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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNIVERSITY OF BRITISH COLUMBIA, Plaintiff, v. CAPTION HEALTH, INC., GE HEALTHCARE TECHNOLOGIES INC. Defendants.	Case No. 5:24-cv-03200-EKL **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** Judge: Hon. Eumi K. Lee

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Plaintiff University of British Columbia ("UBC" or "Plaintiff") files this First Amended Complaint against Caption Health, Inc. ("Caption Health") and GE Healthcare Technologies, Inc. ("GE Healthcare") (collectively "Defendants") to stop Defendants' ongoing infringement of plaintiff's patented innovative AI-based systems and methods for evaluating cardiac ultrasound images.

THE NATURE OF THE ACTION

1. This is a civil action for patent infringement of United States Patent No. 11,129,591 ("the '591 patent") and U.S. Patent No. 10,751,029 ("the '029 patent") (collectively, "the Patents in Suit") under the patent laws of the United States, 35 U.S.C. § 1 et seq.

2. UBC seeks judgment that Defendants have infringed, and continue to infringe, the Patents in Suit based on Defendants' commercialization of plaintiff's patented innovative AI-based systems and methods prior to the expiration of the Patents in Suit.

THE PARTIES

3. UBC is a corporation continued under the University Act of British Columbia, with offices at 6328 Memorial Road, Room 240 Vancouver, B.C., Canada V6T 1Z2.

4. On information and belief, Caption Health is a corporation organized and existing under the laws of Delaware with its principal place of business at 500 West Monroe Street, Chicago, IL 60661.

5. On information and belief, GE Healthcare is a corporation organized and existing under the laws of Delaware with its principal place of business at 500 West Monroe Street, Chicago, IL 60661. On information and belief, GE Healthcare acquired Caption Health in February 2023, and Defendants work in concert in connection with the acts of infringement asserted below. GE HealthCare Form 10-Q at 14 (April 25, 2023) (https://investor.gehealthcare.com/static-files/900530e1-1ce0-4860-b7d0-7e2db5107f64).

JURISDICTION AND VENUE

6. This court has subject matter jurisdiction over the patent infringement claims asserted in this case under 28 U.S.C. §§ 1331 and 1338(a) because this action involves claims arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq.

7. This Court has personal jurisdiction over Caption Health at least because Caption Health maintains a regular and established place of business within this District and has had continuous and systematic business contacts with the State of California and this District. On information and belief, Caption Health has been registered to do business in the State of California since 2013. On information and belief, Caption Health has operated regional offices in at least San Mateo, California and Brisbane, California. *See, e.g.*, http://captionhealth.com; https://web.archive.org/web/20231209012621/https:/www.caption-care.com/privacy-policy; https://www.sbir.gov/sbc/bay-labs-inc; https://www.sbir.gov/sbc/bay-labs-inc.

8. This Court has personal jurisdiction over GE Healthcare at least because GE Healthcare maintains a regular and established place of business within this District, and has had continuous and systematic business contacts with the State of California and this District. On information and belief, GE Healthcare operates regional offices in at least San Ramon, California and San Mateo, California. *See* https://careers.gehealthcare.com/global/en/locations; *see also*, *e.g.*, https://careers.gehealthcare.com/global/en/job/R4004074/Field-Service-Engineer-San-Ramon-CA (job listing based in San Ramon, stating "[t]his role is located in San Ramon, CA and covers the entire Bay Area."); https://careers.gehealthcare.com/global/en/job/R4007392/HC-Technician-1-Biomedical-HC, https://careers.gehealthcare.com/global/en/job/R4007236/HC-Technician-2-Biomedical-HC, https://careers.gehealthcare.com/global/en/job/R4003151/AI-Research-Summer-Fall-Co-op (job listings based in San Ramon); https://careers.gehealthcare.com/global/en/job/R4006523/Biomedical-Engineer-II-Gilroy-CA (job listing based in San Mateo).

9. On information and belief, Caption Health and GE Healthcare have committed infringing activities in California and in this District by making, using, selling, importing, and offering for sale products and systems that infringe upon the '591 patent and '029 patent, or by placing such infringing products and systems into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, or sold by others in this District and/or purchased by consumers in this District.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b) at least because a substantial part of the events or omissions giving rise to UBC's claims occurred in this District, and each of Defendants has a regular and established place of business in this District and has committed, and continues to commit, acts of infringement in this District.

FACTUAL BACKGROUND

A. UBC's Contributions to Echocardiography Research

11. UBC is one of the top research universities in the world and has created numerous innovations that benefit society. UBC has invested over $700 million in research funding for thousands of research projects. https://www.ubc.ca/about/facts.html. Many of UBC's innovations have been acknowledged by patent offices throughout the world, including the United States Patent and Trademark Office.

12. Heart disease is a leading cause of death in this country and throughout the world. To diagnose the health of a heart, cardiac specialists view and analyze images of the heart created by ultrasound devices. A problem that cardiac specialists face, however, is acquiring good images of the heart.

13. Echocardiographic image analysis refers to the analysis of images of the heart created by ultrasound devices. There are numerous challenges unique to acquiring and identifying good echocardiographic images. One of the longstanding challenges is that operators need years of specialized training to properly capture and assess echocardiographic images. Slight changes in where an ultrasound transducer is placed, or the pressure applied when using the transducer, can result in significant variation in the quality and usability of an image. In most cases, the actual quality and usability of the image cannot be ascertained by the naked eye. Given the inability to discern the quality of captured echocardiographic images, operators often send inadequate or unusable images to the lab, only to learn that the procedure must be repeated. As a result, effective echocardiographic analysis can often be significantly delayed, which can delay proper treatment. Given this inefficient use of time and resources, there has long been a need for a better system and method for acquiring quality echocardiographic images.

14. Before the ’591 and ’029 inventions, there were many unsuccessful attempts to address these problems. Simply digitizing the assessment process, for example, proved to be deficient due to additional technical challenges. For example, the difficulty in assessing echocardiographic images is exacerbated by the fact that echocardiography involves capturing images from multiple strategic views. Different combinations of anatomical structures need to be visible from each of the various views for a proper diagnosis, and before the ’591 patent and ’029 patent, there was no system that could accurately assess the visibility of these anatomical structures. Additionally, unlike other medical imaging, echocardiography involves capturing the movement of the heart through sequences of images, known as echo cine series. These echo cine series include multiple images (e.g., 20 images) for each view, which further increases the number of images that are assessed. Capturing sequences of images from each of the various views increases the computational demands for assessing the echocardiographic images, especially when assessment feedback is desired quickly. Further, previous approaches were deficient in quality assessment because the anatomical variations as well as the positioning of the ultrasound transducer results in a wider distribution of echo cine series belonging to each quality group, which reasonably results in multi-modal distributions. To exacerbate the issue, echocardiography noise and artifact inference make it even more so challenging to use previous approaches. Thus, even with advances in general imaging techniques in the past few decades, there remained a need for specialized techniques for echocardiographic image analysis.

15. Recognizing this need to improve echocardiographic image analysis, UBC has invented, and continues to invent, improvements to techniques for assessing echocardiographic images. The ’591 patent and ’029 patent are just a few examples of UBC’s innovations in the field.

B. The ’591 Patent

1. Development of the ’591 Invention

16. Around 2013, Dr. Tsang, an experienced cardiologist and recent winner of the Canadian Society of Echocardiography Annual Achievement Award. https://www.ubccardio.com/canadian-cardiovascular-society-recognition-awards-2023/, approached Dr. Abolmaesumi, another of the ’591 inventors, to discuss a problem associated with

echocardiographic image capture and analysis. Dr. Tsang noted that while portable ultrasound machines were highly capable of capturing images of the heart, the images were often inadequate because the operators—typically technicians—were unable to capture usable images. Even experienced operators struggled to identify and capture quality images that were acceptable for analysis. Dr. Tsang had numerous patients who had to return for more imaging.

17. The named inventors on the ’591 patent set out to address the problem. Dr. Abolmaesumi and Dr. Rohling, both established professors and researchers in the field of medical imaging, collaborated with Dr. Tsang about how to create a new system for determining echocardiographic image quality that did not need to rely so heavily on the skill of an ultrasound machine operator. They discussed how diagnoses depended on viewing images of the heart from specific views, and that the quality of echocardiographic images taken from various views depended on different features in the images. They determined that to analyze the three-dimensional structure of the heart, a two-part process involving analyzing echocardiographic images of at least two different views would be ideal. They also discussed whether neural networks could be used to improve analysis of the echocardiographic images.

18. While the inventors recognized the benefits of neural networks, application of neural networks for determining quality of echocardiographic images was not an obvious choice at the time. Systems for determining echocardiographic image quality typically relied on modeling techniques involving comparison to standard shapes or models. However, standard modeling techniques were deficient given the complexity in determining the quality of echocardiographic images of a moving heart and were not sensitive enough to distinguish small variations amongst images. Along with Dr. Abdi, a former student at UBC, Dr. Abolmaesumi, Dr. Rohling, and Dr. Tsang discussed how to design a neural network architecture that would make up for these deficiencies. Dr. Abdi, with guidance from the other inventors, worked on several iterations of a prototype of the neural network architecture to implement the team’s ideas through trial and error, including by updating network designs and composing parameters that provided more effective image quality assessments. *See*, *e.g.*, A. H. Abdi, et. al., *Automatic quality assessment of apical four-chamber echocardiograms using deep convolutional neural networks*, Medical Imaging 2017:

Image Processing, 10133 (Feb. 2017); A. H. Abdi, et. al., *Automatic Quality Assessment of Echocardiograms Using Convolutional Neural Networks: Feasibility on the Apical Four-Chamber View*, IEEE Transactions on Medical Imaging, Vol. 36, 6:1221-1230 (June 2017); A. H. Abdi, et. al., *Quality Assessment of Echocardiographic Cine Using Recurrent Neural Networks: Feasibility on Five Standard View Planes*, Medical Image Computing and Computer Assisted Intervention 2017, Lecture Notes in Computer Science, 10435:302-310 (Sept. 2017). Ultimately, through hundreds of hours of effort, the inventors came up with the innovations disclosed and claimed in the ’591 patent.

