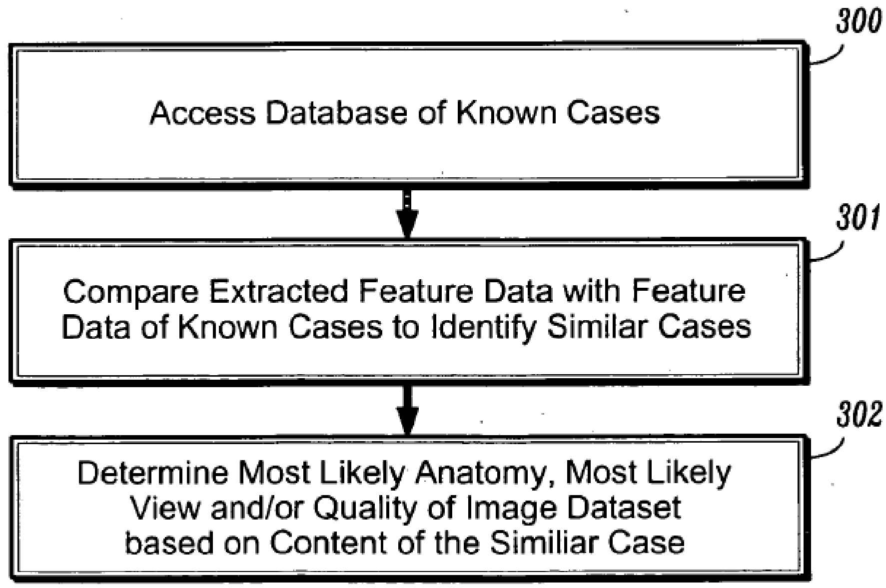

FIG. 3

Ex1005, Fig. 3.

FIG. 3 is a flow diagram illustrating methods for implementing automated decision support for medical images using database query methods according to exemplary embodiments of the invention. The methods of FIG. 3 may be implemented by the modules (103), (104) and/or (105) of FIG. 1 and in step 202 of FIG. 2. In one exemplary embodiment, a query can be formulated using the feature data extracted from the image dataset and the database of known cases would be accessed (step 300) and searched using the query. The extracted feature data comprising the query would be compared to features of known cases to identify similar cases (step 301). The content of the identified cases would then be used to determine the most likely anatomy or view for the subject image, or to determine the quality of the acquired image (step 302).

Ex1005, [0037].

> For example, consider the problem of identifying the apical four-chamber view in echocardiography. A set of typical apical four chamber views would reveal a number of features, such as the presence of four chambers, and a general shape for the heart. It is also described by the lack of other features, such as the absence of the aortic outflow track (which would lend itself to the so-called apical five chamber view). These features could be extracted from a test image, and compared to a set of features from the known view.

Ex1005, [0038].

> The same concept would be used in anatomy identification. For example, consider an ultrasound image of a kidney. Features would be extracted and compared with a database of cases representing all kinds of anatomy, including liver, gall bladder, kidney, etc. One could even have right and left kidneys in the database. Based on a comparison with these known cases, and the most likely anatomy would be reported.

Ex1005, [0039].

> Methods for indexing a database of images, and using low-level features to search the database can be implemented using the techniques disclosed in commonly assigned U.S. patent application Ser. No. 10/703,024, filed on Nov. 6, 2003, entitled "System and Method for Performing Probabilistic Classification and Decision Support Using Multidimensional Medical Image Databases", which is incorporated herein by reference. In one embodiment, the database could be

> constructed with either the images, or with just the feature representations of the images. The system could identify similar images, and then determine anatomy, view and/or quality based on the content of the similar images.

Ex1005, [0040].

128. As to template-based methods (Fig. 4), Krishnan discloses that the modules 103, 104, and 105 would use extracted feature data from images to compare to features of templates.

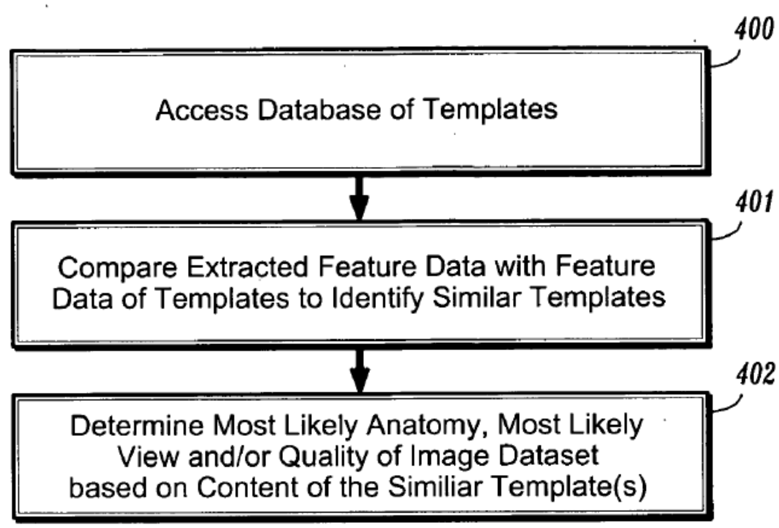

FIG. 4

Ex1005, Fig. 4.

> FIG. 4 is a flow diagram illustrating methods for implementing automated decision support for medical images using template-based methods according to exemplary embodiments of the invention. In one exemplary embodiment, <u>a query can be formulated using the feature data extracted from the image dataset and the database of templates</u>

> would be accessed (step 400) and searched using the query. The extracted feature data comprising the query would be compared to features of the templates to identify similar templates (step 401). The content of the identified templates would then be used to determine the most likely anatomy or view for the subject image, or to determine the quality of the acquired image (step 402). As noted above, the database of known cases could be used to construct templates. For example, templates could be constructed for different cardiac views: apical four chamber, apical two chamber, etc. The system could then assess similarity to each of these templates, which provides a simpler operational approach then searching a database.

Ex1005, [0041].

129. As to the classification methods embodiment (Fig. 5), Krishnan discloses inputting extracted features of images into the "classifiers." Ex1005, [0042]-[0044].

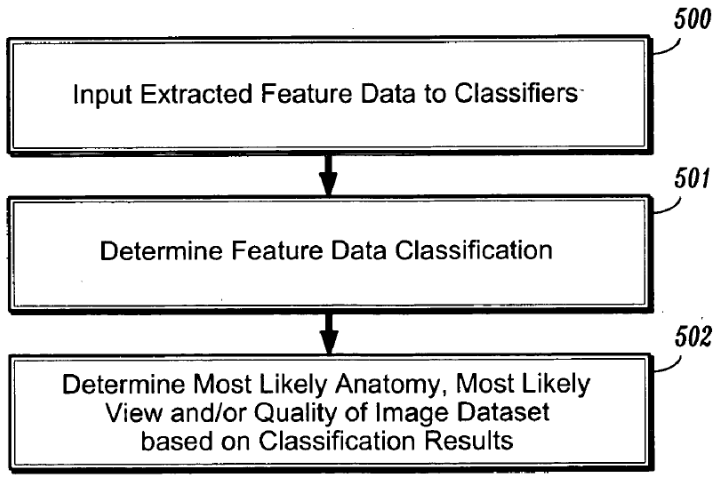

FIG. 5

Ex1005, Fig. 5.

130. Specifically, according to this alternative embodiment, "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)." *Id.*, [0042].

> FIG. 5 is a flow diagram illustrating methods for implementing automated decision support for medical images using classification according to exemplary embodiments of the invention. 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). The classification results would be used to determine the most likely anatomy or view, or assess image quality (step 502).

Ex1005, [0042].

131. "The classification results would be used to determine the most likely anatomy or view, or assess image quality (step 502)." Ex1005, [0042]. "For example, a bank of classifiers could be constructed to classify the images <u>based on the features extracted</u>." *Id.*, [0043]. "These classifiers would use the set of <u>features as an input</u>, and classify the image as belonging to a particular anatomy, view, or level or quality." *Id*. Krishnan discloses that the "classifiers" (i.e., modules 103/104/105) (*id.*, [0023]) may be "built using neural networks" (*id.*, [0044]).

> For example, <u>a bank of classifiers could be constructed to classify the images based on the features extracted</u>. That is, a set of classifiers would be "learned" based on a database of cases. <u>These 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</u>. In the exemplary embodiment of FIG. 1<u>, the classification system (108) includes the knowledge base (110) that is used to process the extracted features/parameters and classify the images</u>. The knowledge base (110) maintains one or more trained classification models, parameters, and/or other data structures of learned knowledge, etc.

Ex1005, [0043].

> It is to be understood that the term "classifiers" as used herein generally refers to various types of classifier frameworks, such as hierarchical classifiers, ensemble classifiers, etc. In addition, a

> classifier design can include a multiplicity of classifiers that attempt to partition data into two groups and organized either organized hierarchically or run in parallel and then combined to find the best classification. Further, a classifier can include ensemble classifiers wherein a large number of classifiers (referred to as a "forest of classifiers") all attempting to perform the same classification task are learned, but trained with different data/variables/parameters, and then combined to produce a final classification label. <u>The classification methods implemented may be "black boxes" that are unable to explain their prediction to a user (which is the case if classifiers are built using neural networks, example)</u>. The classification methods may be "white boxes" that are in a human readable form (which is the case if classifiers are built using decision trees, for example). In other embodiments, the classification models may be "gray boxes" that can partially explain how solutions are derived (e.g., a combination of "white box" and "black box" type classifiers).

Ex1005, [0044].

