

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Medivis, Inc.
Petitioner

v.

Novarad Corp.
Patent Owner

Case IPR2023-00042
US Patent No. 11,004,271

DECLARATION OF MAHESH S. MULUMUDI, M.D.

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I, Mahesh S. Mulumudi, M.D., declare as follows:

1. I am over 21 years of age and otherwise competent to make this declaration. I make this declaration based upon facts and matters within my own knowledge and on information provided to me by others.

2. I have been retained as an expert witness to provide testimony on behalf of Novarad Corp. (“Patent Owner”) as part of the above-captioned *inter partes* review proceeding (“IPR”).

3. More specifically, I have been asked primarily to assist in evaluating the grounds raised in the Petition (Paper 3) and in Dr. Kazanzides’ declaration (Ex. 1012) in support of that Petition.

4. I reserve the right to supplement this Declaration in response to additional evidence that may come to light.

5. I am not currently, nor have I ever been, employed by Patent Owner. Nor have I previously served as an expert witness on behalf of Patent Owner.¹

6. I understand that Patent Owner owns U.S. Patent No. 11,004,271 (“the ’271 Patent”), entitled AUGMENTING REAL-TIME VIEWS OF A PATIENT WITH THREE-DIMENSIONAL DATA,” the validity of which Medivis, Inc. (“Petitioner”) challenges.

¹ Nor have I performed work for, met, or ever spoken with Dr. Steven Cvetko or Dr. Wendell Gibby, the named inventors in the ’271 Patent.

7. I have reviewed the specification of the '271 Patent as well as its prosecution history. I am familiar with the '271 Patent. A copy of the '271 Patent was provided as Exhibit 1001.

8. I am familiar with the technology at issue at the time of the '271 Patent, which Petitioner has assumed to be on or before March 30, 2017. Petition at 10.

9. I have also reviewed the Petition. The Petition presents several grounds for challenging the claims of the '271 Patent, which appear deficient to me for reasons I address in more detail below. *See infra* at ¶¶ 98-179.

10. I have also reviewed the declaration of Dr. Kazanzides (Ex. 1012), which I also address.

11. I have also reviewed the following references cited by Petitioner as prior art and other documents included in the exhibit list below:

Exhibit	Description
Ex. 1001	U.S. Patent No. 11,004,271 (the '271 Patent)
Ex. 1002	Excerpts of file history of Application No. 16/574,524, now the '271 Patent
Ex. 1003	Excerpts of file history of Application No. 15/894,595, now U.S. Patent No. 10,475,244.
Ex. 1004	Excerpts of file history of Application No. 15/474,702, now U.S. Patent No. 9,892,564.

Ex. 1005	Excerpt of Amira 5 User's Guide (" <i>Amira</i> ")
Ex. 1006	U.S. Publication No. US 2016/0191887 A1 to Casas (" <i>Casas</i> ")
Ex. 1007	S. Pujols, Ph.D. et al., 3D Visualization of DICOM Images for Radiological Applications (" <i>3D Visualization</i> ")
Ex. 1008	International Publication No. WO 2015/164402 A1 to Doo et al. (" <i>Doo</i> ")
Ex. 1009	X. Chen et al., "Development of Surgical Navigation System Based On Augmented Reality Using an Optical See-Through Head-Mounted Display," 55 JOURNAL OF BIOMEDICAL INFORMATICS 124-131 (2015) (" <i>Chen</i> ")
Ex. 1010	Main Application GUI for 3D Slicer < https://www.slicer.org/wiki/Documentation/4.6/Slicer/Application/MainApplicationGUI > (" <i>3D Slicer</i> ")
Ex. 1011	E. Azimi et al. "Augmentation Reality Goggles with an Integrated Tracking System for Navigations in Neurosurgery," IEEE VIRTUAL REALITY 123-124, 123 (IEEE 2012) (" <i>AR Goggle for Neurosurgery</i> ")
Ex. 1012	Declaration of Peter Kazantzides, Ph.D.
Ex. 1013	Curriculum Vitae of Peter Kazantzides Ph.D.

12. I am being compensated for my time in connection with the IPR at a rate of \$700 per hour. I am also being compensated for any out-of-pocket expenses for my work in this review. My compensation as an expert is in no way dependent upon the results of any investigations I undertake, the substance of any opinion I express, or the ultimate outcome of the review proceedings.

