

1 Ramsey M. Al-Salam, Bar No. 109506
2 RAlsalam@perkinscoie.com
3 Dorianne Salmon, *pro hac vice*
4 DSalmon@perkinscoie.com
5 PERKINS COIE LLP
6 1201 Third Avenue, Suite 4900
7 Seattle, Washington 98101-3099
8 Telephone: +1.206.359.8000
9 Facsimile: +1.206.359.9000

6 Moeka Takagi, Bar No. 333226
7 MTakagi@perkinscoie.com
8 PERKINS COIE LLP
9 3150 Porter Drive
10 Palo Alto, California 94304-1212
11 Telephone: +1.650.838.4300
12 Facsimile: +1.650.838.4350

10 Attorneys for Plaintiff
11 University of British Columbia

12 **UNITED STATES DISTRICT COURT**
13 **NORTHERN DISTRICT OF CALIFORNIA**
14 **SAN JOSE DIVISION**

16 UNIVERSITY OF BRITISH COLUMBIA,
17 Plaintiff,
18 v.
19 CAPTION HEALTH, INC.,
20 GE HEALTHCARE TECHNOLOGIES INC.
21 Defendants.

Case No. 5:24-cv-03200-EKL

**FIRST AMENDED COMPLAINT FOR
PATENT INFRINGEMENT**

Judge: Hon. Eumi K. Lee

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

6 **THE NATURE OF THE ACTION**

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

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

13 **THE PARTIES**

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

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

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

25 **JURISDICTION AND VENUE**

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

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

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

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

28

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

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

23 **B. The '591 Patent**

24 **1. Development of the '591 Invention**

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

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

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

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

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

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

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

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

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

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

27
28

1 **2. The Consideration and Grant of the '591 Patent**

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

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

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

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

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

19 27. Shortly after the meeting, at Mr. Koepsell's request, Robert Rohling emailed Mr.
20 Koepsell papers that were discussed during the meeting. The papers sent were A. H. Abdi, et. al.,
21 *Automatic quality assessment of apical four-chamber echocardiograms using deep convolutional*
22 *neural networks*, Medical Imaging 2017: Image Processing, 10133 (Feb. 2017), and A. H. Abdi, et.
23 al., *Automatic Quality Assessment of Echocardiograms Using Convolutional Neural Networks:*
24 *Feasibility on the Apical Four-Chamber View*, IEEE Transactions on Medical Imaging, Vol. 36,
25 6:1221-1230 (June 2017). The second paper was available in preprint format on the IEEE website
26 by May 2017. A copy of the correspondence sent from Mr. Rohling to Mr. Koepsell is attached as
27 Exhibit C.

28

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

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

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

11 31. Caption Health did not respond to the letter.

12 32. Having heard no response, UBC's counsel sent another letter to Mr. Cashman on
13 May 24, 2022, attaching the original May 5, 2022, letter and requesting a response regarding the
14 '591 patent. A copy of the May 24, 2022, letter is attached hereto as Exhibit E.

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

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

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

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

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

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

6 4. Overview of the '591 Patent

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

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

17 40. Further, the employed neural networks are trained to assess echocardiographic
18 images of a specific view category. *See, e.g., id.*, 5:62-6:20. As described above, it is typical to
19 capture echocardiographic images from various view or anatomical planes to allow determination
20 of certain clinical measurements or diagnosis. *See, e.g., id.*, 5:46-49. Since the desirable
21 characteristics for each of these different views can differ, there may be different criteria for
22 assessing echocardiographic images based on the view they represent. *See, e.g., id.*, 5:62-67. For
23 example, a quality assessment value for the “AP2” view category may depend on the left ventricle,
24 left atrium, and mitral valve in the image, while a quality assessment value for the “AP3” category
25 may depend on the aortic valve, mitral valve, left atrium, left ventricle, and septum. *See, e.g., id.*,
26 15:28:39. As the specification explains, the employed neural networks are trained with images and
27 their associated view category information, so that neural network parameters that are eventually
28 used to assess image quality can evaluate quality based on criteria specific to certain view

1 categories. *See, e.g., id.*, 17:60-63, 18:27-35. Employment of neural networks associated with
2 specific view categories of echocardiographic images was not known or conventional and provided
3 an improvement over typical analyses. For example, a neural network is better able to consider in
4 its analysis the “variability in the echocardiographic image data than when analysis of the
5 echocardiographic image relies on an average template or atlas with average shape.” *See, id.*,
6 11:44-51. Applying specialized neural networks for specific view categories thus improves the
7 system’s ability to assess echocardiographic image quality. Thus, the claims provide an
8 improvement to a specific technology in a particular field.

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

20 C. The ’029 Patent

21 1. Development of the ’029 Invention

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

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

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

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

19 2. The Consideration and Grant of the '029 Patent

20 45. The United States Patent Office quickly recognized the importance of the claimed
21 invention. In a Non-Final Office Action, the Examiner rejected the claims for minor informalities
22 and as anticipated by Patent Publication No. 2019/0125298 ("298 publication"), the publication
23 that led to issuance of the '591 patent. *See* App. No. 16/557,261, January 8, 2020, Non-Final
24 Rejection. The Examiner allowed the application shortly thereafter upon finding the '298
25 publication was not prior art because it fell under the 102(b)(2)(C) exception. *See id.*, Mar. 19,
26 2020, Amendment/Request for Reconsideration-After Non-Final Rejection at 8-10 (describing that
27 the '298 publication and App. No. 16/557,261 were subject to an obligation of assignment to UBC);
28 *see id.*, June 25, 2020, Notice of Allowance.