132. In my opinion, and critically, Krishnan does not disclose that classification module 108/learning engine 109/knowledge base 110 shown in Figure 1 are associated with feature extraction module 102. Rather, Krishnan discloses that classification module 108/learning engine 109/knowledge base 110 may support "classification methods" performed by modules 103/104/105. *Id.*, [0023]. Modules 103/104/105 still "process extracted feature data" received from module 102 when

implementing classification methods. *Id.* In other words, as I described above, regardless of whether modules 103/104/105 are implemented in alternative embodiments according to database querying, template-based, or classification methods, the function of module 102 is the same—it extracts feature data according to "known" non-neural-network techniques and provides the feature data as input to modules 103/104/105. The classifiers may separately be "built using neural networks" (*id.*, [0044]), and modules 103/104/105 may utilize classification methods to process the feature data that has already been extracted by module 102 (which was extracted according to non-neural network techniques).

> [T]he various modules (103), (104)[,] and (105) can implement classification methods that utilize the classification module (108) to process extracted feature data to classify the image dataset under consideration. In the exemplary embodiment of FIG. 1, the classification module (108) comprises a learning engine (109) and knowledge base (110) to implement a principle (machine) learning classification system. 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/labeled cases. The classifiers are implemented by the various decision

> support modules (102~105) for performing their respective functions.[4]

Id., [0023].

133. Thus, in my opinion, a person having ordinary skill in the art would have understood that Krishnan does not disclose implementing module 102 using classification methods, where the "classifiers" may be built using neural networks. Rather, as I explained, Krishnan discloses only that modules 103, 104, and 105 may be implemented—according to one alternative embodiment—using classification methods, and that module 102 would still perform feature extraction using "known" segmentation and/or filtering methods.

134. Given that Krishnan excludes module 102 from using classification methods and discloses that modules 103/104/105 receive extracted features from module 102 regardless of which of the three alternative embodiments for modules 103/104/105 is employed, a person having ordinary skill in the art would have understood that the "known" techniques module 102 employs for feature extraction

[4] Once again, although Krishnan refers to module 102 as implementing "classifiers" in this sentence, this is clearly an error because the first sentence in the paragraph states that only modules 103/104/105 "can implement classification methods."

would not have employed neural networks. Indeed, I was working in this field at the time of Krishnan's filing, and in my opinion a person having ordinary skill in the art would have interpreted Krishnan to be referring to "known" non-neural network techniques. As I discussed in §VII.A, this is also consistent with the fact that the shift from non-learning-based feature extraction to neural network-based feature learning did not occur until 2012 with the introduction of AlexNet. At the time of Krishnan's filing in 2005, "known segmentation and/or filtering methods" would have been understood by a person having ordinary skill in the art to refer exclusively to conventional, non-learning-based techniques such as edge detection, thresholding, region-based methods, watersheds, and dynamic programming-based optimization approaches—none of which involve neural networks.

135. In my opinion, a person having ordinary skill in the art would also have understood that the extracted features that are input into modules 103, 104, and 105 are not the same thing as the images. Krishnan's feature extraction is a separate preprocessing step, and the extracted features are engineered attributes of the images, not the images themselves.

136. Rather, as I described previously, Krishnan discloses the feature extraction that automatic feature analysis module 102 performs can utilize "known segmentation and/or filtering methods" to isolate "features or anatomies of interest" based on expected image characteristics, such as "edges, identifiable structures,

boundaries, changes or transitions in colors or intensities, changes or transitions in spectrographic information." *See id.*, [0034]. Krishnan discloses that "[t]hese features could include any kind of characteristic that could be extracted from the image" and provides "a particular shape or texture"[5] as examples. *See id.*

137. Krishnan discloses that the extracted features are information collected from image content (e.g., edges, regions, intensities, etc.) and are more limited than the raw image. Instead, they capture only certain aspects of what the image depicts. Thus, a person having ordinary skill in the art would have understood that the extracted features are not the holistic visual content of an image, rather they are image features/descriptors that a human designer expected to be useful for a specific task such as identifying the anatomy and view, diagnostic image quality, etc.

138. Krishnan makes this distinction clear when it describes the feature extraction step as "automatically extract[ing] and process[ing] relevant information from the medical image data to provide various decision support function(s) for evaluating the medical images" and disclosing embodiments where a "database

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[5] Krishnan's reference to "a particular shape or texture" again suggests that the features are extracted using non-neural network techniques.

could be constructed with either the images, or with just the feature representations of the images." *See id*., [0016], [0040].

> FIG. 1 illustrates a high-level block diagram of a system (100) for providing automated decision support for medical imaging, according to an exemplary embodiment of the invention. In general, the exemplary system (100) comprises a data processing module (101) that implements various methods for analyzing medical image data (10) in one or more imaging modalities (e.g., ultrasound image data, MRI data, nuclear medicine data, etc.) <u>to automatically extract and process relevant information from the medical image data to provide various decision support function(s) for evaluating the medical images</u>. In the exemplary embodiment, the data processing module (101) comprises an automatic feature analysis module (102), an anatomy identification module (103), a view identification module (104) and an image quality assessment module (105).

Ex1005, [0016].

> Methods for indexing a database of images, and using low-level features to search the database can be implemented using the techniques disclosed in commonly assigned U.S. patent application Ser. No. 10/703,024, filed on Nov. 6, 2003, entitled "System and Method for Performing Probabilistic Classification and Decision Support Using Multidimensional Medical Image Databases", which is incorporated herein by reference. In one embodiment, the <u>database could be constructed with either the images, or with just the feature representations of the images</u>. The system could identify similar

> images, and then determine anatomy, view and/or quality based on the content of the similar images.

Ex1005, [0040].

139. Further, as I described above regarding Figures 1 and 2, Krishnan discloses a sequential pipeline where features are extracted by module 102 (step 201) and then, in step 202, modules 103, 104, and 105 receive extracted features as inputs. After features are extracted by module 102, it would not be possible to reverse the process and reconstruct the original image from the features.

140. I note that Krishan discloses, for example, that "[a] set of typical apical four chamber views would reveal a number of features, such as the presence of four chambers, and a general shape for the heart." Ex1005, [0038]. However, these are features meant for computational analysis. Their quantitative representation (say, a numeric vector of values) would not allow a technician or clinician to interpret the anatomical structures, the view, or image quality from these features and could not be used to display the heart's anatomy.

> For example, consider the problem of identifying the apical four-chamber view in echocardiography. A set of typical apical four chamber views would reveal a number of features, such as the presence of four chambers, and a general shape for the heart. It is also described by the lack of other features, such as the absence of the aortic outflow track (which would lend itself to the so-called apical five chamber

> view). These features could be extracted from a test image, and compared to a set of features from the known view.

Ex1005, [0038].

141. Thus, in my opinion, even in the alternative embodiment in which modules 103/104/105 employ classification methods, Krishnan does not disclose that these modules take images as input—for example, to derive extracted features from the images or to train the classifiers. Instead, according to all three alternative embodiments, modules 103/104/105 take extracted features produced by module 102 as input. Ex1005, [0018]-[0020], [0034]-[0037], [0042]-[0043].

B. Chen (Ex1009)

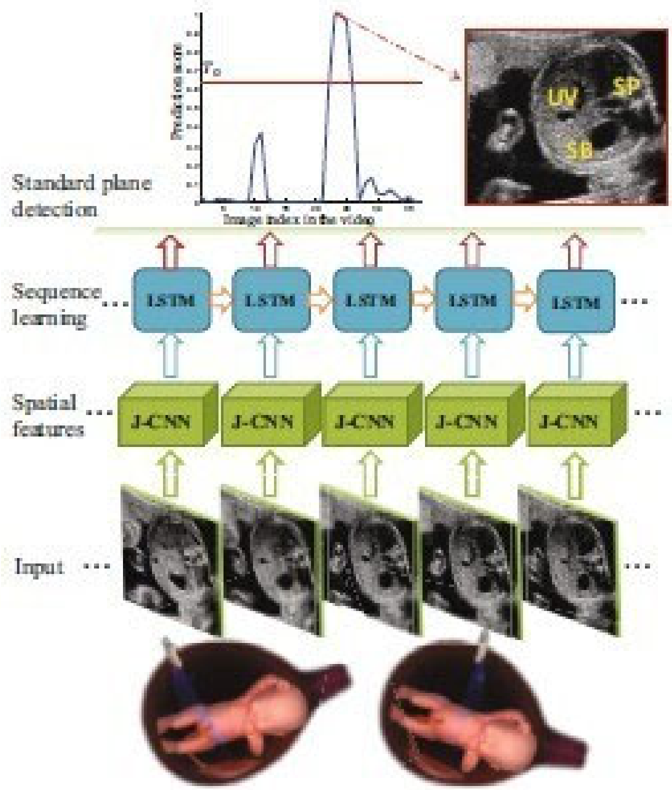
142. Chen is directed to automatically detecting standard fetal ultrasound planes from ultrasound videos using neural networks. Ex1009, Abstract. Specifically, Chen describes "a knowledge transferred recurrent neural network (T-RNN)," "which is a hybrid model integrating deep convolutional neural networks (CNN) and recurrent neural networks (LSTM model)." *Id.*, 509. The T-RNN detects fetal ultrasound standard planes from ultrasound video sequences. *See id.*, 514.

143. Chen uses joint learning of CNNs ("J-CNN") (Ex1009, 509), and the J-CNN takes raw ultrasound image frames as input—not extracted features. *See* Ex1009, 510 (table 1 showing the input is a "227x227x1" image frame), 511 ("Given the input frame I_{mk}, the probability map of the ROI [regions of interest] is computed

by the J-CNN model…"); Ex2052, 13:8-10 (Dr. Deo confirming that Chen's J-CNN takes raw ultrasound image frames as input).