19. The patented system has various features. For example, a neural network is trained with thousands of images from multiple views of the heart, each image being labeled with a quality score. In this manner, the neural network can, for each view of the heart, create numerous parameters that are relevant to the quality of an image and that can later be used to assess quality of echocardiographic images. In developing a prototype, the inventors recognized that they could not simply apply a neural network to echocardiographic images and expect results. As described above, there are unique aspects of echocardiography that make it challenging to analyze the quality of echocardiographic images, such as capturing images from various views where each view has different features relating to quality. There is no one-size-fits-all approach for training and applying a neural network for determining the quality of echocardiographic images—simply training a neural network with a large number of echocardiographic images will not provide a system that can effectively recognize quality of echocardiographic images. The inventors rectified this deficiency by conceiving and designing systems and methods involving a neural network architecture that take into account the view categories of images and provide assessment parameters that are specialized for specific view categories. The resulting quality analysis is more accurate, reducing the need for operators to retake patients’ echocardiographic images and doctors to review captured images multiple times.

20. The inventors also sought to optimize computer performance and efficiency when faced with the technical issue of heavy computational resource usage typically associated with neural networks. To do so, the inventors conceived of having a different assessment neural network

for each view of the heart, but also having such neural networks share certain layers, with the goal of reducing computer processing and memory usage requirements of the computers training and executing the neural network. In developing their prototype, the inventors included multiple regression models that shared weights across the common shared layers and included separate view-specific layers. They found that splitting the neural network into a common portion and a view category specific portion facilitates more efficient training, such as by requiring fewer learning parameters than would be required if using fully separate neural networks. They further found that implementing the common portion reduces the amount of training performed overall, decreasing computational resources directed to training and reducing the need to store and process training images. The patented system thus allows for allocation of computational resources that would typically be used for training, as well as storage and processing of training images to be directed elsewhere. The inventors also found that their neural network architecture reduces memory usage by using fewer learning parameters, for example, by facilitating data compression and easier transfer of parameters to a machine.

21. The inventors also implemented the neural network architecture with common shared layers because they recognized that training images are not easily obtainable in echocardiography. While the use of neural networks in other contexts may allow outsourcing of labelling of training images, labelling for echocardiographic image analysis relies on highly skilled individuals, such as cardiologists, to provide their expertise. As described above, the neural network architecture with common shared layers has the benefit of a reduced amount of training and the need for fewer training images. Thus, the patented system did not need to rely on collection of as many training images and labelling from experts.

22. Once they were satisfied that they had conceived and reduced to practice a system that dramatically improved the capture and assessment of echocardiographic images, the inventors filed a patent application disclosing their invention. The original provisional application was filed on April 21, 2016.

2. The Consideration and Grant of the '591 Patent

23. The United States Patent Office did not take long to recognize the importance of the invention. After considering over 60 references cited by UBC or the Examiner, the Examiner cited one reference in an Office Action as anticipating the claims. *See* App. No. 16/095,601, May 5, 2021, Non-Final Rejection. However, the Examiner allowed the application shortly after UBC's amendment and response upon recognizing that the Office Action had mischaracterized the cited reference and that the reference did not disclose the claimed features. *See id.*, August 5, 2021, Amendment/Request for Reconsideration-After Non-Final Rejection; *see id.*, August 18, 2021, Notice of Allowance.

24. Thus, after only one Office Action rejecting the claims, the Patent Office issued a "notice of allowance," acknowledging the invention was patentable, and on September 28, 2021, the '591 patent, a copy of which is attached as Exhibit A, was issued.

3. Caption Health's Knowledge and Infringement of the '591 Patent

25. In May 2017, the inventors of the '591 patent had a teleconference with Kilian Koepsell, founder and then Chief Technical Officer of Bay Labs (now Caption Health).

26. During the meeting, the inventors disclosed the innovations claimed in the '591 patent to Mr. Koepsell. The inventors and Mr. Koepsell also discussed possible collaborations between the UBC and Bay Labs teams.

27. Shortly after the meeting, at Mr. Koepsell's request, Robert Rohling emailed Mr. Koepsell papers that were discussed during the meeting. The papers sent were A. H. Abdi, et. al., *Automatic quality assessment of apical four-chamber echocardiograms using deep convolutional neural networks*, Medical Imaging 2017: Image Processing, 10133 (Feb. 2017), and A. H. Abdi, et. al., *Automatic Quality Assessment of Echocardiograms Using Convolutional Neural Networks: Feasibility on the Apical Four-Chamber View*, IEEE Transactions on Medical Imaging, Vol. 36, 6:1221-1230 (June 2017). The second paper was available in preprint format on the IEEE website by May 2017. A copy of the correspondence sent from Mr. Rohling to Mr. Koepsell is attached as Exhibit C.

28. In early 2022, not long after the ’591 patent issued, UBC and the inventors discovered that Caption Health was marketing its AI-based cardiac ultrasound software that practiced the claims of the ’591 patent and that was remarkably close to the prototype the inventors created.

29. UBC wrote to Caption Health and attempted to resolve this dispute without litigation.

30. On May 5, 2022, UBC’s counsel sent a letter to Steve Cashman, President and Chief Executive Officer of Caption Health, bringing the infringement of the ’591 patent to Caption Health’s attention and offering discussions to resolve the matter without litigation. A copy of the May 5, 2022, letter is attached hereto as Exhibit D.

31. Caption Health did not respond to the letter.

32. Having heard no response, UBC’s counsel sent another letter to Mr. Cashman on May 24, 2022, attaching the original May 5, 2022, letter and requesting a response regarding the ’591 patent. A copy of the May 24, 2022, letter is attached hereto as Exhibit E.

33. On June 13, 2022, Caption Health CEO Steve Cashman sent an email acknowledging receipt of the May 2022 letters and promising a prompt response following review of the letters. A copy of the email is attached hereto in Exhibit F.

34. On June 27, 2022, Mr. Cashman sent another email alleging that the May 5 letter did not include enough information to engage in a productive discussion and asking for ”more information…, such as detailed claim mapping and interpretation in relation to [Caption Health’s] current products.” A copy of the email is attached hereto in Exhibit F.

35. In response, UBC provided the requested information, including a claim chart, in a letter to Mr. Cashman on November 11, 2022, again requesting a response. A copy of the November 11, 2022, letter is attached hereto as Exhibit G and incorporated herein by reference.

36. Caption Health never responded to the November 11, 2022, letter and has not otherwise provided any substantive response to UBC.

37. GE Healthcare acquired Caption Health in February 2023 for about $150 million. GE HealthCare Form 10-Q at 14 (April 25, 2023) (https://investor.gehealthcare.com/static-

files/900530e1-1ce0-4860-b7d0-7e2db5107f64); *GE HealthCare to Acquire Caption Health, Expanding Ultrasound to Support New Users Through FDA-Cleared, AI-Powered Image Guidance*, BusinessWire (Feb. 9, 2023) (https://www.businesswire.com/news/home/20230209005244/en/GE-HealthCare-to-Acquire-Caption-Health-Expanding-Ultrasound-to-Support-New-Us).

4. Overview of the '591 Patent

38. UBC owns all rights, title, and interest in the '591 patent, including those necessary to bring this action, and including the right to recover past and future damages.

39. The claims of the '591 patent are directed to inventions related to capturing and evaluating cardiac ultrasound images. Specifically, the claims address the problems described above of "echocardiographic systems…[that] may not assist echocardiographers in capturing high quality echocardiographic images for use in subsequent quantified clinical measurement of anatomical features." '591 patent, 1:29-34. The claimed inventions solved this problem with new and improved methods and systems formed by training and employing neural networks for assessing the quality of echocardiographic images and providing quantitative analysis to help operators optimize the quality of such images. *See, e.g.*, *id.*, 5:30-45, 6:13-20.

40. Further, the employed neural networks are trained to assess echocardiographic images of a specific view category. *See, e.g.*, *id.*, 5:62-6:20. As described above, it is typical to capture echocardiographic images from various view or anatomical planes to allow determination of certain clinical measurements or diagnosis. *See, e.g.*, *id.*, 5:46-49. Since the desirable characteristics for each of these different views can differ, there may be different criteria for assessing echocardiographic images based on the view they represent. *See, e.g.*, *id.*, 5:62-67. For example, a quality assessment value for the "AP2" view category may depend on the left ventricle, left atrium, and mitral valve in the image, while a quality assessment value for the "AP3" category may depend on the aortic valve, mitral valve, left atrium, left ventricle, and septum. *See, e.g.*, *id.*, 15:28:39. As the specification explains, the employed neural networks are trained with images and their associated view category information, so that neural network parameters that are eventually used to assess image quality can evaluate quality based on criteria specific to certain view

categories. *See, e.g.*, *id.*, 17:60-63, 18:27-35. Employment of neural networks associated with specific view categories of echocardiographic images was not known or conventional and provided an improvement over typical analyses. For example, a neural network is better able to consider in its analysis the "variability in the echocardiographic image data than when analysis of the echocardiographic image relies on an average template or atlas with average shape." *See, id.*, 11:44-51. Applying specialized neural networks for specific view categories thus improves the system's ability to assess echocardiographic image quality. Thus, the claims provide an improvement to a specific technology in a particular field.

41. The claimed inventions include additional technical improvements, such as the use of neural networks with common shared layers and a different set of view category specific layers. *See, e.g.*, 12:10-21, FIG. 8. The neural network architecture includes multiple regression models that share weights across the common shared layers and includes separate view-specific layers. *See, e.g.*, 12:31-35, FIG. 8. Splitting the neural network into a common portion and a view category specific portion facilitates more efficient training, such as by requiring fewer learning parameters than would be required if using fully separate neural networks. *See, e.g.*, 13:53-59. The use of fewer learning parameters also reduces memory usage, for example, by facilitating data compression and easier transfer of parameters to a machine. *See, e.g.*, 13:59-61, 24:9-10. Thus, the claims provide specific technological advances in using neural networks for analysis of echocardiographic images for the purpose of quality assessment.