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

4 **3. Overview of the ’029 Patent**

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

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

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

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

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

22 **D. Defendants’ Infringing Products**

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

1 [healthcare-launches-enhanced-venue-family-point-of-care-ultrasound-systems-featuring-ai-](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)
2 [driven-caption-guidance?npclid=botnpclid](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
3 point-of-care ultrasound systems is available in the United States.”).

4 52. Defendants market their infringing products as incorporating the infringing scan
5 guidance technology under the names “Caption Guidance,” “Caption AI, ” or “Caption AI
6 Guidance.” Caption Guidance is “a medical software tool that utilizes Artificial Intelligence (AI)
7 for providing echocardiography.” G. Yatnalkar, *EMMA International: Caption Guidance – FDA’s*
8 *First Authorized AI-Based Cardiac Ultrasound Software*, by Govind (Feb. 15, 2021). Caption
9 Guidance, or Caption AI Guidance, is incorporated into a series of point-of-care ultrasound
10 products called “the Venue Family.” *GE HealthCare Launches Enhanced Venue Family Point-of-*
11 *Care Ultrasound Systems Featuring AI-Driven Caption Guidance*, GE Healthcare (Oct. 6, 2023),
12 [https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-launches-enhanced-](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)
13 [venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-](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)
14 [guidance?npclid=botnpclid](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-](https://www.linkedin.com/posts/rolandrott_ultrasound-gehealthcare-rsna-activity-7135509649302126594-J-2g/?utm_source=share&utm_medium=member_ios)
15 [gehealthcare-rsna-activity-7135509649302126594-J-](https://www.linkedin.com/posts/rolandrott_ultrasound-gehealthcare-rsna-activity-7135509649302126594-J-2g/?utm_source=share&utm_medium=member_ios)
16 [2g/?utm_source=share&utm_medium=member_ios](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,
17 Roland Rott, marketing “the Venue Family with Caption AI Guidance”). Similarly, Caption AI
18 “provides real-time visual guidance to prompt users on probe movements and includes a quality
19 meter to ensure the user obtains the best possible images. Once an image is captured, the AutoEF
20 feature automatically calculates a left ventricular ejection fraction (LVEF). In addition, users can
21 efficiently scan with AutoCapture and Save Best Clip features to capture the best quality image
22 from each view.” *GE HealthCare Introduces Caption AI on Vscan Air SL Wireless Handheld*
23 *Ultrasound System to Help More Clinicians Capture Diagnostic-Quality Cardiac Images*, GE
24 Healthcare (Apr. 3, 2024), [https://www.gehealthcare.com/about/newsroom/press-releases/ge-](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)
25 [healthcare-introduces-caption-ai-on-vscan-air-sl-wireless-handheld-ultrasound-system-to-help-](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)
26 [more-clinicians-capture-diagnostic-quality-cardiac-images](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
27 handheld ultrasounds called “Vscan Air SL.” *Id.* While the features described below focus on
28 Caption Guidance, on information and belief, Caption AI provides similar features. *See id.*; see

1 also [https://www.gehealthcare.com/products/ultrasound/handheld-ultrasound/vscan-air-caption-](https://www.gehealthcare.com/products/ultrasound/handheld-ultrasound/vscan-air-caption-ai)
2 [ai](https://www.gehealthcare.com/products/ultrasound/handheld-ultrasound/vscan-air-caption-ai).

3 Find Caption Guidance

4 Discover the Venue Family

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



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



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



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

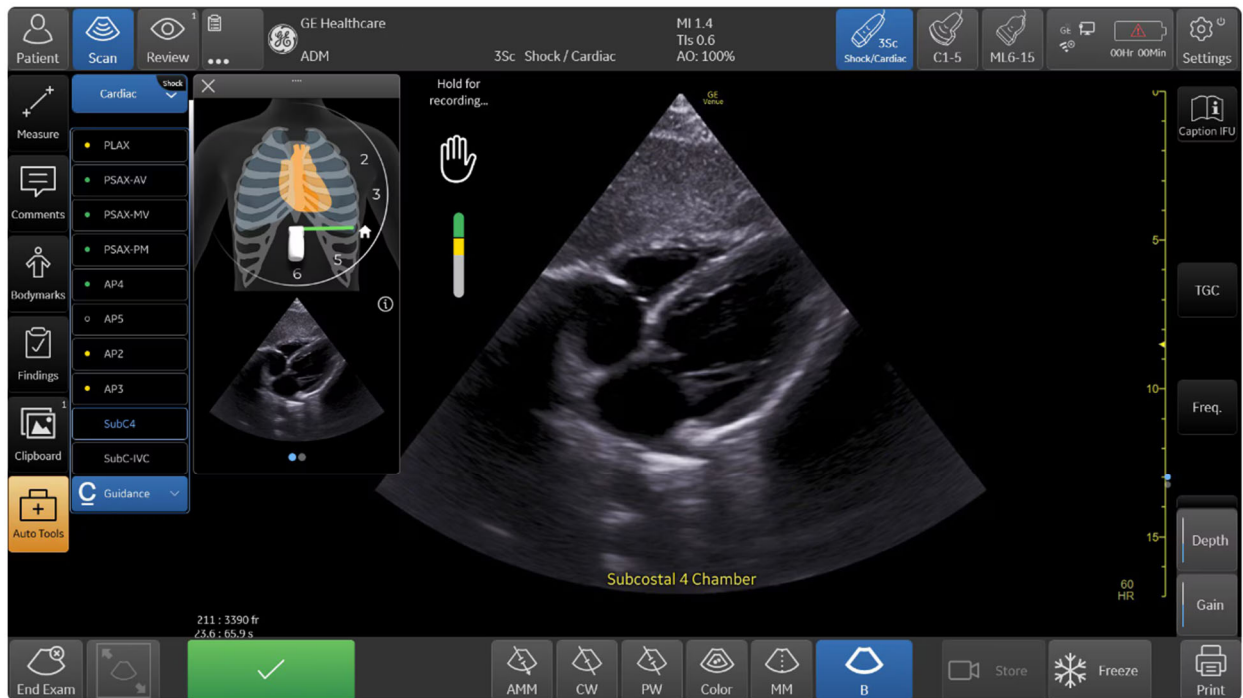
38 <https://www.gehealthcare.com/campaigns/venue-family-caption-guidance>.