144. The J-CNN extracts "deep learning based spatial feature representations" from each frame. Ex1009, 508; *see id.*, 511 ("Features in the penultimate layer (i.e., activations of F6 layer) of the J-CNN model are then extracted from the ROI of each frame"). These learned spatial features are then input into the LSTM, and "the temporal information is explored via the LSTM model based on the features of ROIs in consecutive frames extracted from the J-CNN model." *Id.*, 509.

145. Inputting images into the J-CNN and spatial features into the LSTM is depicted below in Figure 2.



Ex1009, Fig. 2 (left side).

146. Critically, Chen's feature extraction (J-CNN) and classification (LSTM) are integrated in a single end-to-end system. They are not separate modules like Krishnan's module 102 and modules 103-105. *See* Ex1009, 509 (describing the T-RNN as "a hybrid model integrating deep convolutional neural networks (CNN) and recurrent neural networks (LSTM model)").

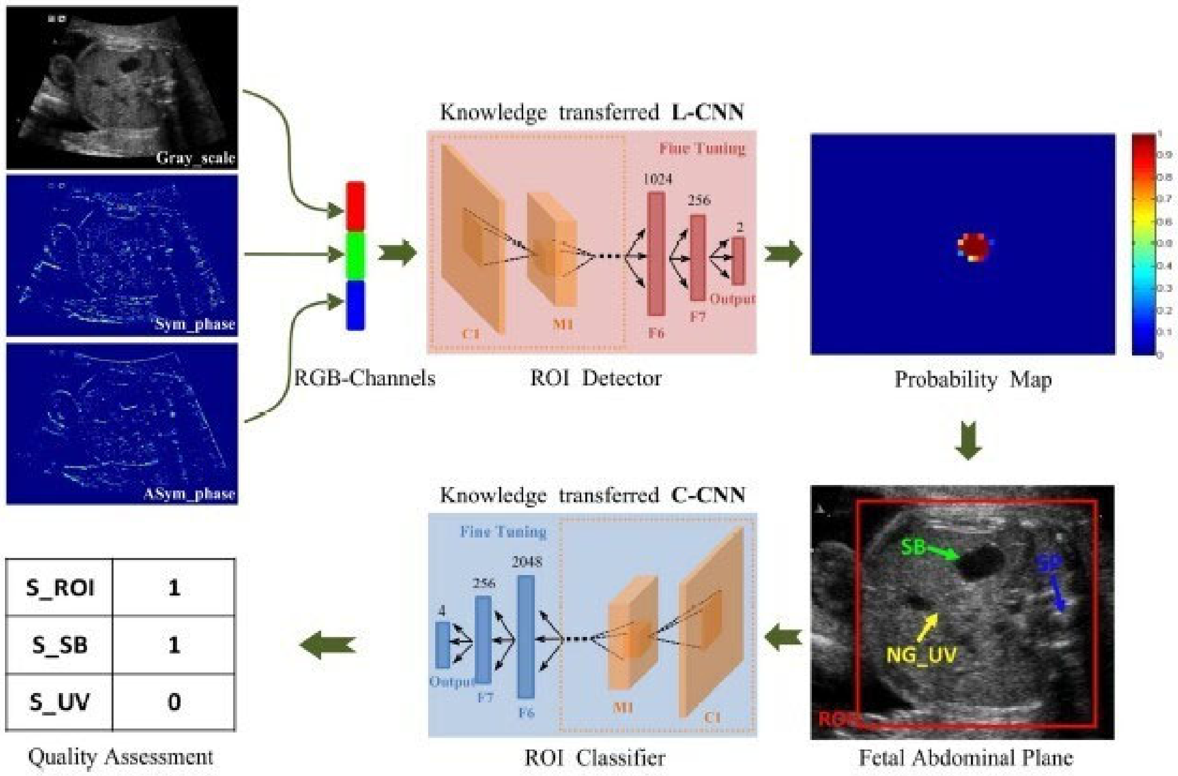
147. Chen's neural networks do not output any quality assessment value. Thus, Chen's neural networks are only trained to output identified fetal ultrasound standard planes. *See id.*, 509 ("ROI classifier is first trained based on the joint learning of convolutional neural networks (J-CNN) across multi-tasks to locate the

most discriminative regions for US standard plane detection.”). Chen states that it discloses “a general framework [that] can be easily extended to other [ultrasound] standard plane or anatomical structure detection,” but does not specifically explain how its framework would be modified to work with other implementations. *See id.*

C. Wu (Ex1010)

148. Wu is directed to quality assessment of fetal ultrasound images. Ex1010, Abstract. Wu utilizes two deep convolutional neural networks (denoted L-CNN and C-CNN). *Id.*, Fig. 3.

149. Wu’s L-CNN takes the original ultrasound image together with symmetric and asymmetric phase features as its three inputs. *Id.*, 4 (“For the L-CNN, the input sources include the original US image, symmetric and asymmetric phase features.”); *id.,* 5-6 (describing computation of phase features from 2-D log-Gabor filters). These inputs are spatial image data, unlike the engineered feature descriptors that Krishnan’s module 102 outputs.



Ex1010, Fig. 3.

150. Wu's L-CNN and C-CNN are integrated through knowledge transfer. The L-CNN extracts features from images to identify a region of interest (ROI) in the image, the C-CNN receives the ROI as an input, and "[t]he knowledge learned from the L-CNN will be introduced to the C-CNN as initialization for the learning of four-class differentiation of [ultrasound] images." *See id.*, 4 ("The L-CNN will help to locate the ROI of fetal abdominal region, which is the input of the C-CNN. The knowledge learned from the L-CNN will be introduced to the C-CNN as initialization for the learning of four-class differentiation of [ultrasound] images.").

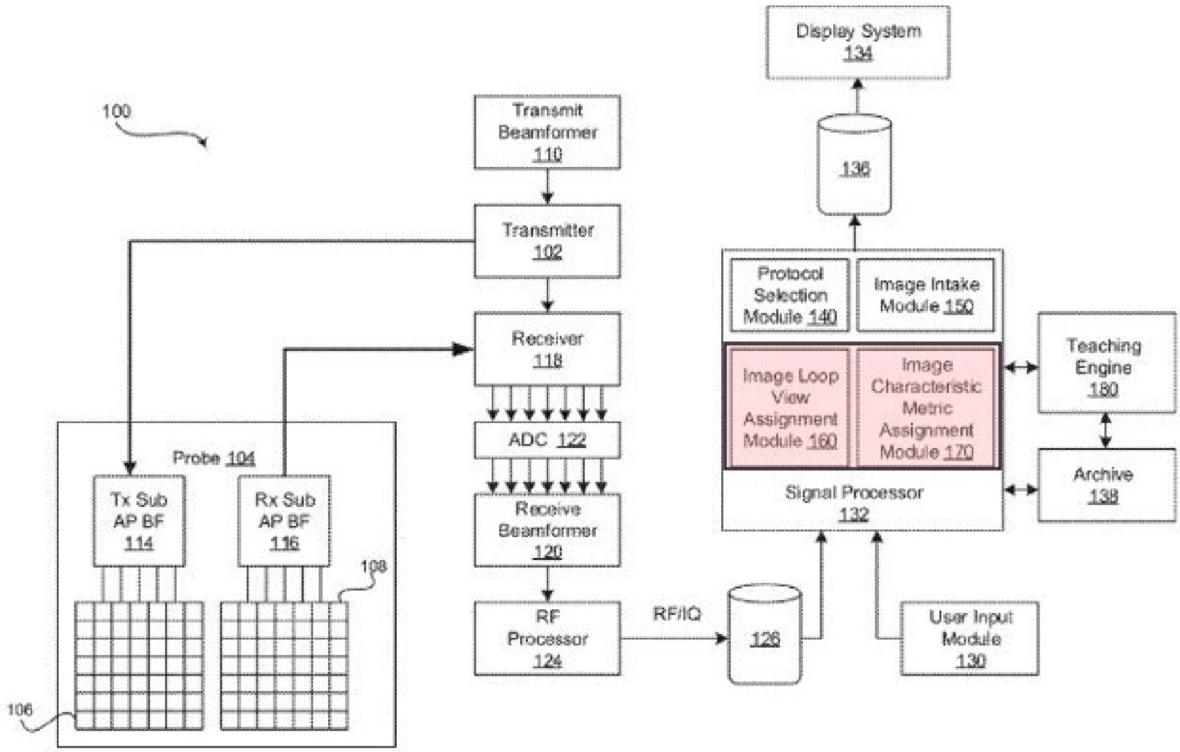
151. The C-CNN further outputs a quality assessment. *Id.*, 3 ("[T]he C-CNN model attempts to categorize the ROIs into 4 classes of all possible cases of the goodness of depiction for SB and UV structures."), Abstract ("Based on the ROI found by the L-CNN, the C-CNN evaluates the image quality by assessing the goodness of depiction for the key structures of stomach bubble and umbilical vein.").

152. Wu's L-CNN for feature extraction and C-CNN for quality assessment thus are integrated. In other words, they are not independent modules that could be separated and recombined with other systems without modification.

153. Notably, Wu does not perform view identification—it is limited to quality assessment of fetal abdominal images. Ex1010, Abstract. Wu states that its "proposed [quality assessment] scheme can be easily generalized to other types of fetal [ultrasound] views," but does not specifically describe how its system would be modified to do so. *See id.*, 3.

D. Aase (Ex1006)

154. Aase is directed to automatic selection of ultrasound image loops from continuously captured ultrasound stress echocardiographic images. Ex1006, Abstract. Central to Aase are image loop view assignment module 160 and image characteristic metric assignment module 170.