C. The '029 Patent

1. Development of the '029 Invention

42. In addition to the inventions disclosed in the '591 patent, the inventors also discussed and worked on other improvements relating to capture and assessment of ultrasound images. One of the problems they considered was that providing only a quality assessment value might not be ideal in certain contexts, especially when an ultrasound operator is inexperienced and is unable to recognize other contextual details about an ultrasound image. For example, for echocardiographic images, differences between certain view categories may not be apparent to an inexperienced operator and thus information about what view category is being shown in an image

is useful. Thus, the inventors agreed that that it would be beneficial to provide supplemental information, such as an image property related to specific features or structures of an image, to the operator during capture of ultrasound images.

43. However, designing a practical system that could determine a quality assessment value and image property from ultrasound images, and provide them to an operator during examination, was challenging. For example, training and deploying such a system requires a large amount of computing power and resources, and processing assessment results during use could take a long time. Thus, the inventors conceived of a system that combined quality assessment and image property assessment, such that extracted feature representations could be used for assessment in an efficient manner. For example, the inventors designed an architecture where at least some of the extracted feature representations for both assessments could be extracted from a commonly defined neural subnetwork. This design reduced the processing time and resources that would typically be required for performing two assessments, which expanded the possibilities of implementing the design on a portable device.

44. In addition to working on implementing a system with the combined quality assessment and image property assessment to improve the capture and assessment of ultrasound images, the inventors filed a patent application disclosing their invention. The original provisional application leading to the ’029 Patent was filed on August 31, 2018.

2. The Consideration and Grant of the ’029 Patent

45. The United States Patent Office quickly recognized the importance of the claimed invention. In a Non-Final Office Action, the Examiner rejected the claims for minor informalities and as anticipated by Patent Publication No. 2019/0125298 (“’298 publication”), the publication that led to issuance of the ’591 patent. *See* App. No. 16/557,261, January 8, 2020, Non-Final Rejection. The Examiner allowed the application shortly thereafter upon finding the ’298 publication was not prior art because it fell under the 102(b)(2)(C) exception. *See id.*, Mar. 19, 2020, Amendment/Request for Reconsideration-After Non-Final Rejection at 8-10 (describing that the ’298 publication and App. No. 16/557,261 were subject to an obligation of assignment to UBC); *see id.*, June 25, 2020, Notice of Allowance.

46. Thus, finding no prior art that anticipated or rendered the claimed invention obvious, the Patent Office issued a "notice of allowance" acknowledging the invention was patentable, and on August 5, 2020, the '029 patent, a copy of which is attached as Exhibit B, was issued.

3. Overview of the '029 Patent

47. UBC owns all rights, title, and interest in the '029 patent, including those necessary to bring this action, and including the right to recover past and future damages.

48. The claims of the '029 patent are directed to inventions related to capturing and evaluating ultrasound images. Specifically, the claims address the problems relating to how "[a]ccurate diagnosis in ultrasound requires high quality ultrasound images, which may need to show or contain different specific features and structures depending on various properties of the images," and that recognizing such features can be especially difficult for inexperienced ultrasound operators. '029 patent, 1:22-31. The claimed inventions solved this problem with new and improved methods and systems formed by training and employing an algorithm, for example using a neural network, for assessing ultrasound images for quality, along with specific features or structures, to facilitate more accurate analysis of the images and help operators optimize the capture of desirable images. *See, e.g.*, *id.*, 5:5-22.

49. The employed algorithm is trained to assess ultrasound images for quality, as well as an image property that is helpful for further assessing specific features or structures captured in the images. *See, e.g.*, *id.*, 5:23-33. Since the desirable characteristics for various ultrasounds images can differ, there may be different criteria for assessing ultrasound images based on their context. *See, e.g.*, *id.*, 5:5-22. For example, in addition to quality, it may be helpful for an operator to know specific image properties indicating characteristics about a certain ultrasound examination when capturing ultrasound images. *See, e.g.*, *id.*, 20:50-21:30. As the specification explains, the algorithm derives one or more extracted feature representations from a set of ultrasound images. *See, e.g., id.*, 5:34-31. The employed algorithm combines quality assessment and image property assessment to enable simultaneous determination of a quality assessment value and an image category. *See, e.g.*, *id.*, 5:34-39. With respect to echocardiography, examples of image properties include the view category, left ventricular ejection fraction, and left atrial ejection fraction. *See,*

e.g., *id*., 20:41-59. Thus, in one embodiment, an employed neural network can simultaneously determine a quality assessment value and view category of echocardiographic images. *Id*. Employment of such an algorithm was not known or conventional and provided an improvement over typical analyses. For example, since some "view categories for ultrasound imaging may be quite similar to an inexperienced eye and switching between them may require precise adjustments of the probe's position and orientation," using the algorithm could "reduce the adverse effect of inter-operator variability on the quality of the acquired ultrasound images." *See, e.g., id*., 5:23-33. Thus, the claims provide an improvement to a specific technology in a particular field.

50. The claimed inventions include additional technical improvements as described in the specification. When using a neural network, for example, "the architecture of the neural network…may allow the analyzer to be implemented by a device that does not require an extremely high computing power, such as, for example an application on a mobile device or running on an off-the-shelf mobile device with the result being that the analyzer…may be portable and/or cost effective." *See, id*., 5:40-46. Additionally, "by combining quality assessment and another image property assessment, such as view categorization, a highly shared neural network may yield faster processing time compared to using a separate quality assessment and image property assessment." *See, id*., 5:46-51. Further, "by combining quality assessment and another image property assessment, such as view categorization, the joint training of the two modalities may prevent the neural network from overfitting the label from either modality." *See, id*., 5:51-55. Thus, the claims provide specific technological advances for analysis of ultrasound images for the purpose of quality assessment and image property assessment.

D. Defendants' Infringing Products

51. On information and belief, Defendants make, use, sell, offer to sell, and/or import into the United States ultrasound products that incorporate scan guidance technology to help operators assess the quality of echocardiographic images. https://www.gehealthcare.com/campaigns/venue-family-caption-guidance ("Thanks to Caption Guidance™ AI-driven software on the Venue family, even new ultrasound users can capture cardiac images successfully."); https://www.gehealthcare.com/about/newsroom/press-releases/ge-

healthcare-launches-enhanced-venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-guidance?npclid=botnpclid (Oct. 6, 2023) ("Caption Guidance on the Venue Family point-of-care ultrasound systems is available in the United States.").

52. Defendants market their infringing products as incorporating the infringing scan guidance technology under the names "Caption Guidance," "Caption AI, " or "Caption AI Guidance." Caption Guidance is "a medical software tool that utilizes Artificial Intelligence (AI) for providing echocardiography." G. Yatnalkar, *EMMA International: Caption Guidance – FDA's First Authorized AI-Based Cardiac Ultrasound Software*, by Govind (Feb. 15, 2021). Caption Guidance, or Caption AI Guidance, is incorporated into a series of point-of-care ultrasound products called "the Venue Family." *GE HealthCare Launches Enhanced Venue Family Point-of-Care Ultrasound Systems Featuring AI-Driven Caption Guidance*, GE Healthcare (Oct. 6, 2023), https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-launches-enhanced-venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-guidance?npclid=botnpclid; *see also* https://www.linkedin.com/posts/rolandrott_ultrasound-gehealthcare-rsna-activity-7135509649302126594-J-2g/?utm_source=share&utm_medium=member_ios (LinkedIn post by GE HealthCare CEO, Roland Rott, marketing "the Venue Family with Caption AI Guidance"). Similarly, Caption AI "provides real-time visual guidance to prompt users on probe movements and includes a quality meter to ensure the user obtains the best possible images. Once an image is captured, the AutoEF feature automatically calculates a left ventricular ejection fraction (LVEF). In addition, users can efficiently scan with AutoCapture and Save Best Clip features to capture the best quality image from each view." *GE HealthCare Introduces Caption AI on Vscan Air SL Wireless Handheld Ultrasound System to Help More Clinicians Capture Diagnostic-Quality Cardiac Images*, GE Healthcare (Apr. 3, 2024), https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-introduces-caption-ai-on-vscan-air-sl-wireless-handheld-ultrasound-system-to-help-more-clinicians-capture-diagnostic-quality-cardiac-images. Caption AI is incorporated into handheld ultrasounds called "Vscan Air SL." *Id.* While the features described below focus on Caption Guidance, on information and belief, Caption AI provides similar features. *See id.*; *see*

also https://www.gehealthcare.com/products/ultrasound/handheld-ultrasound/vscan-air-caption-ai.


Find Caption Guidance

Discover the Venue Family

Whether you're looking for an adaptable model that goes from cart to table to wall, or a console system with a large screen, there is a versatile, robust, and simple system made for your point of care.

Venue™ Point of Care Ultrasound
Designed for simplicity, speed, and precision, Venue is the premier solution of our point of care ultrasound systems.

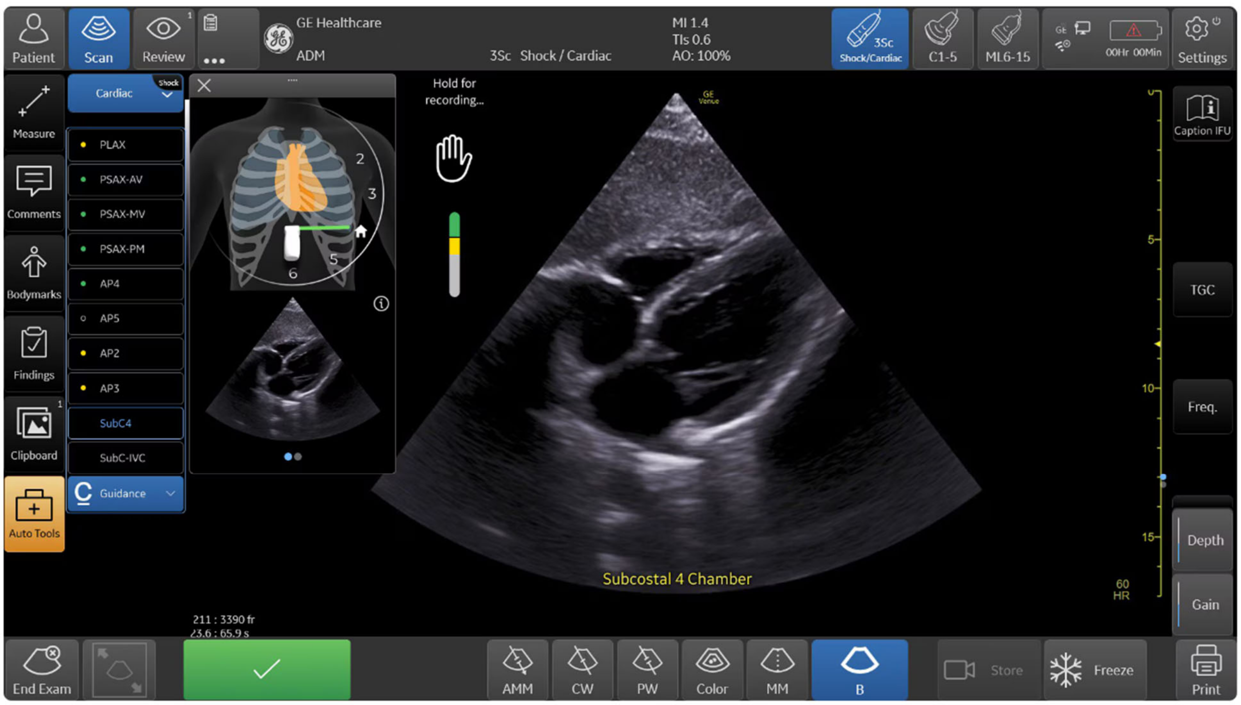
Venue Go™ Point of Care Ultrasound
The take anywhere Venue Go adapts to your point of care and allows you to go from cart to table to wall with ease.