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

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



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

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

23 55. The ’253 application is directed to ultrasound guidance dynamic progression
24 methods and systems. The ’253 application describes “[a]n ultrasound guidance dynamic
25 progression method [that] includes selecting a predetermined ultrasound diagnostic workflow in
26 memory of an ultrasound diagnostic computing system.” ’253 application, Abstract. It further
27 describes a system that comprises “at least one processor” configured to perform the method. *See,*
28 *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”).

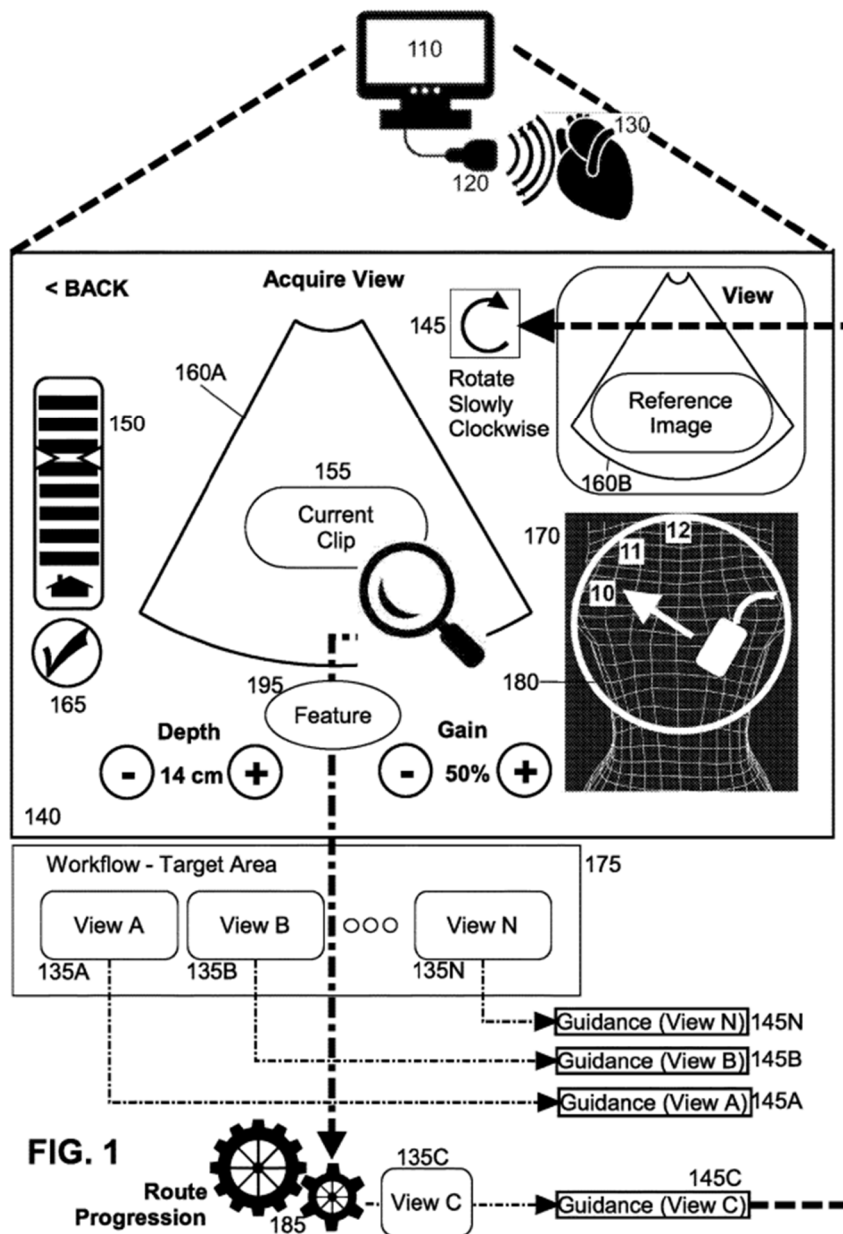


FIG. 1

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

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

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

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

23 59. Caption Guidance determines quality assessment values representing view category
24 specific quality assessment of echocardiographic images. Caption Guidance implements a “quality
25 meter” that “indicates a sliding scale of quality of the imagery...relative to a known view sought to
26 be acquired for the target organ.” *Id.*, ¶ 22; *see also In Caption AI Product Demo | AI-Guided*
27 *Ultrasound System*, <https://www.youtube.com/watch?v=URmb72IA4b4>. A success icon is
28