Ex1006, Fig. 2.

155. Module 160 utilizes deep learning or neural networks to analyze the anatomical structures within the ultrasound frames and automatically assign a "view type" to each captured loop. *Id.*, [0032]-[0033]. Module 170 utilizes deep learning or neural networks to provide an "image characteristic metric" (e.g., score of image quality) to the image loops. *Id.*, [0035]. Aase's modules 160 and 170 each receive image loops as input—not extracted features. *Id.*, [0033] (as to module 160, disclosing that "the input layer may have a neuron for each pixel or a group of pixels from an image loop 220, 320"), [0035] (as to module 170, disclosing that "[t]he input layer may include a neuron for each pixel or a group of pixels from an image loop 220, 320").

156. The feature extraction processing for modules 160 and 170 is embedded in the initial layers within the neural networks of these modules. *See id.*, [0033] ("Each neuron of each layer may perform a processing function and pass the processed ultrasound image information to one of a plurality of neurons of a downstream layer for further processing. As an example, neurons of a first layer may learn to recognize edges of structure in the ultrasound image data. The neurons of a second layer may learn to recognize shapes based on the detected edges from the first layer. The neurons of a third layer may learn positions of the recognized shapes relative to detected landmarks in the ultrasound image data."); *id.*, [0035] ("As an example, neurons of a first layer may learn to recognize a blocked ultrasound transducer aperture, such as by an ultrasound operator finger, a rib of a patient, or any suitable obstruction. The neurons of a second layer may learn to recognize shadows in ultrasound image data caused by a patient's ribs or a breathing lung, among other things. The neurons of a third layer may learn to recognize movement noise caused by the probe 104 transitioning from one image view type to another image view type.").

157. Because Aase's feature extraction is embedded within its neural networks, the feature extraction and classification functions of modules 160 and 170 are integrated. In other words, they are not independent modules that could be separated and recombined with other systems without modification.

158. Since the neural networks of modules 160 and 170 expect specific learned feature representations produced by these initial layers, Aase's subsequent classification layers would not perform as designed if they were to receive features that they were never trained on. *See id*.

X. PETITIONER HAS NOT ESTABLISHED BY A PREPONDERANCE OF THE EVIDENCE THAT ANY CHALLENGED CLAIM IS UNPATENTABLE

159. I understand that Petitioner has the burden to show with particularity why the challenged claims are unpatentable. I further understand that the Petition must specify where each element of a challenged claim is found in the prior art patents or printed publications that Petitioner relies upon.

160. As I explain below, it is my opinion that the Petition has not shown that any challenged claim is unpatentable.

A. Ground A: Krishnan Does Not Anticipate Claims 1-3, 9, 11, 21-22, 27, and 29-30

1. Krishnan Fails to Disclose That "Deriv[ing] One or More Extracted Feature Representations" From Ultrasound Images Is Performed Using a Neural Network (Limitations 1(b)/21(b)/30(b))

a. Limitations 1(b)/21(b)

161. Starting with limitations 1(b) and 21(b), when properly construed, these limitations require "deriv[ing] one or more extracted feature representations from the set of ultrasound images," where the extracted feature representations are learned

using a neural network. §VIII.A.

162. The Petition asserts that automatic feature analysis module 102 discloses these limitations. Petition, 24-26 (for 1(b), citing Krishnan's automatic feature analysis module 102 in Figure 1, Krishnan's paragraphs 17 and 34, and Krishnan's Figure 2); *id.*, 39 (for limitation 21(b), pointing back to analysis of limitation 1(b)).

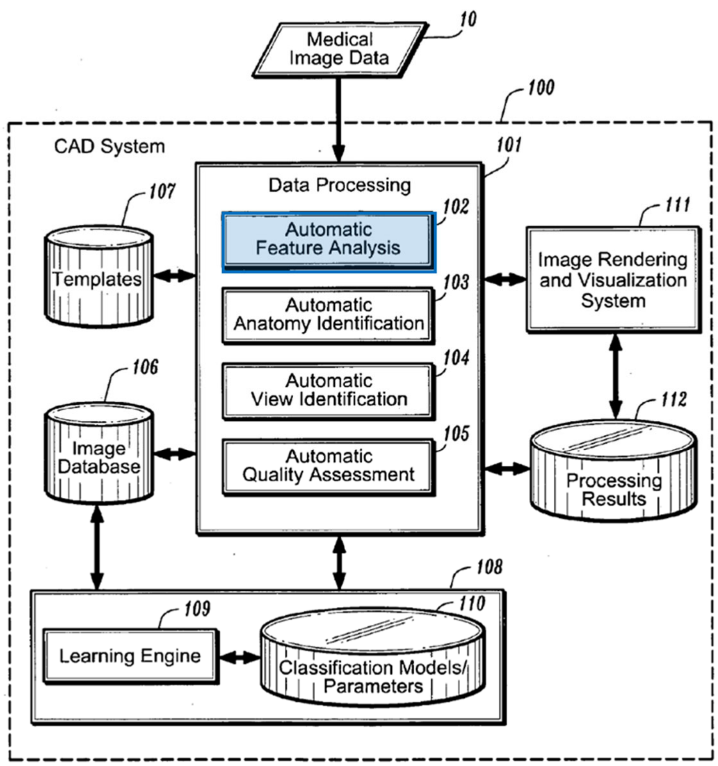


FIG. 1

Ex1005, Fig. 1.

163. As a threshold matter, the Petition does not allege that Krishnan's module 102 is a neural network for limitations 1(b) and 21(b). This is dispositive

under UBC's proposed construction and demonstrates that claims 1 and 21 have not been shown to be unpatentable. Indeed, the Petition does not even cite the Figure 5 embodiment for these limitations (which is the only embodiment that employs "classification methods" that employ classifiers that may be built using neural networks). Moreover, Dr. Deo also confirmed during his deposition that he did not opine that module 102 performs feature extraction using a neural network. Ex2051, 83:2-7 ("Q In your declaration, for limitation 1B, you did not opine that module 102 performs feature extraction using a neural network; is that right? A That's correct. Yes. Because 1B itself didn't mention a neural network. So there was no need to opine on it there."). And Petitioner has conceded in the parallel district court litigation that module 102 employs "non-neural network techniques." Ex2048, 18 ("Indeed, Krishnan acknowledges <u>known non-neural network techniques for extracting features from images</u> stating: 'Feature extraction can implement known segmentation and/or filtering methods for segmenting features or anatomies of interest…'").

164. Even if Petitioner belatedly attempts to argue that any module in Krishnan learns extracted features using a neural network, Petitioner would be incorrect. Specifically, even if the Petition had cited the Figure 5 embodiment, automatic feature analysis module 102 is not a neural network and does not employ neural network techniques. As explained in §IX.A, Krishnan does not disclose that

the neural network techniques associated with classification module 108/learning engine 109/knowledge base 110 are associated with feature extraction module 102. Rather, Krishnan discloses that classification module 108/learning engine 109/knowledge base 110 only support "classification" methods performed by modules 103/104/105, where the classifiers may be "built using neural networks." Ex1005, [0023], [0044]. To the extent isolated sentences in Krishnan refer to module 102 as employing classification methods, those are clearly errors because Krishnan elsewhere only refers to modules 103/104/105 as the modules that "can implement classification methods." *Id.*, [0023]; §IX.A. In this regard, there are other clear typographical errors in Krishnan when referring to the modules, and Dr. Deo admitted that Krishnan includes other typographical errors. Ex2051, 54:7-20, 55:20-25.

165. Rather than employ neural network techniques, Krishnan discloses that automatic feature analysis module 102 uses "known methods" such as segmentation or filtering to extract features by reference to "known or anticipated image characteristics." Ex1005, [0034] ("Feature extraction can implement <u>known segmentation and/or filtering methods</u> for segmenting features or anatomies of interest by reference to <u>known or anticipated image characteristics</u>, such as edges, identifiable structures, boundaries, changes or transitions in colors or intensities, changes or transitions in spectrographic information, etc., <u>using known methods</u>.");

Indeed, Petitioner has conceded in the parallel litigation that module 102 employs "non-neural network techniques" (Ex2048, 18), and the Petition elsewhere appears to admit that automatic feature analysis module 102 does not employ a neural network for learning extracted feature representations. For example, when summarizing Krishnan, the Petition omits automatic feature analysis module 102 when discussing modules that may employ "machine learning." Petition, 15 (stating that "modules 103-105 shown in Figure 1 perform their respective functions using machine learning") (citing Ex1005, [0023]); *see also id.* ("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.").

166. In sum, Krishnan's approach relies on module 102 extracting features according to manual/hand-crafted rules. These features are thus detected and generated using non-learning-based methods (e.g., segmentation, filtering) that were known in 2005 at the time of the filing of the application leading to the publication of Krishnan. *See* Ex1005, Cover. This would not have conveyed to a person having ordinary skill in the art that module 102 could be employed as a neural network for extracting features.

167. Petitioner also cannot rely on modules 103/104/105 as neural networks for deriving extracted features from images. Modules 103/104/105 do not perform

feature extraction and do not receive images. Instead, these modules "would use the set of [extracted] features as an input"—that is, the features that module 102 extracts using non-neural network techniques are used as inputs to modules 103/104/105 in each of the three alternative embodiments. *Id.,* [0043], step 500 of Fig. 5 ("Input Extracted Feature Data to Classifiers").

168. Thus, when limitations 1(b)/21(b) are properly construed such that "extracted feature representations" are "feature representations that are learned using a neural network," Krishnan fails to disclose these limitations.

b. Limitation 30(b)

169. Turning to limitation 30(b), the agreed construction requires that the structure corresponding to the function of "means for deriving one or more extracted feature representations from the set of ultrasound images" is "a processor and memory operating a neural network." Ex2031, §I.A.