I. QUALIFACTIONS

13. I believe I am qualified to serve as a technical expert in this proceeding based on my educational and work experience, including my 20+ years of experience in imaging, virtual reality, augmented reality with biofeedback, and treating peripheral vascular and coronary artery diseases from 2000 through today.

14. This declaration sets forth my opinions, which I formed based on my study of the evidence; my understanding as an expert in the field; and my training, education, research, knowledge, and personal and professional experience. All of my opinions stated in this declaration are based on my own personal knowledge, expertise, training, education, and professional judgment. In forming my opinions, I have relied on my knowledge and experience in human factors, user interface design, user interaction design, human-computer interaction, and software engineering.

15. If I am called upon to do so, I would be competent to testify to the matters set forth herein. My qualifications to testify about the technical subject matter in this case and the relevant technology are outlined in my curriculum vitae and this section of this declaration. A copy of my current curriculum vitae is provided for this proceeding as Exhibit 2003.

16. I earned my Bachelor of Medicine and Bachelor of Surgery, the equivalent to a Doctor of Medicine degree, from Kurnool Medical College in 1990.

After graduation, I completed an internship at the Government General Hospital in India.

17. Upon completion of my internship, I continued my studies at the University of Texas at Austin as a PhD student in the Department of Pharmacology and Toxicology from 1992 to 1994. As a PhD student, I researched the effects of multiple oral doses of ICI D2138 on allergen induced bronchoconstriction, conducting Phase I and Phase II of the clinical studies at Health Quest Research.

18. I completed my residency in Internal Medicine at Detroit Medical Center in 1997. Following my residency, in 1998, I was the primary investigator for the Phase IIIb clinical trial of a cyclooxygenase inhibitor versus naproxen sodium in the treatment of osteoarthritis.

19. From 2000 to 2005, I was engaged in two cardiology fellowships at the Oschner Clinic Foundation in New Orleans, Louisiana. During these fellowships, I organized clinical research investigating the role of abciximab in improving myocardial blush after primary coronary intervention for acute ST segment elevation myocardial infarction. I also researched the concept of kidney frame counts in the renal angiography and the relationship of tissue myocardial perfusion to the intravascular ultrasound of the epicardial coronary arteries in orthotopic heart transplant patients.

20. Following my fellowships, I became certified in Interventional Cardiology through the American Board of Internal Medicine in 2005. In 2013, I became board certified in Cardiovascular Disease through the American Board of Internal Medicine.

21. I have filed for nineteen patents involving the invention of electronic devices in conjunction with anatomic regions.

22. I am the author of fifteen research papers in professional journals and proceedings in cardiac and renal assessment and functions.

23. I am the inventor of a virtual reality application that leverages biofeedback to offer mindfulness exercises in an effort to reduce stress and enhance focus. I also created a virtual reality telemedicine solution that enhances remote healthcare delivery by enabling purposeful and engaging interactions between patients and their healthcare providers.

24. I currently serve as President and CEO of StratoScientific, Inc.; Division Chief of Medicine; Section Head of Cardiology; and Medical Director of Interventional Cardiology and Chest Pain Programs at Providence Regional Medical Center in Washington. I am also the Director of Vascular Laboratory and Heart & Vascular Department at the Everett Clinic. From 2006 through 2012, I served as Facilities Medical Director I the Department of Heart & Vascular, Neurology, and Nephrology at the Everett Clinic.

25. More information about my educational and professional background can be found in my curriculum vitae, Exhibit 2003.

26. The combination of my education, research, training, and work experience in cardiovascular health and virtual reality technology in healthcare as it relates to improving the patient experience enables me to provide analysis and opinions on the subject matter of this litigation.

27. I am being compensated for my work on this case and my fee is not contingent on the outcome of this case or on any of my opinions or the technical positions I explain in this report. In addition, I have no financial interest in the outcome of this case, or any of the parties involved this case. I have worked on a number of litigation cases, several of which were related to the role technology plays in the standard of care received by patients.

28. Based on the above credentials and experience, and as further documented in my attached CV, I believe that I have the necessary education, training, research, scholarship, and experience to analyze the '271 Patent and opine on how a person of ordinary skill in the art (as further defined below) would have understood it and its validity in the context of the relevant prior art.