1 displayed in connection with the quality meter if the “corresponding quality value...meets or
2 exceeds a threshold quality for the specified view.” *Id.*

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

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

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

1 Guidance, the AI Algorithm used for image or video frame selection is the Deep Convolutional
2 Neural Network (DCNN).”); Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices*
3 *to Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June
4 2021) (“The AI-guided image acquisition software...Caption Guidance...provides real-time
5 guidance during scanning to assist the user in obtaining anatomically correct images from standard
6 transthoracic echocardiographic (TTE) transducer positions...The software monitors image quality
7 continuously, simultaneously providing iterative prescriptive cues to improve the image via the DL
8 algorithm.”); *FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial*
9 *Intelligence to Guide User*, FDA News Release (Feb. 7, 2020), [https://www.fda.gov/news-](https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user)
10 [events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-](https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user)
11 [artificial-intelligence-guide-user](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
12 learning to train the software to differentiate between acceptable and unacceptable image quality.”).

13 63. The Caption Guidance neural networks are trained to provide quality assessment
14 values that are specific to certain view categories. For example, “a second neural network...may
15 be trained to characterize guidance instructions relative to contemporaneously acquired imagery of
16 the target organ.” ’235 application, ¶ 28. The “second neural network...is trained to produce
17 recommend[ed] guidance to achieve the optimal acquisition of generated imagery for the target
18 organ for the particular one of the views...relative to the generated imagery contemporaneously
19 presented in a display of the host computing system.” *Id.* The Caption Guidance “DL algorithms
20 were trained using more than 5 million observations associating transducer orientation, the
21 diagnostic correctness of the resulting image, and the outcome of subsequent manipulations with
22 diagnostic quality.” Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to*
23 *Acquire Echocardiograms for Limited Diagnostic Use*, JAMA Cardiology, 6:624-632, 625 (June
24 2021). Caption Guidance’s “DL algorithm estimates image quality via a component called the
25 quality meter, suggesting probe manipulations using prescriptive guidance.” *Id.*

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

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

10 65. Defendants announced plans to incorporate Caption Guidance into additional
11 products. [https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-launches-](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)
12 [enhanced-venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-](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)
13 [guidance?npclid=botnpclid](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
14 technology into other ultrasound systems, including handheld systems, helping to further expand
15 access to diagnostic care as well as the use of ultrasound in a variety of care settings.”).

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

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

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

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

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

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

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

4 70. The Accused Products perform “associating the first at least one echocardiographic
5 image with a first view category of a plurality of predetermined echocardiographic image view
6 categories.” *See, e.g.,* Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to*
7 *Acquire Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 (“In
8 order to help users to acquire high-quality echocardiograms, the guidance algorithm must be able
9 to estimate the positioning of the ultrasound probe from the current imaging and provide real-time
10 guidance based on that estimation for the user to arrive at the ideal positioning and image. It must
11 first be able to grade the quality of the imagery and determine whether it meets diagnostic criteria.
12 Therefore, the AI-guidance deep learning algorithm makes three simultaneous estimates: 1)
13 diagnostic quality of the imagery, 2) six-dimensional (6D, probe position plus orientation)
14 geometric distance between current probe location and a probe location anticipated to optimize the
15 image, and 3) corrective probe manipulations to improve diagnostic quality. Importantly, the deep
16 learning algorithm makes these estimates from only the ultrasound imagery; no trackers, fiducial
17 markers, or additional sensors are needed for operation.”); *see also id.* (“Training the network: As
18 shown in eFigure 1, the deep learning algorithm was developed to guide operators to 10 diagnostic
19 views of the heart: parasternal long axis view (PLAX); parasternal short axis view at aortic valve
20 level (PSAX-AV), mitral valve level (PSAX-MV), and papillary muscle level (PSAX-PM); apical
21 2, 3, 4, 5 chamber views (Ap2, Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior
22 vena cava view (SC-IVC). Fifteen (15) registered sonographers captured imagery on subjects over
23 a range of BMI and clinical pathology to train the deep learning algorithm. This training dataset
24 contained >5,000,000 individual data points on transducer location/orientation and observed
25 imagery using ultrasound machines from multiple vendors. This dataset was curated and augmented
26 with approximately 500,000 labels from expert sonographers and cardiologists annotating
27 diagnostic quality and suggesting prescriptive guidance actions to improve the imaging (eFigure 1
28 left). Using this dataset, the algorithm was trained to estimate the 6D distance to each of the 10

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

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

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

18 72. The Accused Products perform “producing signals representing the first quality
19 assessment value for causing the first quality assessment value to be associated with the first at
20 least one echocardiographic image.” For example, the Accused Products automatically capture an
21 echocardiographic image and associate the image with the determined quality assessment value.
22 “When the real-time quality meter exceeds a preset threshold, it automatically records a video clip
23 (termed an *auto-capture*).” *See, e.g.,* Narang, et. al., *Utility of a Deep-Learning Algorithm to Guide*
24 *Novices to Acquire Echocardiograms for Limited Diagnostic Use, (Original Investigation)* at 625-
25 26 (“The DL algorithm estimates image quality via a component called the quality meter,
26 suggesting probe manipulations using prescriptive guidance (eFigure 1 in the Supplement). When
27 the real-time quality meter exceeds a preset threshold, it automatically records a video clip (termed
28 an *auto-capture*). Quality is continuously monitored throughout scanning, so the operator can