170. Thus, the parties' agreed construction <u>requires</u> that the extracted feature representations be learned using a "processor and memory operating a neural network."

171. I note that the Petition is unclear, but Petitioner appears to argue that feature extraction module 102 may employ a neural network. Petition, 45-46 (identifying module 102 as a "classifier," asserting that "classifiers can be 'built using neural networks,'" and asserting that "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") (citing Ex1007 and Ex1014).

172. As I discussed above, Petitioner is incorrect, because even in the Figure 5 embodiment employing classification methods, module 102 does not employ a neural network to learn extracted features. §X.A.1.

173. Perhaps recognizing that Krishnan does not disclose employing a neural network for feature extraction, Petitioner cites Ex1007 and Ex1014 to argue that this was "well-known" prior to the '029 patent's priority date. Petition, 46. However, Petitioner asserts anticipation based on Krishnan, which only discloses using "known," non-learning-based feature extraction methods such as segmentation and filtering as of its filing/publication date in 2005. Ex1005, [0034].

174. I further note that Ex1007 and Ex1014 are dated at least 10 years after Krishnan's 2005 filing/publication. In my opinion, these exhibits do not inform—and certainly do not expand—the scope of the "known" feature extraction methods Krishnan discloses. Ex1007 (filed in 2015 and published in 2018); Ex1014 (publication dated in 2016). My opinion is that a person having ordinary skill in the art would have understood that the "known" methods that Krishnan discloses as of 2005 did not employ neural networks for feature extraction.

175. Accordingly, Petitioner's arguments with respect to limitation 30(b)

fail as well.

176. Thus, as with limitations 1(b) and 21(b), Krishnan does not disclose limitation 30(b) because Krishnan does not disclose learning extracted features with a neural network.

c. Additional Extrinsic Evidence Demonstrates That Krishnan's Feature Extraction Step Does Not Involve Learning

177. Although it is my opinion that Krishnan itself makes clear that its feature extraction does not involve learning extracted feature representations using a neural network, I note that additional evidence also demonstrates that Krishnan—which was filed/published in 2005—does not disclose learning extracted features.

178. The shift from non-learning-based methods for feature extraction as disclosed in Krishnan to new methods involving feature learning did not occur until 2012, when the deep learning revolution made feature learning viable at scale. For example, the 2012 paper "*ImageNet classification with deep convolutional neural networks*" ("AlexNet") demonstrated that a large convolutional neural network trained on 1.2 million images assigned an image among the 5 most-likely labels with an error rate of 17% (called top-5 error rate, with ImageNet containing images belonging to about 1,000 different labels), demonstrating performance far better than the previously leading approaches using hand-crafted features (26.2% with SIFT + Fisher vectors). *See* Ex1029, Abstract, Ex2035; Ex2036; Ex2037; Ex2038; Ex2039.

179. Prior to this, computer-vision pipelines used manually engineered features like SIFT (Scale-Invariant Feature Transform) and SURF (Speeded Up Robust Features), and progress relied on creating clever methods for feature extraction. *See* Ex2036, 1.

180. Further, it was known that conventional approaches using such manually engineered features were problematic. *See e.g.*:

> Although model-based methods for echo quality assessment can achieve good performance, these methods are view-specific because they require to generate a specific model or template for each view. In addition, the accurate generation of the template relies heavily on human experts or the image's contrast. For example, methods . . . [that] are designed for a specific B-mode view (A4C [] or PLAX []), require manual annotation [], and...rely heavily on the presence of the sharp edges in the image...would fail when applied to low contrast images.

Ex2037, 8.

181. The AlexNet results, however, showed that learned features can outperform hand-crafted ones. *See* Ex2036, 1 (explaining that "for much of the intervening time between the early 1990s and the <u>watershed results of 2012 (Krizhevsky *et al.*, 2012)</u>," features were manually engineered and that deep networks were not trained on large datasets). The impact was so significant that the

Royal Swedish Academy of Sciences recognized one of the authors, Hinton, "for foundational discoveries and inventions that enable machine learning with artificial neural networks" including devising algorithms for "autonomously find[ing] properties in data." *See* Ex2038; Ex2039.

182. Thus, in my opinion, a person having ordinary skill in the art would have understood Krishan did not disclose learning extracted feature representations using a neural network.

2. Petitioner Fails to Show That Krishnan Discloses a "Quality Assessment Value" Under the Construction Petitioner Is Bound by in this IPR (Limitations 1(c)/21(c)/30(c))

183. Limitations 1(c)/21(c)/30(c) each recite a "quality assessment value." Ex1001, claims 1, 21, 30. As I discussed in §VIII.B., I understand that Petitioner is bound in this proceeding to apply the construction for this term as "score of diagnostic image quality." Paper 15, 3 ("[T]he Office accepts Petitioner's 'consent' as a stipulation to construe 'quality assessment value' herein— and in any other proceeding before the Office that involves Petitioner and the same claim term—as 'score of diagnostic image quality,' as Petitioner proposed in district court").

184. To establish anticipation, I understand that Petitioner cannot mix teachings from distinct embodiments and instead must demonstrate that Krishnan discloses an embodiment that anticipates the claims.

185. For other limitations of claims 1 and 21, Petitioner relies on Krishnan's

classifier embodiment. For example, for limitation 1(d), Petitioner maps to the Figure 5 classifier embodiment. Petition, 30-31 ("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).'") (citing Ex1005, [0042]); *id*., 31 (citing Fig. 5, quoting step 502 ("Determine … Most Likely View … of Image Dataset"), and stating "[t]hus, Krishnan discloses" limitation 1(d)).

186. For limitation 21(d), Petitioner points back to its analysis of 1(d) without further analysis. *Id.*, 39.

187. For claim 30, Petitioner relies on the classifier embodiment of Figure 5 for limitation 30(b) as well at this limitation, 30(c). *Id.*, 45-49.

188. As I explained above, there are three alternative embodiments of the quality assessment module 105 in Krishnan (that is, the database querying, template based, and classification methods). Dr. Deo also agreed during his deposition that the other embodiments of module 105, such as implementation of database querying and template-based methods, are "alternatives" to the classifier embodiment. *See* Ex2051, 57:7-58:14. It is my opinion that there is no suggestion in Krishnan that the teachings regarding a "quality assessment value" as to the database querying and template-based alternative embodiments were intended to apply to the classifier

embodiment. Thus, I understand that teachings regarding what the "quality assessment value" may be in Krishnan relating to "alternative" embodiments are irrelevant, and Petitioner must demonstrate that the classifier embodiment produces a "score of diagnostic image quality" for limitations 1(c), 21(c), and 30(c).

189. Petitioner generally relies on Krishnan's quality assessment module 105 for teaching the quality assessment value of limitations 1(c), 21(c), and 30(c). Petition, 26-28 (1(c)), 38-39 (21(c)), 47-48 (30(c)). Petitioner cites general statements regarding a "level of diagnostic quality," a "range of values," or a "score." Petition, 26-28 (1(c): citing Ex1005, [0020], [0032], [0036]), 39 (21(c): pointing to analysis of 1(c)), 47-48 (30(c): citing Ex1005, citing Ex1005, [0020], [0021], [0023], [0043]). Other than paragraph 43, the disclosures in the cited paragraphs (including a "score") are general teachings that are not necessarily related to the classifier embodiment. Paragraph 43 describes the classifier embodiment and discloses that the quality assessment value may be a "level of quality," but states nothing about a "score." Ex1005, [0043] (referring to a "level of quality").

190. In my opinion, Petitioner has failed to show that Krishnan's quality assessment module 105 produces a "score of diagnostic image quality" when implemented according to the classifier embodiment. As to the classifier embodiment, I note that Dr. Deo opined in his declaration that the output could be a

score or could be a binary output, but Krishnan does not necessarily disclose that the output is a score. *See* Ex1002, ¶267 ("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)."). Dr. Deo then confirmed during his deposition that the quality assessment value in the classifier embodiment is not <u>necessarily</u> a score. Ex2051, 126:24-127:5 ("Q So when we're talking about your opinions regarding Krishnan's classifier on limitation 12B, is it your opinion that Krishnan teaches the classifier output could be a score or could be binary, but doesn't necessarily disclose one or the other? A That's correct. Yes."). Although Dr. Deo's opinions were stated with respect to limitation 12(b), they are general statements regarding Krishnan's classifier embodiment and apply with equal force to these limitations.

191. Thus, in my opinion, the Petition fails to show that Krishnan discloses the claimed "quality assessment value" under the construction that Petitioner is bound to in this IPR.

B. Ground B: The Krishnan-Chen Combination Does Not Render Obvious Claims 3-8 and 23-26

192. Petitioner's arguments related to the combination of Krishnan and Chen fail. As an initial matter, because Petitioner did not establish that the base independent claims 1 and 21 are taught by Krishnan as discussed above, Petitioner

has also failed to show that any of dependent claims 3-8 and 23-26 are unpatentable over Krishnan in view of Chen for at least this reason. *See* §X.A. In addition, it is my opinion that Petitioner fails to show that the combination of Krishnan and Chen renders obvious claims 3-8 and 23-26 for the reasons below.

1. Petitioner's Proposed Combination Is Unclear and Was Contradicted by Its Expert

193. Petitioner provides its motivation to combine theory with respect to claims 3 and 4 (Petition, 51-58) and otherwise refers back to the same theory for the rest of the claims (Petition, 58-64).