II. MY EXPERTISE AND THE PERSON OF ORDINARY SKILL IN THE ART

29. My opinions in this declaration are based on my experience in this technical field. More specifically, my over 20+ years of experience in imaging, virtual reality, augmented reality with biofeedback, and treating peripheral vascular and coronary artery diseases from 1983 through today. I am qualified to provide expert opinions on some aspects of the technology described in the '271 Patent and on the references cited by Petitioner and Dr. Kazanzides.

30. I understand that my opinion must be taken from the perspective of what would have been known or understood by a person of ordinary skill in the art (“POSITA”) at the time of the invention.

31. I understand that Dr. Kazanzides has concluded that the relevant art is “systems and methods for using augmented reality during medical procedures.” Ex. 1012, ¶ 23.

32. I further understand that Petitioner has defined POSITA at the time of the '271 Patent as “a person with a bachelor’s degree in computer science, electrical engineering, or a related field with several years of experience in the design, development, and study of augmented reality devices and either (a) familiar with conventional medical imaging data and visualization of data for medical

procedures or (b) working with a team including someone with such familiarity.”

Ex. 1012, ¶ 25.

33. I understand, and have been informed, that for purposes of assessing the obviousness of a claimed invention, the level of ordinary skill possessed by a POSITA is informed by, among other things, the type of problems encountered in the relevant art, the prior art solutions to those problems, the rapidity with which innovations are made in the relevant art, the sophistication of the relevant technology, and the educational level of active workers in the field.

III. LEGAL STANDARDS

34. I am not an attorney. My analysis and opinions are based on my expertise as an interventional cardiologist, as well as the instructions I have been given by counsel for the legal standards relating to patent validity.

35. I understand that a claim of an issued patent may be found to be unpatentable if the claim is not novel or would have been obvious in view of the prior art. I understand that this determination is made from the perspective of a person having ordinary skill in the art who is presumed to be aware of all prior art.

36. I understand that a patent claim will not be unpatentable due to what is called anticipation unless all elements of a claim, arranged in the same way, are found in a single reference. I have also been informed that for anticipation, each

and every claim limitation must be explicitly or inherently disclosed in the prior art.

37. I have also been informed and understand that anticipation by inherent disclosure is appropriate only when the reference necessarily includes the unstated limitation. Thus, it has been explained to me that inherency may not be established by probabilities or possibilities, and the mere fact that a certain thing *may* result from a given set of circumstances is insufficient.

38. I understand that a patent claim will not be unpatentable due to obviousness unless the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious to a POSITA at the time of the invention.

39. I understand that the following factors are considered in assessing obviousness: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art at the time of the invention; and (4) “objective indicia of non-obviousness,” also referred to as secondary considerations of non-obviousness. Those objective indicia include considerations such as whether a product covered by the claims is commercially successful due to the merits of the claimed invention, whether there was a long felt need for the solution provided by the claimed invention, whether others failed to find the solution provided by the claimed invention, and whether

there was acceptance by others of the claimed invention as shown by praise from others in the field.

40. I also understand that one should analyze whether the prior art references disclose each and every element of the claim as those references would have been read by a POSITA. I understand that obviousness cannot be proven by mere conclusory statements.

41. I understand that a claim is not proved obvious merely by showing that each of the individual elements existed somewhere in the prior art.

42. I understand that when a combination of prior art references is relied upon to assert obviousness, the party asserting obviousness must also identify a reason or motivation that would have prompted one of ordinary skill in the art to combine the elements of the references in the same way as the claimed invention and with a reasonable expectation of success.

43. I also understand that in assessing obviousness, it is improper to rely upon hindsight and that one should avoid using the claimed invention as a roadmap to piece together disclosures from the prior art.

44. I understand that in this *inter partes* review proceeding, the claims of the '271 Patent are generally given their ordinary and customary meaning as understood by a POSITA in light of the patent's specification and the prosecution history.

45. I also understand that claim terms should be given their broadest reasonable interpretation to a POSITA, which interpretation must be consistent with the patent's specification.