Venue Fit™ Point of Care Ultrasound
A simple, fast and precise way to assess a patient's medical status at the point of care, meet Venue Fit, the newest member of the Ve...

https://www.gehealthcare.com/campaigns/venue-family-caption-guidance.

https://www.gehealthcare.com/products/ultrasound/handheld-ultrasound/vscan-air-caption-ai.

53. Caption Guidance is designed to provide "[p]reliminary probe placement information [that] shows you where to place and how to orient the ultrasound probe." *Id.* As the operator begins the exams, "a handy reference image shows [the operator] the image [they] are trying to acquire." *Id.* During the scan, Caption Guidance further provides "prescriptive guidance…on the screen" including a "Quality Meter" that rises when the operator "get[s] closer to an image of diagnostic quality." *Id.*

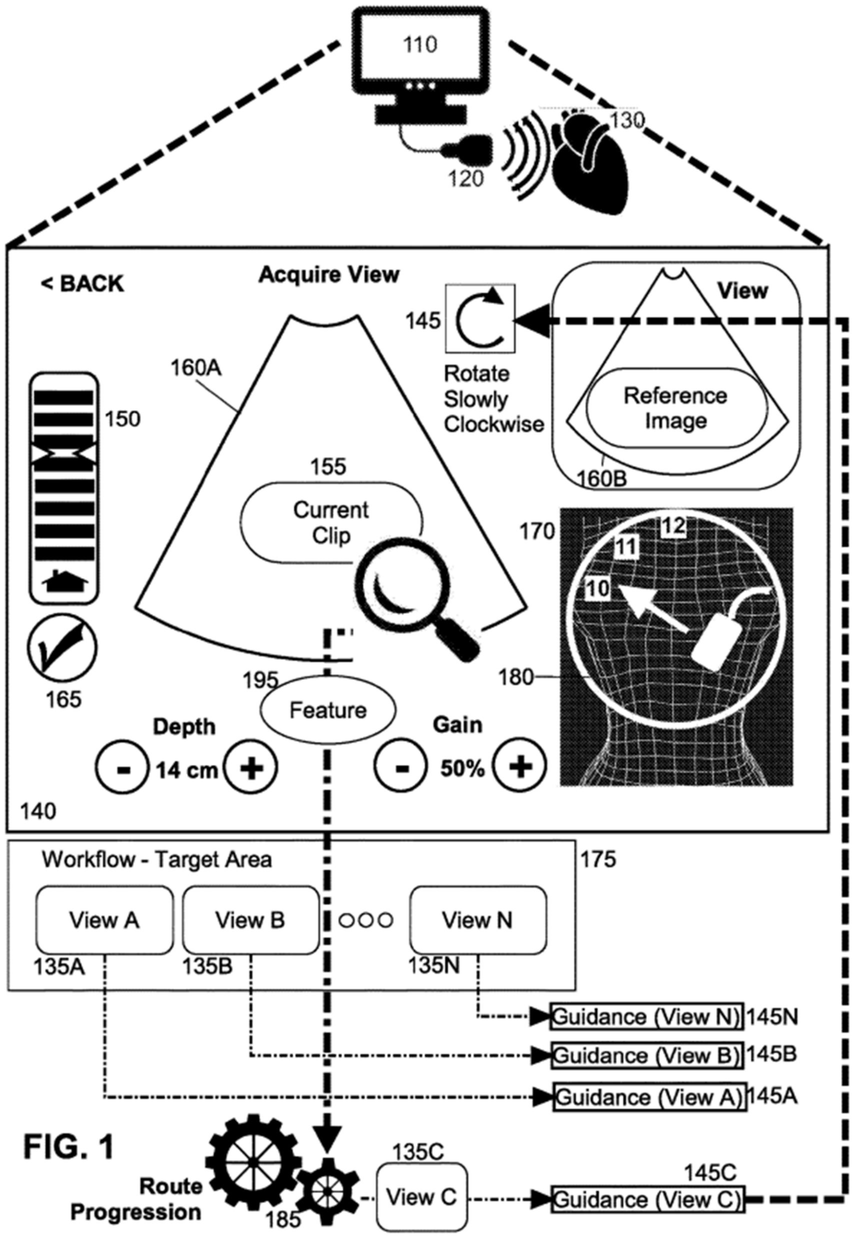


https://www.gehealthcare.com/campaigns/venue-family-caption-guidance.

54. On information and belief, Caption Health's patent publication, U.S. Patent Publication No. 2021/0052253 ("the '253 application"), describes the functionality of Caption Guidance. A copy of the '253 application is attached hereto as Exhibit H.

55. The '253 application is directed to ultrasound guidance dynamic progression methods and systems. The '253 application describes "[a]n ultrasound guidance dynamic progression method [that] includes selecting a predetermined ultrasound diagnostic workflow in memory of an ultrasound diagnostic computing system." '253 application, Abstract. It further describes a system that comprises "at least one processor" configured to perform the method. *See, e.g., id.*, ¶¶ [0026], [0035]-[0037]. The '253 application describes implementation of a "quality

meter" ('253 application, 150 of Fig. 1, ¶ 26), which is a feature of Caption Guidance. https://www.gehealthcare.com/campaigns/venue-family-caption-guidance ("Quality Meter The meter rises as the image improves and gets closer to diagnostic-quality").



Id., Fig. 1

56. The '253 application describes that Caption Guidance is incorporated in "an ultrasound diagnostics data processing system configured for ultrasound guidance dynamic progression." '253 application, ¶ 26. This system is used "in connection with the imaging of a heart." *Id.*, ¶ 20; *see also* Fig. 1 (i.e., target organ 130). Caption Guidance "provides real-time guidance during scanning to assist the user in obtaining anatomically correct images from standard

transthoracic echocardiographic (TTE) transducer positions." Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June 2021).

57. Caption Guidance acquires a video clip comprising a series of echocardiographic images. '253 application, ¶ 20 ("ultrasound imaging system 110 with ultrasound imaging probe 120 conducts an ultrasound imaging operation in order to acquire a video clip as near real-time imagery 155 of a target organ 130"). The video clip is acquired by scanning using a transducer. Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June 2021) ("The AI-guided image acquisition software…Caption Guidance…provides real-time guidance during scanning to assist the user in obtaining anatomically correct images from standard transthoracic echocardiographic (TTE) transducer positions."); *see also In Caption AI Product Demo | AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4.

58. Caption Guidance associates captured echocardiographic images with view categories. For example, the Caption Guidance workflow "includ[es] a sequence of views of a target organ" where "a first one of the views in the sequence" is selected. '253 application, ¶ 9. Caption Guidance then "acquir[es] imagery in the computing system in association with the selected first one of the views in the sequence." *Id.*; *see also In Caption AI Product Demo | AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4. The sequence of views includes predetermined echocardiographic image view categories, such as "a parasternal long axis view, a parasternal short axis view, an apical two, three, four or five chamber view or a subcoastal view." *Id.*, ¶ 20.

59. Caption Guidance determines quality assessment values representing view category specific quality assessment of echocardiographic images. Caption Guidance implements a "quality meter" that "indicates a sliding scale of quality of the imagery…relative to a known view sought to be acquired for the target organ." *Id.*, ¶ 22; *see also In Caption AI Product Demo | AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4. A success icon is

displayed in connection with the quality meter if the "corresponding quality value…meets or exceeds a threshold quality for the specified view." *Id.*

60. Once a quality assessment value is determined for an echocardiographic image, Capture Guidance automatically captures an echocardiographic image and associates the image with the determined quality assessment value. For example, "[w]hen the real-time quality meter exceeds a preset threshold, it automatically records a video clip (termed an *auto-capture*)." Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June 2021); *see also* H. Hong, Ph.D., *Caption Health: Flattening the Ultrasound Learning Curve with Breakthrough AI-Guided Echocardiography System*, 4:30-4:40, https://www.youtube.com/watch?v=NCFFAlHSPrc ("Finally, [it] recognizes when the user reaches the target and automatically captures the images in diagnostic quality."); *In Caption AI Product Demo | AI-Guided Ultrasound System*, 0:48-1:00, https://www.youtube.com/watch?v=URmb72IA4b4 ("As Sarah gets closer to the optimal view, the meter rises. Once the software detects a diagnostic quality image, the meter turns green and the clip is automatically recorded without having to press any buttons.").

61. Caption Guidance performs the steps above for multiple echocardiographic images, such as those corresponding to multiple view categories. '253 application, ¶ 21 ("For each of the views 135A, 135B, 135N, corresponding guidance 145A, 145B, 145N is determined and presented in sequence of the views 135A, 135B, 135N of the workflow 175 within the user interface 140 as respective graphical instructions 145. In this regard, the corresponding guidance 145A, 145B, 145N includes different directives for positioning and posing the ultrasound imaging probe 120 so as to produce the imagery 155 for a corresponding one of the views 135A, 135B, 135N."); *id.*, ¶ 20 ("a sequence of views…may include a parasternal long axis view, a parasternal short axis view, an apical two, three, four or five chamber view or a subcoastal view.").