194. Petitioner offers unclear and contradictory descriptions for the proposed combination. Thus, Petitioner fails in my opinion to set forth a combination with particularity.

195. Petitioner first proposes to use Chen's neural network architecture to perform feature extraction in the Krishnan and Chen combination. Petition, 52-54 ("Rationale to combine: … Therefore, it would have been natural and obvious to a POSITA to combine the teachings of Krishnan and Chen by <u>using the neural network architecture disclosed in Chen to perform feature extraction</u> as described in Krishnan."), 57-58 ("Rationale to combine: A POSITA would be motivated to combine Krishnan-Chen in the manner proposed (i.e., <u>to use the T-RNN model disclosed in Chen to perform feature extraction and view identification as taught in</u>

Krishnan) for the same reasons already explained in Section IX.C.1 above. Ex1002, ¶214.”).

196. As discussed above, for the base independent claims 1 and 21, Petitioner relies on Krishnan’s automatic feature analysis module 102 for performing feature extraction using “known methods” such as segmentation or filtering to extract features by reference to “known or anticipated image characteristics.” *See* §X.A; Ex1005, [0034]. Thus, Petitioner’s initial proposal for the combination is to use Chen’s neural network architecture to perform feature extraction feature in place of Krishnan’s automatic feature analysis module 102 (and to remove modules 103-105 as well) without separately analyzing how Chen’s wholesale replacement discloses each limitation of claim 1.

197. However, Petitioner then contradicts this proposal and argues that a person having ordinary skill in the art would merely “add[]” the neural networks described in Chen to Krishnan’s existing classifiers “without modification.” Petition, 55 (“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. Implementing Chen with Krishnan would merely have involved adding the neural network classifier described in Chen, without modification, to the bank of classifiers described in Krishnan. Ex1002, ¶209.”); *id.*, 58 (“And, merely adding Chen’s T-RNN to Krishnan’s ‘bank of classifiers’ to

perform the same functions already described in Krishnan, would not require any modification of Krishnan or Chen. Ex1002, ¶216.”).

198. Dr. Deo provides the same arguments. Ex1002, ¶209 (“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.”); *id.*, ¶215 (“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 [no] experimentation on the part of the POSITA.”)[6].

199. The Petition provides no explanation for how wholesale replacement or the alleged addition of Chen’s neural network architecture to Krishnan without modification would work. Dr. Deo was also unable to explain how the proposed combination would work at his deposition, and in fact offered contradictory opinions.

200. For example, Dr. Deo contradicted the “adding” theory from his declaration by instead arguing that module 102, and potentially other modules,

[6] Dr. Deo clarified that the word “know” should be replaced with “no.” *See* Ex2051, 110:1-14.

would be replaced. *See* Ex2051, 107:11-21 (initially stating that the combination requires "no modification" to Krishnan), 108:1-109:19 (subsequently stating that Chen's neural network replaces Krishnan's module 102); 110:16-111:1 (stating the combination would require "little" experimentation); 111:13-22 (stating that the replacement of module 102 is "necessary"); 112:5-113:24 (stating that the combination may or may not require module 104 to be replaced).

201. At best, Petitioner offers two mutually exclusive paths—the combination can either replace Krishnan's module 102 and other modules with Chen's T-RNN neural network or "add" Chen's T-RNN to Krishnan's classifiers 103-105 (with module 102 still in place). Petitioner, however, never explains with particularity what its combination actually is and how Chen's neural network architecture would successfully be added to Krishnan (with or without modification).

202. Thus, in my opinion, Petitioner has not set forth a proposed combination with particularity.

2. A Person Having Ordinary Skill in the Art Would Not Have Been Motivated to Combine Krishnan and Chen and Would Not Have Reasonably Expected a Combination to Succeed

203. Even if the Petition had clearly articulated how Krishnan and Chen would be combined, in my opinion a person having ordinary skill in the art would not have been motivated to combine them. Krishnan discloses a conventional system

that relies on human-designed/hand-crafted rules to extract features with module 102 using "known segmentation and/or filtering methods." Ex1005, [0034]. Krishnan's module 102 removes the ability to train on raw images and discover patterns that human-designed rules could not find. The end-to-end approach in Chen is not compatible with the conventional approach disclosed in Krishnan, which uses a pipeline of serial modules rather than an integrated end-to-end neural network technique. A person having ordinary skill in the art seeking to implement a neural network that derives extracted features from images—or that is trained by receiving images as input and outputting quality assessment values and image properties—would not have found Krishnan's fundamentally different approach to be an appropriate starting point.

204. Even assuming a motivation, the combination certainly would require more than no or little modification and a person having ordinary skill in the art would not have had a reasonable expectation of success in combining Krishnan and Chen. The Petition advances two incompatible theories: (1) using Chen's T-RNN to perform feature extraction and, apparently, replacing modules 102-105; and (2) "adding" Chen's neural network (T-RNN) to Krishnan's bank of classifiers, with module 102 still in place (and potentially modules 103-105 still in place).

205. As to (1), Petitioner cannot reasonably contend that replacing modules 102-105 with Chen's T-RNN would require "little" or "no" modification, because it

is a wholesale replacement of Krishnan's sequential pipeline with a new architecture. Moreover, a wholesale replacement would not satisfy the claim, e.g., because Chen does not disclose outputting any quality assessment value.

206. As to (2), if Chen's T-RNN is "added" to Krishnan's classifiers 103-105 with module 102 still in place, this also would not require "little" or "no" modification. Chen's T-RNN includes J-CNN, which is designed to receive ultrasound image frames, not the extracted features that module 102 outputs. Ex1009, Fig. 2; Ex2052, 13:8-10. But if Krishnan's module 102 remains, Chen's J-CNN would instead receive extracted features. A person having ordinary skill in the art would not have expected reliable or useful results when Chen's J-CNN receives inputs it was not designed to receive. Indeed, Dr. Deo admitted during his deposition that classification modules 103-105 take extracted features as inputs and that module 102 is distinct because it does not implement classification methods like modules 103-105. *See* Ex2051, 54:22-55:10 (module 103 takes extracted features as input), 56:4-10 (module 104 takes extracted features as input), 56:23-57:4 (module 105 takes extracted features as input), 59:23-60:9 (module 102 is not listed as module that implements classification methods like modules 103-105). Because module 102 outputs extracted features and not images, Chen's J-CNN would not function as it was designed in Petitioner's combination because it would not receive raw images. Moreover, the Petition does not explain what role modules 103-105 would serve

alongside Chen's T-RNN, which itself includes classification layers.

207. Further, it was known that conventional feature extraction, like that provided by Krishnan's module 102, would not work well on low-contrast ultrasound images. *See* Ex2037, 8 ("[M]ethods . . . [that] are designed for a specific B-mode view (A4C [] or PLAX []), require manual annotation [], and...rely heavily on the presence of the sharp edges in the image...would fail when applied to low contrast images"). Therefore, feeding features extracted from ultrasound image into a deep neural network designed for raw images would not have had a reasonable expectation of success. *See id*.

208. In addition, if module 102 were to be replaced with Chen's feature extracting neural network while keeping Krishnan's modules 103-105 as-is, a person having ordinary skill in the art would not have reasonably expected the combination to succeed. Modules 103-105 were designed to input features that were extracted according to hand-crafted/human designed rules from module 102. Ex1005, [0034] ("<u>Feature extraction can implement known segmentation and/or filtering methods</u> for segmenting features or anatomies of interest <u>by reference to known or anticipated image characteristics</u>."). Feeding these modules learned features from a neural network would require redesigning and retraining modules 103-105 to accept different inputs. The Petition does not describe any of the modifications that would be needed and simultaneously asserts that only little or no modification would be

required, which is irreconcilable. Petition, 55, 58.

C. Ground C: Krishnan-Aase Does Not Render Obvious Claims 9/27 and 10/28

209. Because Petitioner did not establish that the base independent claims 1 and 21 are taught by Krishnan as discussed above, Petitioner has also failed to show that any of dependent claims 9-10 and 27-28 are obvious over Krishnan in view of Aase. *See* §X.A. But even if the independent claims were shown to be unpatentable, Petitioner has failed to meet its burden to show that these dependent claims would have been obvious.

210. For claims 9-10 and 27-28, the Petition proposes a combination of Krishnan and Aase, where Krishnan uses Aase's view-category-specific and quality-assessment-value specific neural networks. Petition, 65 ("Based on the express teachings in Krishnan, it would have been obvious to a POSITA to implement Krishnan using a view-category-specific neural network and a quality-assessment-value-specific neural network as described in Aase."), 66-67 ("Thus, whereas 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, Aase explicitly includes a view-category-specific neural network classifier and a quality-assessment-value-specific neural network classifier. Ex1002, ¶¶243-245."), 67 ("Aase makes explicit what Krishnan already discloses or

suggests, 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."), 67-68 ("A POSITA would also have had a reasonable expectation of success since Krishnan and Aase are directed to the same field of endeavor, and Krishnan already expressly describes using a bank or set of neural network classifiers. Implementing Krishnan in a manner that achieves the claimed subject matter <u>would not require any material modification or experimentation</u>. Ex1002, ¶¶247-248."), 69 ("Krishnan-Aase further teaches inputting the extracted features from a set of ultrasound images into separate quality assessment and view identification specific neural network classifiers, as claimed. *See* Section IX.D.1. Thus, Krishnan-Aase teaches all the elements of [10]/[28]. Ex1002, ¶¶249-254.").

211. For the same reasons described regarding Krishnan-Chen, a person having ordinary skill in the art would not have been motivated to combine Krishnan's conventional system that relies on human-designed/hand-crafted rules to extract features with Aase's neural network approach. §X.B.2.