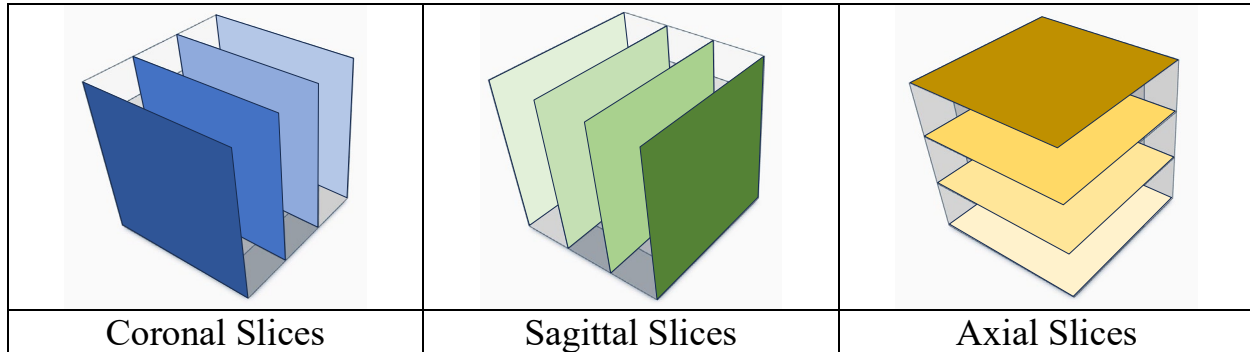
46. Similarly, I understand that the prosecution history contains the complete record of all the proceedings before the Patent and Trademark Office and may contain contemporaneous exchanges between the patent applicant and the PTO about what the claims mean. Thus, I understand that the prosecution history can inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution.

47. I understand that where a patent expressly defines a claim term, that definition may also inform the understanding of a POSITA. I have applied these standards in my analysis in this declaration.

IV. OVERVIEW OF THE USE OF AUGMENTED REALITY (AR) IN MEDICAL PRACTICE AT THE TIME OF THE '271 PATENT

48. One common source of medical imaging is a computed tomography (CT) scan, which uses X-rays to create detailed images of the inside of the body. When the X-ray source and detectors rotate around the patient, they record from many different angles. Conventionally, a computer then uses this 3D data to reconstruct a set of 2D images or slices. This set of 2D slices are conventionally

reconstructed along one of three planes: coronal (front to back), sagittal (left to right), or axial (top to bottom):



Each of these 2D images represents distribution of X-ray attenuation in the patient's body.

49. Each 2D CT scan image consists of a grid of 2D pixels. The value of the pixel corresponds to the radiodensity of the tissue within the pixel. While each pixel represents a small volume element, or voxel², of the patients body, a 2D CT scan image actually provides no information about the patient anatomy between the slices.



² A voxel is the 3D equivalent of a pixel.

50. Another common source of medical imaging is a magnetic resonance imaging (MRI) scan, which uses a strong magnetic field and radio waves to create images of the inside of the body. The output of an MRI scan, conventionally, is one of three sets of 2D images or slices (coronal, sagittal, and axial), similar to a CT scan. Again, each 2D image consists of a grid of 2D pixels. The value of the pixel corresponds to the strength of the MRI signal received at that pixel, which depends on the type of tissue in the pixel. The pixel value also depends on the MRI sequence used, among other factors. While each pixel represents a small volume of element of the patient's body, a 2D MRI scan image provides no information about layers of the patient anatomy between the 2D slices.

51. There are various methods for visualizing CT and MRI scan data, including “slice-by-slice viewing,” “multiplanar reconstruction (MPR), surface rendering, and direct volume rendering (DVR). One of the earliest, and still most common, methods for visualizing medical imaging data is “slice-by-slice viewing.” This is where individual 2D slices are viewed sequentially, one at a time, in the direction they were compiled. Traditionally, CT and MRI slices are acquired and viewed along only one axis, typically the axial or transverse plane (horizontal slices as if looking from the feet towards the head). This “slice-by-slice viewing” method does not provide a complete 3D view of anatomical structures within the volume of a patient.