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

16 73. The Accused Products perform the steps described above (*see supra* ¶¶ 69-72) for
17 multiple echocardiographic images corresponding to multiple view categories. *See, e.g.*, ’253
18 application, ¶ 21 (“For each of the views 135A, 135B, 135N, corresponding guidance 145A, 145B,
19 145N is determined and presented in sequence of the views 135A, 135B, 135N of the workflow
20 175...In this regard, the corresponding guidance 145A, 145B, 145N includes different directives
21 for positioning and posing the ultrasound imaging probe 120 so as to produce the imagery 155 for
22 a corresponding one of the views 135A, 135B, 135N.”); *see also supra* ¶ 61. Thus, the Accused
23 Products perform “receiving signals representing a second at least one echocardiographic image,”
24 “associating the second at least one echocardiographic image with a second view category of the
25 plurality of predetermined echocardiographic image view categories, said second view category
26 being different from the first view category,” “determining, based on the second at least one
27 echocardiographic image and the second view category, a second quality assessment value
28 representing a view category specific quality assessment of the second at least one

1 echocardiographic image,” and “producing signals representing the second quality assessment
2 value for causing the second quality assessment value to be associated with the second at least one
3 echocardiographic image.”

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

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

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

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

1 imagery for the target organ for the particular one of the views...relative to the generated imagery
2 contemporaneously presented in a display of the host computing system.” ’253 application, ¶ 28;
3 *see also* Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire*
4 *Echocardiograms for Limited Diagnostic Use (Supplemental Online Content)* at 2 (“In order to
5 help users to acquire high-quality echocardiograms, the guidance algorithm must be able to estimate
6 the positioning of the ultrasound probe from the current imaging and provide real-time guidance
7 based on that estimation for the user to arrive at the ideal positioning and image. It must first be
8 able to grade the quality of the imagery and determine whether it meets diagnostic criteria.
9 Therefore, the AI-guidance deep learning algorithm makes three simultaneous estimates: 1)
10 diagnostic quality of the imagery, 2) six-dimensional (6D, probe position plus orientation)
11 geometric distance between current probe location and a probe location anticipated to optimize the
12 image, and 3) corrective probe manipulations to improve diagnostic quality. Importantly, the deep
13 learning algorithm makes these estimates from only the ultrasound imagery; no trackers, fiducial
14 markers, or additional sensors are needed for operation.”); *see also id.* (“Training the network: As
15 shown in eFigure 1, the deep learning algorithm was developed to guide operators to 10 diagnostic
16 views of the heart: parasternal long axis view (PLAX); parasternal short axis view at aortic valve
17 level (PSAX-AV), mitral valve level (PSAX-MV), and papillary muscle level (PSAX-PM); apical
18 2, 3, 4, 5 chamber views (Ap2, Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior
19 vena cava view (SC-IVC). Fifteen (15) registered sonographers captured imagery on subjects over
20 a range of BMI and clinical pathology to train the deep learning algorithm. This training dataset
21 contained >5,000,000 individual data points on transducer location/orientation and observed
22 imagery using ultrasound machines from multiple vendors. This dataset was curated and augmented
23 with approximately 500,000 labels from expert sonographers and cardiologists annotating
24 diagnostic quality and suggesting prescriptive guidance actions to improve the imaging (eFigure 1
25 left). Using this dataset, the algorithm was trained to estimate the 6D distance to each of the 10
26 views, define 81 unique prescriptive guidance actions, and diagnostic thresholds for each of the 10
27 views.”); *see also supra* ¶¶ 59, 62-64. Each of the trained neural networks output assessment
28

1 parameters, resulting in “the sets of assessment parameters being a set of neural network
2 parameters.” *See id.*

3 77. To determine the “first quality assessment value,” the Accused Products perform
4 “determining that a first set of assessment parameters of the sets of assessment parameters is
5 associated with the first view category” and “in response to determining that the first set of
6 assessment parameters is associated with the first view category, inputting the first at least one
7 echocardiographic image into the neural network defined by the first set of assessment parameters.”
8 The “neural network defined by the first set of assessment parameters” can “apply[] a first function
9 based on the first set of assessment parameters to the first at least one echocardiographic image.”
10 As described above (*see supra* ¶¶ 59, 62-64, 76), to determine quality assessment values, the
11 Accused Products use neural networks that are trained to provide quality assessment values that are
12 specific to certain view categories and that have an input layer for receiving echocardiographic
13 images. To determine the “first quality assessment value” that is associated with “the first view
14 category,” the Accused Products thus use assessment parameters derived from a neural network
15 trained to provide quality assessment values specific to “the first view category.” Specifically, the
16 Accused Products determine a first set of assessment parameters associated with the first view
17 category, and in response input the first echocardiographic image for analysis by the determined
18 first set assessment parameters. Similarly, to determine the “second quality assessment value” that
19 is associated with “the second view category,” the Accused Products use assessment parameters
20 derived from a neural network trained to provide quality assessment values specific to “the second
21 view category.” Specifically, the Accused Products determine a second set of assessment
22 parameters associated with the second view category, and in response input the second
23 echocardiographic image for analysis by the determined second set of assessment parameters.