62. On information and belief, Caption Guidance utilizes neural networks to assess the quality of captured echocardiographic images. G. Yatnalkar, *Caption Guidance – FDA's First Authorized AI-Based Cardiac Ultrasound Software* (Feb. 15, 2021), https://emmainternational.com/fda-authorized-ai-cardiac-ultrasound-software/ ("For Caption

Guidance, the AI Algorithm used for image or video frame selection is the Deep Convolutional Neural Network (DCNN).”); Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June 2021) (“The AI-guided image acquisition software…Caption Guidance…provides real-time guidance during scanning to assist the user in obtaining anatomically correct images from standard transthoracic echocardiographic (TTE) transducer positions…The software monitors image quality continuously, simultaneously providing iterative prescriptive cues to improve the image via the DL algorithm.”); *FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User*, FDA News Release (Feb. 7, 2020), https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user (“The Caption Guidance software was developed using machine learning to train the software to differentiate between acceptable and unacceptable image quality.”).

63. The Caption Guidance neural networks are trained to provide quality assessment values that are specific to certain view categories. For example, “a second neural network…may be trained to characterize guidance instructions relative to contemporaneously acquired imagery of the target organ.” ’235 application, ¶ 28. The “second neural network…is trained to produce recommend[ed] guidance to achieve the optimal acquisition of generated imagery for the target organ for the particular one of the views…relative to the generated imagery contemporaneously presented in a display of the host computing system.” *Id*. The Caption Guidance “DL algorithms were trained using more than 5 million observations associating transducer orientation, the diagnostic correctness of the resulting image, and the outcome of subsequent manipulations with diagnostic quality.” Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June 2021). Caption Guidance’s “DL algorithm estimates image quality via a component called the quality meter, suggesting probe manipulations using prescriptive guidance.” *Id*.

64. The Caption Guidance neural networks each have an input layer configured to receive echocardiographic images and an output layer configured to output quality assessment values. Caption Guidance uses “convolutional neural networks constructed by stacking

computational layers, each taking input from the layer below, transforming and passing it along to the layer above." *Id.* Caption Guidance "has several interconnected DL algorithms making 3 simultaneous estimates: (1) diagnostic quality of the imagery, (2) 6-dimensional geometric distance (by position and orientation) between current probe location and the location anticipated to optimize the image, and (3) corrective probe manipulations to improve diagnostic quality." *Id.* "[A]s the neural network…is presented with contemporaneously acquired imagery of the target organ for the particular one of the views…, the neural network produces a recommended movement or pose of the ultrasound imaging probe…in order to acquire generated imagery deemed acceptable for the particular one of the views." '253 application, ¶ 28.

65. Defendants announced plans to incorporate Caption Guidance into additional products. https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-launches-enhanced-venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-guidance?npclid=botnpclid (Oct. 6, 2023) ("GE HealthCare plans to integrate this innovative AI technology into other ultrasound systems, including handheld systems, helping to further expand access to diagnostic care as well as the use of ultrasound in a variety of care settings.").

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,129,591

66. UBC incorporates by reference and re-alleges all of the foregoing paragraphs of this First Amended Complaint and exhibits attached hereto as is fully set forth herein.

67. Defendants infringe at least claims 1 and 15 of the '591 patent by making, using, selling, importing, offering for sale its "Venue Family" products and Vscan Air SL products that incorporate Caption Guidance or Caption AI (the "Accused Products").

68. Each of the Accused Products is "[a] computer-implemented system for facilitating echocardiographic image analysis…comprising at least one processor…" and is used for "[a] computer-implemented method of facilitating echocardiographic image analysis." *See, e.g.*, '253 application, ¶¶ [0026], [0035]-[0037]; Venue Family Caption Guidance™ product page, https://www.gehealthcare.com/campaigns/venue-family-caption-guidance ("Preliminary probe placement information shows you where to place and how to orient the ultrasound probe. As you begin the exam, a handy reference image shows you the image you are trying to acquire.";

"prescriptive guidance [is] provided on the screen…the Quality Meter rise[s] as you get closer to an image of diagnostic quality."); *see also* Venue Family POCUS R5 Brochure (August 2024), https://www.gehealthcare.com/-/jssmedia/gehc/us/images/products/ultrasound/venue/feature-cards/brochure-venue-family-pocus-r5-jb29262xx.pdf?rev=-1; *see also* Vscan Air SL Product Page, https://www.gehealthcare.com/products/ultrasound/handheld-ultrasound/vscan-air-caption-ai ("Vscan Air SL with Caption Guidance™ software provides real-time guidance that shows you, step-by-step, how to maneuver the probe to capture diagnostic-quality standard echocardiographic views anytime, anywhere*. … Caption AI provides handheld ultrasound users with confidence in acquiring cardiac views for rapid assessments at the point of care."); *see also supra* ¶¶ 52-64.

69. The Accused Products perform "receiving signals representing a first at least one echocardiographic image." For example, the Accused Products acquire a series of echocardiographic images when an operator scans a patient using a transducer. *See, e.g.*, '253 application, ¶ 20; Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June 2021); *see also* Venue Family POCUS R5 Brochure (August 2024) at 3, https://www.gehealthcare.com/-/jssmedia/gehc/us/images/products/ultrasound/venue/feature-cards/brochure-venue-family-pocus-r5-jb29262xx.pdf?rev=-1 ("Caption Guidance helps even new users capture diagnostic-quality images with its built-in AI-driven software"); *see also id.* at 4 ("Real-time, turn-by-turn on-screen guidance prompts your probe movements to help new POCUS users capture diagnostic-quality cardiac images."); *In Caption AI Product Demo: AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4, at 0:37-0:59 ("Sarah makes specific transducer movements to optimize the image. On the left, the quality meter tells her how close she is to capturing a diagnostic quality image. As Sarah gets closer to the optimal view, the meter rises. Once the software detects a diagnostic quality image, the meter turns green and the clip is automatically recorded without having to press any buttons"); H. Hong, Ph.D., *Caption Health: Flattening the Ultrasound Learning Curve with Breakthrough AI-Guided Echocardiography System*, at 4:30-4:40 ("Finally, [it] recognizes when the user reaches the target and automatically captures the images in diagnostic quality"); *see also* Vscan Air™ Product Tutorial | Caption AI™,

https://www.youtube.com/watch?v=Tbj92hMXAiU at 2:05-2:20 ("You will see a blue box move from the bottom left of the screen to the top right, indicating a view has been captured.); *see also supra* ¶¶ 55, 57.

70. The Accused Products perform "associating the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories." *See, e.g.,*, Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 ("In order to help users to acquire high-quality echocardiograms, the guidance algorithm must be able to estimate the positioning of the ultrasound probe from the current imaging and provide real-time guidance based on that estimation for the user to arrive at the ideal positioning and image. It must first be able to grade the quality of the imagery and determine whether it meets diagnostic criteria. Therefore, the AI-guidance deep learning algorithm makes three simultaneous estimates: 1) diagnostic quality of the imagery, 2) six-dimensional (6D, probe position plus orientation) geometric distance between current probe location and a probe location anticipated to optimize the image, and 3) corrective probe manipulations to improve diagnostic quality. Importantly, the deep learning algorithm makes these estimates from only the ultrasound imagery; no trackers, fiducial markers, or additional sensors are needed for operation."); *see also id.* ("Training the network: As shown in eFigure 1, the deep learning algorithm was developed to guide operators to 10 diagnostic views of the heart: parasternal long axis view (PLAX); parasternal short axis view at aortic valve level (PSAX-AV), mitral valve level (PSAX-MV), and papillary muscle level (PSAX-PM); apical 2, 3, 4, 5 chamber views (Ap2, Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior vena cava view (SC-IVC). Fifteen (15) registered sonographers captured imagery on subjects over a range of BMI and clinical pathology to train the deep learning algorithm. This training dataset contained >5,000,000 individual data points on transducer location/orientation and observed imagery using ultrasound machines from multiple vendors. This dataset was curated and augmented with approximately 500,000 labels from expert sonographers and cardiologists annotating diagnostic quality and suggesting prescriptive guidance actions to improve the imaging (eFigure 1 left). Using this dataset, the algorithm was trained to estimate the 6D distance to each of the 10

views, define 81 unique prescriptive guidance actions, and diagnostic thresholds for each of the 10 views."); *see also supra* ¶¶ 55, 58. For example, the Accused Products receives a selection from "a sequence of views of a target organ" where "a first one of the views" in "a sequence of views of a target organ." '253 application, ¶ 9. The Accused Products then "acquir[es] imagery in the computing system in association with the selected first one of the views in the sequence." *Id.* The sequence of views includes "a plurality of predetermined echocardiographic image view categories," such as "a parasternal long axis view, a parasternal short axis view, an apical two, three, four or five chamber view or a subcoastal view." *Id.*, ¶ 20.