212. Moreover, this proposed combination of Krishnan and Aase is fundamentally flawed. As is, Aase's feature extraction processing is embedded in the initial layers within the neural networks of its view-assignment-specific neural network (module 160) and quality-assessment-specific neural network (module 170). *See* Ex1006, [0033] ("Each neuron of each layer may perform a processing

function and pass the processed ultrasound image information to one of a plurality of neurons of a downstream layer for further processing. As an example, neurons of a first layer may learn to recognize edges of structure in the ultrasound image data. The neurons of a second layer may learn to recognize shapes based on the detected edges from the first layer. The neurons of a third layer may learn positions of the recognized shapes relative to detected landmarks in the ultrasound image data."); *id*., [0035] ("As an example, neurons of a first layer may learn to recognize a blocked ultrasound transducer aperture, such as by an ultrasound operator finger, a rib of a patient, or any suitable obstruction. The neurons of a second layer may learn to recognize shadows in ultrasound image data caused by a patient's ribs or a breathing lung, among other things. The neurons of a third layer may learn to recognize movement noise caused by the probe 104 transitioning from one image view type to another image view type.").

213. However, in Petitioner's proposed combination, Aase's quality-assessment-specific neural network and view-assignment-specific neural network are separated from Aase's feature extraction neural network. *See* Ex2051, 121:8-122:10 (explaining that initial layers of Aase's neural network classifiers do feature extraction for the purpose of view classification and quality assessment).

214. Rather than receiving specific learned feature representations produced by Aase's own feature extraction layers, Aase's classification neural networks would

instead receive outputs from Krishnan's module 102, which produces entirely different hand-crafted features (e.g., edges, boundaries, intensity transitions, etc.). *See* Ex1005, [0034] ("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.").

215. Since Aase's classification neural networks expect specific learned feature representations produced by its own feature extraction layers, a person having ordinary skill in the art would not have had a reasonable expectation of success when providing Aase's classification layers hand-crafted extracted features. *See* Ex1006, [0033]-[0034]. The hand-crafted features that Krishnan's module 102 outputs are an imperfect representation of the overall content of the original image and contain much less information than the original image. The Petition fails to explain how deep learning with these features would work, and a person having ordinary skill in the art would not have expected that using the extracted features instead of images in the Krishnan-Aase combination would work properly. Additionally, as described above, there would not have been a reasonable expectation of success because it was known that conventional feature extraction, like that provided by Krishnan's module 102, would not work well on low-contrast

ultrasound images. *See* §X.B.2; Ex2037, 8.

216. Thus, the classification layers would need to be modified to accept Krishnan's hand-crafted features, which the Petition never explains.

217. Petitioner also provides no explanation of how Aase's classification neural networks, which are trained end-to-end with Aase's feature extraction neural network, would be trained when Aase's feature extraction neural subnetwork is removed. Petitioner completely ignores these fundamental incompatibilities between Krishnan and Aase, and instead incorrectly suggests that the combination would require no material modification or experimentation. *See e.g.*, Petition, 68 ("Implementing Krishnan in a manner that achieves the claimed subject matter would not require any material modification or experimentation.").

218. Petitioner's expert contradicts the proposed combination as well. Dr. Deo stated in his declaration that the combination "would not require any material modification or experimentation." Ex1002, ¶247. However, he disavowed the Petition's combination during his deposition by testifying that the combination would require removing Krishnan's modules 102-105 and replacing them with Aase. *See* EX2051, 116:13-117:15.

219. Dr. Deo could not explain details about the combination and could only point to paragraphs 245 and 246 of his declaration as purportedly demonstrating this swapping of Krishnan's modules and Aase's neural networks. *See id.*, 118:2-120:5.

220. However, these paragraphs mention nothing about, let alone explain, how Krishnan's modules 102-105 should be removed and swapped out:

> 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.
>
> 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.

Ex1002, ¶¶ 245-46.

221. Neither the Petition nor Dr. Deo's declaration includes anything about removing and swapping out Krishnan's modules 102-105 for the proposed combination of Krishnan and Aase. Petitioner also fails to provide any motivation for a wholesale replacement of Krishnan's modules 102-105 with Aase's modules, and there is no motivation for doing so as I described regarding Krishnan-Chen. §X.B.2.

D. Ground D: Krishnan-Chen-Wu Does Not Render Obvious Claims 12-20

1. Petitioner Fails to Articulate a Proposed Combination of Krishnan, Chen, and Wu, Let Alone a Motivation to Combine With a Reasonable Expectation of Success (Claims 12-20)

222. For this ground, Petitioner relies on a combination of Krishnan in view of Chen and Wu. Petition, 69-87. Even worse than Grounds B or C, for Ground D, Petitioner and Dr. Deo have not even attempted to describe a particular combination.

223. With respect to rationale to combine and reasonable expectation of success, the Petition relies on general statements in Chen and Wu that their implementations can be extended or generalized to other contexts without any specific explanation about how Krishnan would be modified with the

implementations of Chen and Wu.

224. For example, the Petition states that "[it] would have been natural and obvious to a POSITA to combine the teachings of Krishnan, Chen, and Wu by using the neural network architecture disclosed in Chen and Wu to perform the same features described in Krishnan" and then mentions that "Chen and Wu describe techniques for training" Krishnan's classifiers. Petition, 71-72; *id.*, 72 (citing without further support Chen's statement that it discloses "a general framework [that] can be easily extended to other [ultrasound] standard plane or anatomical structure detection problems"); *id.*, 72-73 (citing without further support Wu's statement that its "proposed [quality assessment] scheme can be easily generalized to other types of fetal [ultrasound] views").

225. However, the Petition fails to explain with any particularity how either of the training frameworks of Chen and Wu would be modified to work with Krishnan's implementation. *Id.*, 72-73. Thus, in my opinion, the Petition fails to explain how the references would be combined or why a person having ordinary skill in the art would have been motivated to combine them.

226. Indeed, for the same reasons described regarding Krishnan-Chen, in my opinion a person having ordinary skill in the art would not have been motivated to combine Krishnan's conventional system that relies on human-designed/hand-crafted rules to extract features with Chen's and Wu's neural network approaches.

§X.B.2.

227. In my opinion, Dr. Deo's declaration does not make up for the deficiencies of the Petition. Dr. Deo's declaration provides generalized statements about motivation to combine the references. However, Dr. Deo stops short of specifically explaining how Krishnan would be modified with Chen and Wu to result in claim 12. For example, Dr. Deo first states that "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" and that "[i]t would likewise be intuitive, and a POSITA would be motivated, to use the 'training' techniques disclosed in Chen and Wu." Ex1002, ¶261. Dr. Deo then lists excerpts from Chen and Wu regarding techniques for training and then repeats his assertions regarding motivation to combine. *See id*. ("a POSITA would have been further motivated to implement the training methods described in Chen and Wu").

228. With respect to reasonable expectation of success, the only support that Dr. Deo provides is the same general statements in Chen and Wu cited in the Petition, which state that their implementations can be extended or generalized to other contexts. *See id*., ¶262. However, like the Petition, Dr. Deo fails to specifically explain how either of their frameworks would be modified to work with other implementations. *See id*.

229. The Petition then jumps from general motivation (Krishnan

contemplates neural networks, Chen/Wu teach architectures/training) to claim-by-claim mapping without describing the actual combination. Petition, 71-73.

230. Dr. Deo could not explain the combination during his deposition either. In my opinion, Dr. Deo repeatedly contradicted himself during the deposition and effectively admitted that he had not proposed an actual combination. *See* EX2051, 122:23-123:3 (stating that Krishnan's module 102 is removed from the combination); *id*., 123:4-15 (stating that Krishnan's module 102 is swapped out and modules 103-105 are optional); EX2052, 23:5-20 (stating that it was "never [his] intention" to swap modules); *id*., 24:5-9 (stating that Krishnan's modules are a "scaffold" to which other references provide modern implementations).

231. Accordingly, in my opinion, Petitioner has failed to set forth a particular combination. Further, Petitioner has failed to demonstrate why a person having ordinary skill in the art would have been motivated to combine the references with a reasonable expectation of success.

2. Krishnan (or the Krishnan/Chen/Wu Combination) Fails to Disclose or Teach a Neural Network That Uses a Set of Ultrasound Training Images as an Input (Limitation 12(d))

232. In addition to the general deficiency as to claims 12-20 discussed above, in my opinion, Petitioner has failed to show that the combination discloses limitation 12(d). And because Petitioner has failed to show that limitation 12(d) is disclosed, Petitioner has failed to show that claim 12 and dependent claims 13-20

are unpatentable.

233. Limitation 12(d) recites "training a neural network, the training comprising, for each set of the plurality of sets of ultrasound training images, <u>using the set of ultrasound training images as an input to the neural network</u> 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." In other words, this limitation requires inputting training images into a neural network to train the network.

234. Petitioner relies on Krishnan in view of Chen and Wu for claim 12. Petition, 69-79. However, for limitation 12(d), the Petition cites neither Chen nor Wu and instead relies solely on Krishnan. *Id*., 78-79.

235. For 12(d), the Petition argues that "Krishnan trains one or more neural network classifiers." Petition, 78 (citing Ex1005, [0023], [0044]). The Petition further argues that a "POSITA would also understand that training the neural network would consist of using…training images as input to the neutral network and adjusting the neural network parameters based on…training labels associated with the images being the 'desired output of the neural network.'" *Id*. (citing Ex1002, ¶273; Ex1018, [0037], [0040]-[0041]).

236. Notably, Petitioner does not cite disclosures in Krishnan (or Chen or Wu for that matter) regarding its assertion that training Krishnan's classifiers would

involve inputting training images into them.