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

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

10 79. Defendants have also contributed and continue to contribute to infringement of the
11 ’591 patent in violation of 35 U.S.C. § 271(c) by selling the Accused Products to their customers
12 and/or other end users and instructing them to practice at least claim 15 of the ’591 patent by using
13 the Accused Products. On information and belief, Defendants are aware of the ’591 patent and are
14 aware that when their customers and/or other end users use the Accused Products in accordance
15 with Defendants’ instructions, the customers and/or other end users directly infringe at least claim
16 15 of the ’591 patent. *See supra* ¶¶ 25-36, 82; *see also, e.g., In Caption AI Product Demo | AI-*
17 *Guided Ultrasound System*, <https://www.youtube.com/watch?v=URmb72IA4b4>. The infringing
18 Caption Guidance is a component of the Accused Products and constitutes a material part of the
19 invention of the ’591 patent. The infringing Caption Guidance has no substantial non-infringing
20 uses and is not a staple article of commerce.

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

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

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

1 bringing the infringement of the '591 patent to Defendants' attention. *See* Exhibit D. Pursuant to
2 35 U.S.C. § 284, UBC is entitled to damages for Defendants' infringement acts and treble damages
3 together with interests and costs as fixed by this Court.

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

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

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

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

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

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

23 88. The Accused Products perform “receiving signals representing a set of ultrasound
24 images of the subject.” For example, the Accused Products acquire a series of echocardiographic
25 images when an operator scans a patient using a transducer. *See, e.g.*, Venue Family POCUS R5
26 Brochure (August 2024), [https://www.gehealthcare.com/-](https://www.gehealthcare.com/-/jssmedia/gehc/us/images/products/ultrasound/venue/feature-cards/brochure-venue-family-pocus-r5-jb29262xx.pdf?rev=-1)
27 [/jssmedia/gehc/us/images/products/ultrasound/venue/feature-cards/brochure-venue-family-pocus-](https://www.gehealthcare.com/-/jssmedia/gehc/us/images/products/ultrasound/venue/feature-cards/brochure-venue-family-pocus-r5-jb29262xx.pdf?rev=-1)
28 [r5-jb29262xx.pdf?rev=-1](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

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

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

1 to improve the image via the DL algorithm.”); *FDA Authorizes Marketing of First Cardiac*
2 *Ultrasound Software That Uses Artificial Intelligence to Guide User*, FDA News Release (Feb. 7,
3 2020), [https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-](https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user)
4 [cardiac-ultrasound-software-uses-artificial-intelligence-guide-user](https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user) (“The Caption Guidance
5 software was developed using machine learning to train the software to differentiate between
6 acceptable and unacceptable image quality.”); *see also supra* ¶¶ 62-64.

7 90. Examples of the “one or more extracted feature representations” may include certain
8 patterns correlated with image quality or an image property (e.g., view category). *See e.g.*, Narang
9 et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for*
10 *Limited Diagnostic Use (Supplemental Online Content)* at 2 (“Training the network: As shown in
11 eFigure 1, the deep learning algorithm was developed to guide operators to 10 diagnostic views of
12 the heart: parasternal long axis view (PLAX); parasternal short axis view at aortic valve level
13 (PSAX-AV), mitral valve level (PSAX-MV), and papillary muscle level (PSAX-PM); apical 2, 3,
14 4, 5 chamber views (Ap2, Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior vena
15 cava view (SC-IVC). Fifteen (15) registered sonographers captured imagery on subjects over a
16 range of BMI and clinical pathology to train the deep learning algorithm. This training dataset
17 contained >5,000,000 individual data points on transducer location/orientation and observed
18 imagery using ultrasound machines from multiple vendors. This dataset was curated and augmented
19 with approximately 500,000 labels from expert sonographers and cardiologists annotating
20 diagnostic quality and suggesting prescriptive guidance actions to improve the imaging (eFigure 1
21 left). Using this dataset, the algorithm was trained to estimate the 6D distance to each of the 10
22 views, define 81 unique prescriptive guidance actions, and diagnostic thresholds for each of the 10
23 views.”).

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

1 *Demo: AI-Guided Ultrasound System*, <https://www.youtube.com/watch?v=URmb72IA4b4> at 0:37-
2 0:59 (“Sarah makes specific transducer movements to optimize the image. On the left, the quality
3 meter tells her how close she is to capturing a diagnostic quality image. As Sarah gets closer to the
4 optimal view, the meter rises. Once the software detects a diagnostic quality image, the meter turns
5 green and the clip is automatically recorded without having to press any buttons.”); H. Hong, PhD.,
6 *Caption Health: Flattening the Ultrasound Learning Curve with Breakthrough AI-Guided*
7 *Echocardiography System*, <https://www.youtube.com/watch?v=NCFFAIHSPrc> at 4:30-4:40
8 (“Finally, [it] recognizes when the user reaches the target and automatically captures the images in
9 diagnostic quality.”); Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to*
10 *Acquire Echocardiograms for Limited Diagnostic Use* (Original Investigation) at 625 (“The AI-
11 guided image acquisition software (Caption Guidance [Caption Health, previously known as Bay
12 Labs]), described in greater detail in the eAppendix in the Supplement and shown schematically in
13 eFigure 1 in the Supplement, provides real-time guidance during scanning to assist the user in
14 obtaining anatomically correct images from standard transthoracic echocardiographic (TTE)
15 transducer positions. The AI guidance is software only, developed with DL to emulate sonographer
16 expertise. The software, designed to be compatible with multiple ultrasonography vendors, was
17 installed on a commercially available system (uSmart 3200t Plus [Terason]). The software monitors
18 image quality continuously, simultaneously providing iterative prescriptive cues to improve the
19 image via the DL algorithm.”); *id.* (“The DL algorithms were trained using more than 5 million
20 observations associating transducer orientation, the diagnostic correctness of the resulting image,
21 and the outcome of subsequent manipulations with diagnostic quality. This training data set came
22 from 15 registered sonographers via scans of individuals with a range of body mass index (BMI)
23 values and pathological conditions, further annotated for quality by expert sonographers and
24 cardiologists (A.N., R.P.M., R.M.L., N.J.W., and J.D.T.). eFigure 1 in the Supplement depicts the
25 DL model training data set, expert labeling for image quality, algorithm optimization, and run-time
26 operation during the study”); *see also supra* ¶¶ 59, 62-64.