71. The Accused Products perform "determining, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image." *See, e.g.*, Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use (Original Investigation)* at 625 ("The DL algorithms were trained using more than 5 million observations associating transducer orientation, the diagnostic correctness of the resulting image, and the outcome of subsequent manipulations with diagnostic quality. This training data set came from 15 registered sonographers via scans of individuals with a range of body mass index (BMI) values and pathological conditions, further annotated for quality by expert sonographers and cardiologists (A.N., R.P.M., R.M.L., N.J.W., and J.D.T.). eFigure 1 in the Supplement depicts the DL model training data set, expert labeling for image quality, algorithm optimization, and run-time operation during the study"); *see id.* ("The software monitors image quality continuously, simultaneously providing iterative prescriptive cues to improve the image via the DL algorithm. The guidance software used convolutional neural networks constructed by stacking computational layers, each taking input from the layer below, transforming and passing it along to the layer above. The software has several interconnected DL algorithms making 3 simultaneous estimates: (1) diagnostic quality of the imagery, (2) 6-dimensional geometric distance (by position and orientation) between current probe location and the location anticipated to optimize the image, and (3) corrective probe manipulations to improve diagnostic quality. Importantly, the algorithm makes these estimates from the ultrasonographic

imagery alone; no trackers, fiducial markers, or additional sensors are required."); *see also* Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 ("In order to help users to acquire high-quality echocardiograms, the guidance algorithm must be able to estimate the positioning of the ultrasound probe from the current imaging and provide real-time guidance based on that estimation for the user to arrive at the ideal positioning and image. It must first be able to grade the quality of the imagery and determine whether it meets diagnostic criteria. Therefore, the AI-guidance deep learning algorithm makes three simultaneous estimates: 1) diagnostic quality of the imagery, 2) six-dimensional (6D, probe position plus orientation) geometric distance between current probe location and a probe location anticipated to optimize the image, and 3) corrective probe manipulations to improve diagnostic quality. Importantly, the deep learning algorithm makes these estimates from only the ultrasound imagery; no trackers, fiducial markers, or additional sensors are needed for operation"); *see also supra* ¶¶ 55, 59, 70. For example, the Accused Products implement a "quality meter" that "indicates a sliding scale of quality of the imagery…relative to a known view sought to be acquired for the target organ." '253 application, ¶ 22. A success icon is displayed in connection with the quality meter if the "corresponding quality value…meets or exceeds a threshold quality for the specified view." *Id.*

72. The Accused Products perform "producing signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image." For example, the Accused Products automatically capture an echocardiographic image and associate the image with the determined quality assessment value. "When the real-time quality meter exceeds a preset threshold, it automatically records a video clip (termed an *auto-capture*)." *See, e.g.*, Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, *(Original Investigation)* at 625-26 ("The DL algorithm estimates image quality via a component called the quality meter, suggesting probe manipulations using prescriptive guidance (eFigure 1 in the Supplement). When the real-time quality meter exceeds a preset threshold, it automatically records a video clip (termed an auto-capture). Quality is continuously monitored throughout scanning, so the operator can

retrospectively save the best clip observed if the auto-capture threshold is not exceeded. If auto-capture is not achieved within 2 minutes, the user may activate the option called save best clip or continue scanning to achieve auto-capture. These algorithms operate together to improve the ultrasonographic image, as in eFigure 1 in the Supplement, in which prescriptive guidance improves a parasternal long-axis view. eFigure 2 in the Supplement and Video 1 show additional detail on the user interface"); *see also* H. Hong, Ph.D., *Caption Health: Flattening the Ultrasound Learning Curve with Breakthrough AI-Guided Echocardiography System*, https://www.youtube.com/watch?v=NCFFAlHSPrc, at 4:30-4:40 ("Finally, [it] recognizes when the user reaches the target and automatically captures the images in diagnostic quality"); *see also In Caption AI Product Demo | AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4, at 0:37-0:59 ("Sarah makes specific transducer movements to optimize the image. On the left, the quality meter tells her how close she is to capturing a diagnostic quality image. As Sarah gets closer to the optimal view, the meter rises. Once the software detects a diagnostic quality image, the meter turns green and the clip is automatically recorded without having to press any buttons"); *see also supra* ¶¶ 60, 70-72.

73. The Accused Products perform the steps described above (*see supra* ¶¶ 69-72) for multiple echocardiographic images corresponding to multiple view categories. *See, e.g.*, '253 application, ¶ 21 ("For each of the views 135A, 135B, 135N, corresponding guidance 145A, 145B, 145N is determined and presented in sequence of the views 135A, 135B, 135N of the workflow 175…In this regard, the corresponding guidance 145A, 145B, 145N includes different directives for positioning and posing the ultrasound imaging probe 120 so as to produce the imagery 155 for a corresponding one of the views 135A, 135B, 135N."); *see also supra* ¶ 61. Thus, the Accused Products perform "receiving signals representing a second at least one echocardiographic image," "associating the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category," "determining, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one

echocardiographic image," and "producing signals representing the second quality assessment value for causing the second quality assessment value to be associated with the second at least one echocardiographic image."

74. In the Accused Products, "each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters," where "each of the sets of assessment parameters being a set of neural network parameters that defines a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values." For example, the Accused Products use neural networks with neural network parameters to assess the quality of captured echocardiographic images. *See, e.g.*,, G. Yatnalkar, *Caption Guidance – FDA's First Authorized AI-Based Cardiac Ultrasound Software* (Feb. 15, 2021), https://emmainternational.com/fda-authorized-ai-cardiac-ultrasound-software/ ("For Caption Guidance, the AI Algorithm used for image or video frame selection is the Deep Convolutional Neural Network (DCNN)."); *see also supra* ¶¶ 62-64.

75. The Accused Products use neural networks that have "a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values." *See, e.g.*,, Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, *(Original Investigation)* at 625 ("The AI-guided image acquisition software (Caption Guidance [Caption Health, previously known as Bay Labs]), described in greater detail in the eAppendix in the Supplement and shown schematically in eFigure 1 in the Supplement, provides real-time guidance during scanning to assist the user in obtaining anatomically correct images from standard transthoracic echocardiographic (TTE) transducer positions. The AI guidance is software only, developed with DL to emulate sonographer expertise. … The guidance software used convolutional neural networks constructed by stacking computational layers, each taking input from the layer below, transforming and passing it along to the layer above. The software monitors image quality continuously, simultaneously providing iterative prescriptive cues to improve the image via the DL algorithm. The guidance software used convolutional neural networks

constructed by stacking computational layers, each taking input from the layer below, transforming and passing it along to the layer above. The software has several interconnected DL algorithms making 3 simultaneous estimates: (1) diagnostic quality of the imagery, (2) 6-dimensional geometric distance (by position and orientation) between current probe location and the location anticipated to optimize the image, and (3) corrective probe manipulations to improve diagnostic quality. Importantly, the algorithm makes these estimates from the ultrasonographic imagery alone; no trackers, fiducial markers, or additional sensors are required. The DL algorithms were trained using more than 5 million observations associating transducer orientation, the diagnostic correctness of the resulting image, and the outcome of subsequent manipulations with diagnostic quality.") *see also* Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 ("In order to help users to acquire high-quality echocardiograms, the guidance algorithm must be able to estimate the positioning of the ultrasound probe from the current imaging and provide real-time guidance based on that estimation for the user to arrive at the ideal positioning and image. It must first be able to grade the quality of the imagery and determine whether it meets diagnostic criteria. Therefore, the AI-guidance deep learning algorithm makes three simultaneous estimates: 1) diagnostic quality of the imagery, 2) six-dimensional (6D, probe position plus orientation) geometric distance between current probe location and a probe location anticipated to optimize the image, and 3) corrective probe manipulations to improve diagnostic quality. Importantly, the deep learning algorithm makes these estimates from only the ultrasound imagery; no trackers, fiducial markers, or additional sensors are needed for operation"); *see also supra* ¶¶ 62-64. For example, when a neural network "is presented with contemporaneously acquired imagery of the target organ for the particular one of the views…, the neural network produces a recommended movement or pose of the ultrasound imaging probe…in order to acquire generated imagery deemed acceptable for the particular one of the views." '253 application, ¶ 28.

76. The Accused Products use neural networks that are trained to provide quality assessment values that are specific to certain view categories. For example, a "neural network…is trained to produce recommend[ed] guidance to achieve the optimal acquisition of generated

imagery for the target organ for the particular one of the views…relative to the generated imagery contemporaneously presented in a display of the host computing system." '253 application, ¶ 28; *see also* Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 ("In order to help users to acquire high-quality echocardiograms, the guidance algorithm must be able to estimate the positioning of the ultrasound probe from the current imaging and provide real-time guidance based on that estimation for the user to arrive at the ideal positioning and image. It must first be able to grade the quality of the imagery and determine whether it meets diagnostic criteria. Therefore, the AI-guidance deep learning algorithm makes three simultaneous estimates: 1) diagnostic quality of the imagery, 2) six-dimensional (6D, probe position plus orientation) geometric distance between current probe location and a probe location anticipated to optimize the image, and 3) corrective probe manipulations to improve diagnostic quality. Importantly, the deep learning algorithm makes these estimates from only the ultrasound imagery; no trackers, fiducial markers, or additional sensors are needed for operation."); *see also id*. ("Training the network: As shown in eFigure 1, the deep learning algorithm was developed to guide operators to 10 diagnostic views of the heart: parasternal long axis view (PLAX); parasternal short axis view at aortic valve level (PSAX-AV), mitral valve level (PSAX-MV), and papillary muscle level (PSAX-PM); apical 2, 3, 4, 5 chamber views (Ap2, Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior vena cava view (SC-IVC). Fifteen (15) registered sonographers captured imagery on subjects over a range of BMI and clinical pathology to train the deep learning algorithm. This training dataset contained >5,000,000 individual data points on transducer location/orientation and observed imagery using ultrasound machines from multiple vendors. This dataset was curated and augmented with approximately 500,000 labels from expert sonographers and cardiologists annotating diagnostic quality and suggesting prescriptive guidance actions to improve the imaging (eFigure 1 left). Using this dataset, the algorithm was trained to estimate the 6D distance to each of the 10 views, define 81 unique prescriptive guidance actions, and diagnostic thresholds for each of the 10 views."); *see also supra* ¶¶ 59, 62-64. Each of the trained neural networks output assessment parameters, resulting in "the sets of assessment parameters being a set of neural network parameters." *See id.*

77. To determine the "first quality assessment value," the Accused Products perform "determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category" and "in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters." The "neural network defined by the first set of assessment parameters" can "apply[] a first function based on the first set of assessment parameters to the first at least one echocardiographic image." As described above (*see supra* ¶¶ 59, 62-64, 76), to determine quality assessment values, the Accused Products use neural networks that are trained to provide quality assessment values that are specific to certain view categories and that have an input layer for receiving echocardiographic images. To determine the "first quality assessment value" that is associated with "the first view category," the Accused Products thus use assessment parameters derived from a neural network trained to provide quality assessment values specific to "the first view category." Specifically, the Accused Products determine a first set of assessment parameters associated with the first view category, and in response input the first echocardiographic image for analysis by the determined first set assessment parameters. Similarly, to determine the "second quality assessment value" that is associated with "the second view category," the Accused Products use assessment parameters derived from a neural network trained to provide quality assessment values specific to "the second view category." Specifically, the Accused Products determine a second set of assessment parameters associated with the second view category, and in response input the second echocardiographic image for analysis by the determined second set of assessment parameters.