237. Instead, Petitioner cites Ex1018 ("Pagoulatos"), which is a patent application filed/published in 2017. Pagoulatos is not part of Petitioner's proposed combination, and I understand that the Petitioner cannot rely on a reference that is not part of its proposed combination to supply a missing limitation.

238. Even if Petitioner could rely on Pagoulatos, its disclosures are irrelevant because Krishnan's actual disclosures foreclose any argument that Krishnan discloses a neural network that uses a set of ultrasound training images as input. As I explained regarding Ground A, Krishnan does not disclose neural network "classifiers" that take ultrasound training images as inputs (for either image analysis or training purposes). *See* §X.A.1.

239. Instead, only Krishnan's modules 103-105 may employ classification methods in the Figure 5 embodiment, and those modules receive extracted features as input. Ex1005, [0042] ("<u>[F]eature data extracted</u> from the image dataset would be <u>input to classifiers</u> (step 500) that are <u>trained or designed to process the feature data</u> to classify the image data (step 501)."); *id.*, [0043] ("For example, a bank of classifiers could be constructed to classify the images based on the features extracted…These classifiers would use the set of <u>features as an input</u>, and classify the image as belonging to a particular anatomy, view, or level or quality.").

240. Module 102 does not employ classification methods or classifiers that

may be built with neural networks. Instead, module 102 extracts features from images using non-neural network techniques such as segmentation or filtering, and provides those extracted features as inputs to modules 103-105. *See id.*, [0034] ("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"). As described above, there would not have been a reasonable expectation of success because it was known that conventional feature extraction, like that provided by Krishnan's module 102, would not work well on low-contrast ultrasound images. *See* §X.B.2; Ex2037, 8.

241. Moreover, I understand that Petitioner cannot rely on Chen or Wu to teach limitation 12(d) because it did not analyze either reference for this limitation. But even if the Board were to reconstruct a combination, any version that uses Chen or Wu for feature extraction while retaining Krishnan's separate classifiers 103-105 would not be expected to succeed without modification—which Petitioner does not explain—because modules 103-105 are not designed to provide classification feedback to the feature extractor. Thus, in my opinion, Petitioner has not shown that Chen's/Wu's neural networks could learn how to extract features.

242. Otherwise, this would be a wholesale replacement of Krishnan with Chen and Wu, which the Petition fails to explain at all and moreover would destroy Krishnan's modular architecture.

243. Thus, in my opinion, the Petition fails to demonstrate that the proposed combination of Krishnan, Chen, and Wu discloses a neural network that uses a set of ultrasound images as an input as limitation 12(d) requires.

3. Petitioner's Combination of Krishnan, Chen, and Wu for Claims 14-20 Suffers From Additional Deficiencies

244. For the reasons above, it is my opinion that Petitioner has not shown that the Krishnan, Chen, and Wu combination renders obvious claim 12. As a result, it is my opinion that Petitioner has not shown that dependent claims 13-20—which depend from claim 12—are unpatentable.

245. Moreover, I further note that there are additional deficiencies with respect to Petitioner's analysis of dependent claims 14-20.

246. For claims 14-15, which ultimately depend from claim 12, Petitioner proposes that "Krishnan discloses the 'feature extracting neural network.'" Petition, 80 (claim 14); *id*., 81 (claim 15). But as I explained above, Krishnan's module 102 (which extracts features) is not a neural network.

247. Dr. Deo confirmed during his deposition that Krishnan's module 102 is the alleged feature extracting neural network, but Dr. Deo then contradicted himself and argued he was also relying on Chen and Wu without explicitly citing them. Ex2052, 4:14-9:7. Petitioner, however, does not cite disclosures in Chen or Wu for these claims. Petition, 79-81. Thus, it is my opinion that the Krishnan, Chen, and

Wu combination has not been shown to teach these claims. But even if a combination were reconstructed based on the teachings of Chen and Wu, such a combination would not work for the same reason I described as to claim 12.

248. With respect to claims 16-20, Petitioner has failed to explain what the proposed combination is or how the teachings of one reference would be applied to the other..

249. All of these claims require a "feature extracting neural network." Petition, 81-83 (claim 16); *id*., 83-84 (claim 17); *id*., 84 (claim 18); *id*., 84-87 (claim 19); *id*., 87 (claim 20). The Petition's combinations are unclear as to what the "feature extracting neural network" is and thus fail to meet Petitioner's burden. Petition, 81-87. Further, there is no statement anywhere in Dr. Deo's declaration about how Krishnan would be modified to incorporate the teachings of Chen and Wu. *See* Ex1002, 134-160.

250. Dr. Deo's contradictory testimony only exacerbates the deficiencies. For example, Dr. Deo testified regarding claim 16 that he was not relying on Chen's neural network to extract features in the combination, and then Dr. Deo contradicted himself and stated that Chen was "a possible embodiment" of Krishnan's feature extraction without taking a position. Ex2052, 13:4-7 (stating that he was not relying on Chen's J-CNN as the claimed feature extracting neural network); *id*., 13:15-14:6 (testifying that "Chen is a possible embodiment" of Krishnan's feature extraction

functions).

251. Further, as to claim 19, Dr. Deo testified that Krishnan's module 102 would instead be implemented as Chen's neural network without explaining how the combination would work. *See id.*, 19:9-16 (stating that Chen is implemented as Krishnan's module 102).

XI. DR. DEO'S OPINIONS INCLUDE SEVERAL MATERIAL CONTRADICTIONS

252. In my opinion, Dr. Deo's declaration and deposition testimony include material contradictions on substantive issues. For example, Dr. Deo disavowed the theory from his declaration that Krishnan needed no modification in the proposed combination of Krishnan and Chen and instead argued at his deposition that Krishnan's module 102, and potentially other modules, would need to be replaced. *See* §X.B.1; Ex2051, 107:11-21 (initially stating that the combination requires "no modification" to Krishnan), 108:1-109:19 (subsequently stating that Chen's neural network replaces Krishnan's module 102), 110:16-111:1 (stating the combination would require "little" experimentation), 111:13-22 (stating that the replacement of module 102 is "necessary"), 112:5-113:24 (stating that the combination may or may not require module 104 to be replaced).

253. In another instance, Dr. Deo made contradictory statements regarding the combination of Krishnan and Chen that were not articulated in the Petition. *See*

§X.B.1; Ex2051, 122:23-123:3 (stating that Krishnan's module 102 is removed from the combination), 123:4-15 (stating that Krishnan's module 102 is swapped out and modules 103-105 are optional); Ex2052, 23:5-20 (stating that it was "never [his] intention" to swap modules), 24:5-9 (stating that Krishnan's modules are a "scaffold" to which other references provide modern implementations).

254. Dr. Deo's testimony is internally inconsistent on material issues and, on obviousness issues, repeatedly contradicts his declaration (while in certain places disclaims the existence of a concrete proposed combination at all).

XII. SECONDARY CONSIDERATIONS

255. Secondary considerations of nonobviousness further support my opinion that grounds B, C, and D do not demonstrate that the challenged claims are unpatentable.

256. In my opinion, modifying Krishnan's described methods to be implemented using neural networks that input images to learn extracted features (and are trained with input images rather than extracted features) would not have been obvious and would not have been expected to succeed. Although non-learning-based feature extraction methods like those disclosed in Krishnan had shortcomings, it was known that applying deep learning to images rather than extracted features to implement an end-to-end neural network architecture handling feature extraction and quality assessment like in the '029 patent was not a simple matter. §VII.A. For

example, there was a long known issue with conventional methods, like those described in Krishnan, not working well on low-contrast ultrasound images. *See, e.g.*, Ex2037, 8. The ’029 patent’s end-to-end learning system fulfilled this unmet need.

257. That the ’029 patent overcame these challenges is evidenced by the recognition of others in the field that the ’029 patent was pioneering with respect to its deep learning approach for deriving task-specific training-set-optimal features from ultrasound images. For example, the ’029 patent or the publication leading to the ’029 patent (U.S. Pat. Pub. No. 2020/0069292, “the ’292 application”) has been cited by patent families across major medical-imaging and technology companies. *See, e.g.*, Ex2040 (General Electric Company patent); Ex2041, 9 (App. No. 16/146,770 Non-Final Rejection citing ’292 application during prosecution of Ex2040); Ex2042 (Ultrasound AI Inc. patent); Ex2043, 11 (App. No. 18/431,566 Non-Final Rejection citing ’292 application during prosecution of Ex2042); Ex2044 (Google patent); Ex2045, 3 (Reasons for refusal citing ’292 application during prosecution of Ex2044).

258. Such widespread citation by industry leaders is consistent with my opinion that a person having ordinary skill in the art would have recognized the ’029 patent as disclosing a novel and nonobvious contribution as of its 2018 priority date—specifically, its deep-learning approach for automatically deriving task-

specific feature representations from ultrasound images, rather than relying on the hand-crafted feature extraction techniques that dominated the field previously. This further supports my opinion that a person having ordinary skill in the art would not have found it obvious to modify Krishnan to implement a neural network that derives extracted features from images or is trained by receiving images as input and outputting quality assessment values and image properties.

259. Thus, in my opinion, a person having ordinary skill in the art would not have found it obvious to modify Krishnan to implement a neural network that derives extracted features from images or is trained by receiving images as input and outputting quality assessment values and image properties.

XIII. CONCLUSION

260. For all the above reasons, I find that Petitioner has not met its burden of demonstrating the unpatentability of any challenged claim. Accordingly, I understand that Patent Owner requests that the Board confirm the patentability of claims 1-30 of the ’029 patent.