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

1 For example, the Accused Products determine a view category of the set of ultrasound images based
2 on the extracted feature representation. *See e.g., Narang et. al., Utility of a Deep-Learning*
3 *Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*
4 *(Supplemental Online Content)* at 2 (“Training the network: As shown in eFigure 1, the deep
5 learning algorithm was developed to guide operators to 10 diagnostic views of the heart: parasternal
6 long axis view (PLAX); parasternal short axis view at aortic valve level (PSAX-AV), mitral valve
7 level (PSAX-MV), and papillary muscle level (PSAX-PM); apical 2, 3, 4, 5 chamber views (Ap2,
8 Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior vena cava view (SC-IVC).
9 Fifteen (15) registered sonographers captured imagery on subjects over a range of BMI and clinical
10 pathology to train the deep learning algorithm. This training dataset contained >5,000,000
11 individual data points on transducer location/orientation and observed imagery using ultrasound
12 machines from multiple vendors. This dataset was curated and augmented with approximately
13 500,000 labels from expert sonographers and cardiologists annotating diagnostic quality and
14 suggesting prescriptive guidance actions to improve the imaging (eFigure 1 left). Using this dataset,
15 the algorithm was trained to estimate the 6D distance to each of the 10 views, define 81 unique
16 prescriptive guidance actions, and diagnostic thresholds for each of the 10 views.”).

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

1 save best clip or continue scanning to achieve auto-capture. These algorithms operate together to
2 improve the ultrasonographic image, as in eFigure 1 in the Supplement, in which prescriptive
3 guidance improves a parasternal long-axis view. eFigure 2 in the Supplement and Video 1 show
4 additional detail on the user interface.”); *see also* H. Hong, Ph.D., *Caption Health: Flattening the*
5 *Ultrasound Learning Curve with Breakthrough AI-Guided Echocardiography System*,
6 <https://www.youtube.com/watch?v=NCFFAIHSPrc>; *see also* *In Caption AI Product Demo | AI-*
7 *Guided Ultrasound System*, <https://www.youtube.com/watch?v=URmb72IA4b4at> at 0:37-0:59
8 (“Sarah makes specific transducer movements to optimize the image. On the left, the quality meter
9 tells her how close she is to capturing a diagnostic quality image. As Sarah gets closer to the optimal
10 view, the meter rises. Once the software detects a diagnostic quality image, the meter turns green
11 and the clip is automatically recorded without having to press any buttons.”); *see also supra* ¶¶ 55,
12 60.

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

16 95. In the Accused Products, “deriving the one or more extracted feature representations
17 from the ultrasound images comprises, for each of the ultrasound images, deriving a first feature
18 representation associated with the ultrasound image.” For example, as described above, the
19 Accused Products use neural networks to extract feature representations from and assess the set of
20 ultrasound images, where one of said extracted feature representations is “a first feature
21 representation.” *See supra*, ¶ 89. As described above, examples of the “one or more extracted
22 feature representations” may be certain patterns correlated with image quality or an image property
23 (e.g., view category). *See supra*, ¶ 90.

24 96. In the Accused Products, “deriving the one or more extracted feature representations
25 comprises, for each of the ultrasound images, inputting the ultrasound image into a commonly
26 defined first feature extracting neural subnetwork to generate the first feature representation
27 associated with the ultrasound image.” Additionally, “the at least one processor” of the Accused
28 Products is “configured to, for each of the ultrasound images, input the ultrasound image into a

1 commonly defined first feature extracting neural subnetwork to generate the first feature
2 representation associated with the ultrasound image.” For example, on information and belief, the
3 Accused Products use a common neural subnetwork for deriving the first feature representation.
4 See e.g., Narang et. al., *Utility of a Deep-Learning Algorithm to Guide Novices to Acquire*
5 *Echocardiograms for Limited Diagnostic Use* (Original Investigation) at 625 (“The AI-guided
6 image acquisition software (Caption Guidance [Caption Health, previously known as Bay Labs]),
7 described in greater detail in the eAppendix in the Supplement and shown schematically in eFigure
8 1 in the Supplement, provides real-time guidance during scanning to assist the user in obtaining
9 anatomically correct images from standard transthoracic echocardiographic (TTE) transducer
10 positions. The AI guidance is software only, developed with DL to emulate sonographer expertise.
11 ... The guidance software used convolutional neural networks constructed by stacking
12 computational layers, each taking input from the layer below, transforming and passing it along to
13 the layer above. The software monitors image quality continuously, simultaneously providing
14 iterative prescriptive cues to improve the image via the DL algorithm. The guidance software used
15 convolutional neural networks constructed by stacking computational layers, each taking input
16 from the layer below, transforming and passing it along to the layer above. The software has several
17 interconnected DL algorithms making 3 simultaneous estimates: (1) diagnostic quality of the
18 imagery, (2) 6-dimensional geometric distance (by position and orientation) between current probe
19 location and the location anticipated to optimize the image, and (3) corrective probe manipulations
20 to improve diagnostic quality. Importantly, the algorithm makes these estimates from the
21 ultrasonographic imagery alone; no trackers, fiducial markers, or additional sensors are required.
22 The DL algorithms were trained using more than 5 million observations associating transducer
23 orientation, the diagnostic correctness of the resulting image, and the outcome of subsequent
24 manipulations with diagnostic quality.”); see also Narang et. al., *Utility of a Deep-Learning*
25 *Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use*
26 *(Supplemental Online Content)* at 2 (“Training the network: As shown in eFigure 1, the deep
27 learning algorithm was developed to guide operators to 10 diagnostic views of the heart: parasternal
28 long axis view (PLAX); parasternal short axis view at aortic valve level (PSAX-AV), mitral valve