78. Defendants have also induced and continue to induce the infringement of the '591 patent by others in violation of 35 U.S.C. § 271(b), including by selling the Accused Products to their customers and/or other end users and instructing them to practice at least claim 15 of the '591 patent by using the Accused Products. On information and belief, Defendants are aware of the '591 patent and are aware that when their customers and/or other end users use the Accused Products in

accordance with Defendants' instructions, the customers and/or other end users directly infringe at least claim 15 of the '591 patent. *See supra* ¶¶ 25-36, 82; *see also e.g.*, *In Caption AI Product Demo | AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4. On information and belief, Defendants sell the Accused Products both directly through its own sales force and website. *See* https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-launches-enhanced-venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-guidance?npclid=botnpclid (Oct. 6, 2023) ("Caption Guidance on the Venue Family point-of-care ultrasound systems is available in the United States."); *see also* https://www.gehealthcare.com/shop; https://www.gehealthcare.com/shop/equipment/vscan-air-sl.

79. Defendants have also contributed and continue to contribute to infringement of the '591 patent in violation of 35 U.S.C. § 271(c) by selling the Accused Products to their customers and/or other end users and instructing them to practice at least claim 15 of the '591 patent by using the Accused Products. On information and belief, Defendants are aware of the '591 patent and are aware that when their customers and/or other end users use the Accused Products in accordance with Defendants' instructions, the customers and/or other end users directly infringe at least claim 15 of the '591 patent. *See supra* ¶¶ 25-36, 82; *see also, e.g.*, *In Caption AI Product Demo | AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4. The infringing Caption Guidance is a component of the Accused Products and constitutes a material part of the invention of the '591 patent. The infringing Caption Guidance has no substantial non-infringing uses and is not a staple article of commerce.

80. UBC has never authorized Defendants to make, use, offer to sell, or sell the Accused Products that incorporate the infringing Caption Guidance.

81. As a direct and proximate result of Defendants' acts of infringement, Defendants have derived and received gains, profits, and advantages. UBC has been damaged, and continues to be damaged, by Defendants' infringement in an amount yet to be determined, of at least a reasonable royalty.

82. Defendants' infringement has been and continues to be willful. Defendants had actual knowledge of the '591 patent at least as of May 5, 2022, the date UBC sent its initial letter

bringing the infringement of the '591 patent to Defendants' attention. *See* Exhibit D. Pursuant to 35 U.S.C. § 284, UBC is entitled to damages for Defendants' infringement acts and treble damages together with interests and costs as fixed by this Court.

83. This is an exceptional case. Pursuant to 35 U.S.C. § 285, UBC is entitled to reasonable attorneys' fees for the necessity of bringing this claim.

84. UBC further seeks any other damages to which UBC is entitled under law or in equity.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,751,029

85. UBC incorporates by reference and re-alleges all of the foregoing paragraphs of this First Amended Complaint and exhibits attached hereto as is fully set forth herein.

86. Defendants infringe at least claims 4 and 23 of the '029 patent by making, using, selling, importing, offering for sale its Accused Products.

87. Each of the Accused Products is "[a] system for facilitating ultrasonic image analysis comprising at least one processor…" and is used for "[a] computer-implemented method of facilitating ultrasonic image analysis of a subject." *See, e.g.*, Venue Family Caption GuidanceTM product page, https://www.gehealthcare.com/campaigns/venue-family-caption-guidance ("Preliminary probe placement information shows you where to place and how to orient the ultrasound probe. As you begin the exam, a handy reference image shows you the image you are trying to acquire."; "prescriptive guidance [is] provided on the screen…the Quality Meter rise[s] as you get closer to an image of diagnostic quality."); *see id.* ("Thanks to Caption Guidance™ AI-driven software on the Venue family, even new ultrasound users can capture cardiac images successfully."); *see also supra* ¶¶ 52-64.

88. The Accused Products perform "receiving signals representing a set of ultrasound images of the subject." For example, the Accused Products acquire a series of echocardiographic images when an operator scans a patient using a transducer. *See, e.g.*, Venue Family POCUS R5 Brochure (August 2024), https://www.gehealthcare.com/-/jssmedia/gehc/us/images/products/ultrasound/venue/feature-cards/brochure-venue-family-pocus-r5-jb29262xx.pdf?rev=-1, at 3 ("Caption Guidance helps even new users capture diagnostic-quality

images with its built-in AI-driven software."); *see also id*. at 4 ("Real-time, turn-by-turn on-screen guidance prompts your probe movements to help new POCUS users capture diagnostic-quality cardiac images."); *see also Press Release: GE HealthCare Launches Enhanced Venue Family Point-of-Care Ultrasound Systems Featuring AI-Driven Caption Guidance,* https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-launches-enhanced-venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-guidance?npclid=botnpclid ("The AI-driven Caption Guidance technology gives clinicians step-by-step instructions to confidently acquire ultrasound images for cardiac assessments."); *see also* Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June 2021); *see also supra* ¶¶ 55, 57.

89. The Accused Products perform "deriv[ing] one or more extracted feature representations from the set of ultrasound images." For example, the Accused Products use neural networks to extract feature representations from and assess the set of ultrasound images. *See, e.g.*, G. Yatnalkar, *Caption Guidance – FDA's First Authorized AI-Based Cardiac Ultrasound Software* (Feb. 15, 2021), https://emmainternational.com/fda-authorized-ai-cardiac-ultrasound-software/ ("For Caption Guidance, the AI Algorithm used for image or video frame selection is the Deep Convolutional Neural Network (DCNN). DCNNs are the most powerful and preferred AI algorithms when it comes to imaging applications. The learning begins by training this DCNN with a massive data set of existing images and videos. When the user shifts the probe while performing an ultrasound on the patients' body, new images or videos are generated and these are then compared with the learned data. Based on the minimal difference from image quality comparison, current images and video frames are selected."); Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June 2021) ("The AI-guided image acquisition software…Caption Guidance…provides real-time guidance during scanning to assist the user in obtaining anatomically correct images from standard transthoracic echocardiographic (TTE) transducer positions…The software monitors image quality continuously, simultaneously providing iterative prescriptive cues

to improve the image via the DL algorithm."); *FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User, FDA News Release* (Feb. 7, 2020), https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user ("The Caption Guidance software was developed using machine learning to train the software to differentiate between acceptable and unacceptable image quality."); *see also supra* ¶¶ 62-64.

90. Examples of the "one or more extracted feature representations" may include certain patterns correlated with image quality or an image property (e.g., view category). *See e.g.,* Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 ("Training the network: As shown in eFigure 1, the deep learning algorithm was developed to guide operators to 10 diagnostic views of the heart: parasternal long axis view (PLAX); parasternal short axis view at aortic valve level (PSAX-AV), mitral valve level (PSAX-MV), and papillary muscle level (PSAX-PM); apical 2, 3, 4, 5 chamber views (Ap2, Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior vena cava view (SC-IVC). Fifteen (15) registered sonographers captured imagery on subjects over a range of BMI and clinical pathology to train the deep learning algorithm. This training dataset contained >5,000,000 individual data points on transducer location/orientation and observed imagery using ultrasound machines from multiple vendors. This dataset was curated and augmented with approximately 500,000 labels from expert sonographers and cardiologists annotating diagnostic quality and suggesting prescriptive guidance actions to improve the imaging (eFigure 1 left). Using this dataset, the algorithm was trained to estimate the 6D distance to each of the 10 views, define 81 unique prescriptive guidance actions, and diagnostic thresholds for each of the 10 views.").

91. The Accused Products perform "determin[ing], based on the derived one or more extracted feature representations, a quality assessment value representing a quality assessment of the set of ultrasound images." For example, the Accused Products use neural networks to extract feature representations from and assess the set of ultrasound images, and then determine a quality assessment value based on the extracted feature representations. *See e.g.*, *In Caption AI Product*

Demo: AI-Guided Ultrasound System, https://www.youtube.com/watch?v=URmb72IA4b4 at 0:37-0:59 ("Sarah makes specific transducer movements to optimize the image. On the left, the quality meter tells her how close she is to capturing a diagnostic quality image. As Sarah gets closer to the optimal view, the meter rises. Once the software detects a diagnostic quality image, the meter turns green and the clip is automatically recorded without having to press any buttons."); H. Hong, PhD., *Caption Health: Flattening the Ultrasound Learning Curve with Breakthrough AI-Guided Echocardiography System*, https://www.youtube.com/watch?v=NCFFAlHSPrc at 4:30-4:40 ("Finally, [it] recognizes when the user reaches the target and automatically captures the images in diagnostic quality."); Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use* (Original Investigation) at 625 ("The AI-guided image acquisition software (Caption Guidance [Caption Health, previously known as Bay Labs]), described in greater detail in the eAppendix in the Supplement and shown schematically in eFigure 1 in the Supplement, provides real-time guidance during scanning to assist the user in obtaining anatomically correct images from standard transthoracic echocardiographic (TTE) transducer positions. The AI guidance is software only, developed with DL to emulate sonographer expertise. The software, designed to be compatible with multiple ultrasonography vendors, was installed on a commercially available system (uSmart 3200t Plus [Terason]). The software monitors image quality continuously, simultaneously providing iterative prescriptive cues to improve the image via the DL algorithm."); *id*. ("The DL algorithms were trained using more than 5 million observations associating transducer orientation, the diagnostic correctness of the resulting image, and the outcome of subsequent manipulations with diagnostic quality. This training data set came from 15 registered sonographers via scans of individuals with a range of body mass index (BMI) values and pathological conditions, further annotated for quality by expert sonographers and cardiologists (A.N., R.P.M., R.M.L., N.J.W., and J.D.T.). eFigure 1 in the Supplement depicts the DL model training data set, expert labeling for image quality, algorithm optimization, and run-time operation during the study"); *see also supra* ¶¶ 59, 62-64.

92. The Accused Products perform "determin[ing], based on the derived one or more extracted feature representations, an image property associated with the set of ultrasound images."