1 level (PSAX-MV), and papillary muscle level (PSAX-PM); apical 2, 3, 4, 5 chamber views (Ap2,
2 Ap3, Ap4, and Ap5); and subcostal 4 chamber (SC-4) and inferior vena cava view (SC-IVC).
3 Fifteen (15) registered sonographers captured imagery on subjects over a range of BMI and clinical
4 pathology to train the deep learning algorithm. This training dataset contained >5,000,000
5 individual data points on transducer location/orientation and observed imagery using ultrasound
6 machines from multiple vendors. This dataset was curated and augmented with approximately
7 500,000 labels from expert sonographers and cardiologists annotating diagnostic quality and
8 suggesting prescriptive guidance actions to improve the imaging (eFigure 1 left). Using this dataset,
9 the algorithm was trained to estimate the 6D distance to each of the 10 views, define 81 unique
10 prescriptive guidance actions, and diagnostic thresholds for each of the 10 views. The algorithm,
11 consisting of more than 7,000,000 parameters, was trained using standard machine learning
12 optimization techniques on a 31 tFLOP (trillion floating point operations per second) GPU array.
13 Training the model took approximately 7.2 exaFLOP (1 exaFLOP is one million teraFLOPs or a
14 quintillion (10¹⁸) 32-bit multiplication floating point operations) over two weeks (eFigure 1
15 center). Further information on Caption Guidance may be found in the talk, “Development and
16 Validation of a Breakthrough AI-Guided Echocardiography System” presented at the FDA-hosted
17 public workshop titled, “Evolving Role of Artificial Intelligence in Radiological Imaging” held in
18 Bethesda, Maryland on February 25 and 26, 2020, with slides
19 [<https://www.fda.gov/media/135734/download>], and video
20 [<http://fda.yorkcast.com/webcast/Play/5ac1c24f9e48455c82011ab26837afad1d>], with the relevant
21 portion beginning at 42:10 of the video available.”).

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

1 *System*, <https://www.youtube.com/watch?v=URmb72IA4b4>. On information and belief,
2 Defendants sell the Accused Products both directly through its own sales force and website. *See*
3 [https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-launches-enhanced-](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)
4 [venue-family-point-of-care-ultrasound-systems-featuring-ai-driven-caption-](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)
5 [guidance?npclid=botnpclid](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
6 ultrasound systems is available in the United States.”); *see also*
7 <https://www.gehealthcare.com/shop>; <https://www.gehealthcare.com/shop/equipment/vscan-air-sl>.

8 98. Defendants have also contributed and continue to contribute to infringement of the
9 ’029 patent in violation of 35 U.S.C. § 271(c) by selling the Accused Products to their customers
10 and/or other end users and instructing them to practice at least claim 4 of the ’029 patent by using
11 the Accused Products. On information and belief, Defendants are aware of the ’029 patent and are
12 aware that when their customers and/or other end users use the Accused Products in accordance
13 with Defendants’ instructions, the customers and/or other end users directly infringe at least claim
14 4 of the ’029 patent. *See e.g., In Caption AI Product Demo | AI-Guided Ultrasound System*,
15 <https://www.youtube.com/watch?v=URmb72IA4b4>. The infringing Caption Guidance is a
16 component of the Accused Products and constitutes a material part of the invention of the ’029
17 patent. The infringing Caption Guidance has no substantial non-infringing uses and is not a staple
18 article of commerce.

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

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

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

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

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

5 **DEMAND FOR JURY TRIAL**

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

7 **PRAYER FOR RELIEF**

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

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

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

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

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

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

21 H. Such other and further relief as the Court deems just and proper.
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1 Dated: December 20, 2024

PERKINS COIE LLP

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By: */s/ Ramsey M. Al-Salam*
Ramsey M. Al-Salam, Bar No. 109506
RAlsalam@perkinscoie.com
Dorianne Salmon, *pro hac vice*
DSalmon@perkinscoie.com
PERKINS COIE LLP
1201 Third Avenue, Suite 4900
Seattle, Washington 98101-3099
Telephone: +1.206.359.8000
Facsimile: +1.206.359.9000

Moeka Takagi, Bar No. 333226
MTakagi@perkinscoie.com
PERKINS COIE LLP
3150 Porter Drive
Palo Alto, California 94304-1212
Telephone: +1.650.838.4300
Facsimile: +1.650.838.4350

Attorneys for Plaintiff
University of British Columbia