For example, the Accused Products determine a view category of the set of ultrasound images based on the extracted feature representation. *See e.g.*, Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 ("Training the network: As shown in eFigure 1, the deep learning algorithm was developed to guide operators to 10 diagnostic views of the heart: parasternal long axis view (PLAX); parasternal short axis view at aortic valve level (PSAX-AV), mitral valve level (PSAX-MV), and papillary muscle level (PSAX-PM); apical 2, 3, 4, 5 chamber views (Ap2, Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior vena cava view (SC-IVC). Fifteen (15) registered sonographers captured imagery on subjects over a range of BMI and clinical pathology to train the deep learning algorithm. This training dataset contained >5,000,000 individual data points on transducer location/orientation and observed imagery using ultrasound machines from multiple vendors. This dataset was curated and augmented with approximately 500,000 labels from expert sonographers and cardiologists annotating diagnostic quality and suggesting prescriptive guidance actions to improve the imaging (eFigure 1 left). Using this dataset, the algorithm was trained to estimate the 6D distance to each of the 10 views, define 81 unique prescriptive guidance actions, and diagnostic thresholds for each of the 10 views.").

93. The Accused Products perform "produc[ing] 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." For example, the Accused Products automatically capture an echocardiographic image and associate the image with the determined quality assessment value and view category. *See e.g.*, Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use* (Original Investigation) at 625 ("The DL algorithm estimates image quality via a component called the quality meter, suggesting probe manipulations using prescriptive guidance (eFigure 1 in the Supplement). When the real-time quality meter exceeds a preset threshold, it automatically records a video clip (termed an auto-capture). Quality is continuously monitored throughout scanning, so the operator can retrospectively save the best clip observed if the auto-capture threshold is not exceeded. If auto-capture is not achieved within 2 minutes, the user may activate the option called

save best clip or continue scanning to achieve auto-capture. These algorithms operate together to improve the ultrasonographic image, as in eFigure 1 in the Supplement, in which prescriptive guidance improves a parasternal long-axis view. eFigure 2 in the Supplement and Video 1 show additional detail on the user interface."); *see also* H. Hong, Ph.D., *Caption Health: Flattening the Ultrasound Learning Curve with Breakthrough AI-Guided Echocardiography System*, https://www.youtube.com/watch?v=NCFFAlHSPrc; *see also In Caption AI Product Demo | AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4at at 0:37-0:59 ("Sarah makes specific transducer movements to optimize the image. On the left, the quality meter tells her how close she is to capturing a diagnostic quality image. As Sarah gets closer to the optimal view, the meter rises. Once the software detects a diagnostic quality image, the meter turns green and the clip is automatically recorded without having to press any buttons."); *see also supra* ¶¶ 55, 60.

94. In the Accused Products, "the image property is a view category." For example, as described above, the Accused Products determine a view category of the set of ultrasound images based on the extracted feature representation. *See supra*, ¶¶ 89-90.

95. In the Accused Products, "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." For example, as described above, the Accused Products use neural networks to extract feature representations from and assess the set of ultrasound images, where one of said extracted feature representations is "a first feature representation." *See supra*, ¶ 89. As described above, examples of the "one or more extracted feature representations" may be certain patterns correlated with image quality or an image property (e.g., view category). *See supra*, ¶ 90.

96. In the Accused Products, "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." Additionally, "the at least one processor" of the Accused Products 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." For example, on information and belief, the Accused Products use a common neural subnetwork for deriving the first feature representation. *See e.g.*, Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use* (Original Investigation) at 625 ("The AI-guided image acquisition software (Caption Guidance [Caption Health, previously known as Bay Labs]), described in greater detail in the eAppendix in the Supplement and shown schematically in eFigure 1 in the Supplement, provides real-time guidance during scanning to assist the user in obtaining anatomically correct images from standard transthoracic echocardiographic (TTE) transducer positions. The AI guidance is software only, developed with DL to emulate sonographer expertise. … The guidance software used convolutional neural networks constructed by stacking computational layers, each taking input from the layer below, transforming and passing it along to the layer above. The software monitors image quality continuously, simultaneously providing iterative prescriptive cues to improve the image via the DL algorithm. The guidance software used convolutional neural networks constructed by stacking computational layers, each taking input from the layer below, transforming and passing it along to the layer above. The software has several interconnected DL algorithms making 3 simultaneous estimates: (1) diagnostic quality of the imagery, (2) 6-dimensional geometric distance (by position and orientation) between current probe location and the location anticipated to optimize the image, and (3) corrective probe manipulations to improve diagnostic quality. Importantly, the algorithm makes these estimates from the ultrasonographic imagery alone; no trackers, fiducial markers, or additional sensors are required. The DL algorithms were trained using more than 5 million observations associating transducer orientation, the diagnostic correctness of the resulting image, and the outcome of subsequent manipulations with diagnostic quality."); *see also* Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 ("Training the network: As shown in eFigure 1, the deep learning algorithm was developed to guide operators to 10 diagnostic views of the heart: parasternal long axis view (PLAX); parasternal short axis view at aortic valve level (PSAX-AV), mitral valve level (PSAX-MV), and papillary muscle level (PSAX-PM); apical 2, 3, 4, 5 chamber views (Ap2, Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior vena cava view (SC-IVC). Fifteen (15) registered sonographers captured imagery on subjects over a range of BMI and clinical pathology to train the deep learning algorithm. This training dataset contained >5,000,000 individual data points on transducer location/orientation and observed imagery using ultrasound machines from multiple vendors. This dataset was curated and augmented with approximately 500,000 labels from expert sonographers and cardiologists annotating diagnostic quality and suggesting prescriptive guidance actions to improve the imaging (eFigure 1 left). Using this dataset, the algorithm was trained to estimate the 6D distance to each of the 10 views, define 81 unique prescriptive guidance actions, and diagnostic thresholds for each of the 10 views. The algorithm, consisting of more than 7,000,000 parameters, was trained using standard machine learning optimization techniques on a 31 tFLOP (trillion floating point operations per second) GPU array. Training the model took approximately 7.2 exaFLOP (1 exaFLOP is one million teraFLOPs or a quintillion (1018) 32-bit multiplication floating point operations) over two weeks (eFigure 1 center). Further information on Caption Guidance may be found in the talk, "Development and Validation of a Breakthrough AI-Guided Echocardiography System" presented at the FDA-hosted public workshop titled, "Evolving Role of Artificial Intelligence in Radiological Imaging" held in Bethesda, Maryland on February 25 and 26, 2020, with slides [https://www.fda.gov/media/135734/download], and video [http://fda.yorkcast.com/webcast/Play/5ac1c24f9e48455c82011ab26837afad1d], with the relevant portion beginning at 42:10 of the video available.").

97. Defendants have also induced and continue to induce the infringement of the '029 patent by others in violation of 35 U.S.C. § 271(b), including by selling the Accused Products to their customers and/or other end users and instructing them to practice at least claim 4 of the '029 patent by using the Accused Products. On information and belief, Defendants are aware of the '029 patent and are aware that when their customers and/or other end users use the Accused Products in accordance with Defendants' instructions, the customers and/or other end users directly infringe at least claim 4 of the '029 patent. *See e.g.*, *In Caption AI Product Demo | AI-Guided Ultrasound*

System, https://www.youtube.com/watch?v=URmb72IA4b4. On information and belief, Defendants sell the Accused Products both directly through its own sales force and website. *See* https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-launches-enhanced-venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-guidance?npclid=botnpclid (Oct. 6, 2023) ("Caption Guidance on the Venue Family point-of-care ultrasound systems is available in the United States."); *see also* https://www.gehealthcare.com/shop; https://www.gehealthcare.com/shop/equipment/vscan-air-sl.

98. Defendants have also contributed and continue to contribute to infringement of the '029 patent in violation of 35 U.S.C. § 271(c) by selling the Accused Products to their customers and/or other end users and instructing them to practice at least claim 4 of the '029 patent by using the Accused Products. On information and belief, Defendants are aware of the '029 patent and are aware that when their customers and/or other end users use the Accused Products in accordance with Defendants' instructions, the customers and/or other end users directly infringe at least claim 4 of the '029 patent. *See e.g.*, *In Caption AI Product Demo | AI-Guided Ultrasound System*, https://www.youtube.com/watch?v=URmb72IA4b4. The infringing Caption Guidance is a component of the Accused Products and constitutes a material part of the invention of the '029 patent. The infringing Caption Guidance has no substantial non-infringing uses and is not a staple article of commerce.

99. UBC has never authorized Defendants to make, use, offer to sell, or sell the Accused Products that incorporate the infringing Caption Guidance.

100. As a direct and proximate result of Defendants' acts of infringement, Defendants have derived and received gains, profits, and advantages. UBC has been damaged, and continues to be damaged, by Defendants' infringement in an amount yet to be determined, of at least a reasonable royalty.

101. Defendants' infringement has been and continues to be willful. On information and belief, Defendants had actual knowledge of the '029 patent before the filing of this First Amended Complaint. Pursuant to 35 U.S.C. § 284, UBC is entitled to damages for Defendants' infringement acts and treble damages together with interests and costs as fixed by this Court.

102. This is an exceptional case. Pursuant to 35 U.S.C. § 285, UBC is entitled to reasonable attorneys' fees for the necessity of bringing this claim.

103. UBC further seeks any other damages to which UBC is entitled under law or in equity.

DEMAND FOR JURY TRIAL

104. UBC hereby demands a jury trial for all issues so triable.

PRAYER FOR RELIEF

105. WHEREFORE, UBC respectfully requests that this Court enter judgment in its favor as follows:

A. That Judgment be entered that Defendants have infringed and continues to infringe one or more claims of the '591 patent and '029 patent under 35 U.S.C. § 271;

B. That, in accordance with 35 U.S.C. § 283, Defendants and all their affiliates, employees, agents, officers, directors, attorneys, successors, and assigns and all those acting on behalf of or in active concert or participation with any of them, be preliminarily and permanently enjoined from infringing the '591 patent and '029 patent;

C. That UBC be awarded damages sufficient to compensate UBC for Defendants' infringement and enhanced damages under 35 U.S.C. § 284;

D. That UBC be awarded attorneys' fees and costs pursuant to 35 U.S.C. § 285 or as otherwise permitted by law;

E. That UBC be awarded its costs and expenses in this action; and

H. Such other and further relief as the Court deems just and proper.

Dated: December 20, 2024

PERKINS COIE LLP

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