52. Another method for visualizing a specific anatomical feature from CT and/or MRI data is “surface rendering.” This method involves creating a 3D surface model of an anatomical feature of interest from the medical imaging data. This is done by first performing a segmentation step to identify the voxels within the original 3D dataset that belong to an anatomical structure of interest. After segmentation, a polygonal model of the surface of the identified anatomical structure, *i.e.*, a shell, is generated. Since surface rendering only provides a view of the modeled surface of the previously identified anatomical structure, it is used when the focus is on a specific structure of interest. But it does not provide information about the anatomical areas of interest within the structure to which a modeled surface was rendered.

53. Surface rendering can be time-consuming and requires a high-level of expertise to perform the segmentation step accurately. Also, surface rendering may not accurately represent complex or internal structures because it relies on identifying and rendering the surfaces of structures. As a result, minor errors or noise in the data can cause significant errors in the final surface rendering. In surface rendering, it is common to apply thresholding to distinguish between different types of tissues or materials in the data. However, if thresholds are not set correctly, this can lead to errors or omissions in the final surface rendering. It might also oversimplify the complexity of the data. Also, surface rendering is

unable to represent semi-transparent or overlapping structures accurately which can be a disadvantage with medical imaging where these types of structures are common.

54. Direct volume rendering (DVR) is very different from the other visualization methods described above. DVR is a method for visualizing medical imaging data, including CT and MRI scan or ultrasound data, in three-dimensions. DVR gives physicians a more realistic and intuitive view of complex anatomical situations avoiding geometric assumptions. It can offer perspectives that are not limited to the traditional planes (e.g., axial, sagittal, and coronal), enabling a view of the anatomical structures within the volume of a patient from any direction.

55. Unlike surface rendering, DVR is not feature specific, but takes into account the complete volume of the patient data. While surface models depict the external surfaces or boundaries of an object, DVR creates a 3D image by considering every individual voxel in the dataset allowing for the visualization of internal structures, and not just outer surfaces of a particular anatomical feature.

56. Also, unlike surface rendering, DVR does not require the creation of an intermediate surface representation and does not require segmentation of the data into different structures or tissues. Instead, DVR operates directly on the original 3D dataset (i.e., grid of voxels that make up the raw volume data). Each voxel within the 3D dataset is assigned a color and opacity based on transfer

fuctions. All the voxels are then composited, or blended together, to create a 3D image of the entire volume of the patient anatomy.

57. DVR is incredibly beneficial in surgical applications where the anatomical features of interest do not align along conventional axial, sagittal, or coronal planes or are intertwined with other structures. DVR is not limited to conventional planes. It provides improved depth perception and spatial relationships between different structures, which is crucial in complex surgeries. The other visualization methods described above do not provide these same benefits.

58. Although DVR is more computationally intensive than other visualization methods, it provides a unique comprehensive and flexible visualization of 3D medical imaging. At the same time, because DVR provides a comprehensive and flexible visualization of 3D medical imaging, controls are needed to help isolate and identify areas of interest within a DVR volume—especially in an augmented reality (AR) environment. For example, when projected onto real, non-image, actual views of a patient in an operating room.

V. THE '271 PATENT AND THE CHALLENGED CLAIMS

A. The '271 Patent Requires Direct Volume Rendered 3D Data.

59. The '271 Patent discloses “[a]ugmenting real-time views of a patient with three-dimensional (3D) data.” Ex. 1001, *Abstract*. This “3D data” includes

“an outer layer of the patient and multiple inner layers of the patient.” Ex. 1001, 1:46-49. The ’271 Patent further discloses displaying the full volume of the “3D data,” and any lesser portion of the full volume, including a single slice. *See* Ex. 1001, 5:34-25 (“display a slice of the 3D data instead of a volume of the 3D data”). The 3D slices can be cut along any axis. Ex. 1001, 5:38-40 (“display different slices of the 3D data including, but not limited to, axial slices, coronal slices, sagittal slices, and oblique slices.”); 6:17-21 (“Slices may be ... 3D slices [and] ... [m]ay include curved slices, such as curved slices that follow the natural curve of an anatomical feature, or slices that have depth as well as height and width”). The ’271 Patent further discloses that the user can navigate, *e.g.*, move between, the slices cut along any axis in real time. Ex. 1001, 8:44-47 (“the user may ... change from viewing the axial slice to a sagittal slice, and then from the sagittal slice to a coronal slice, respectively.”). The projected 3D data may be viewed from any angle. Ex. 1001, 4:55-56. (“the 3D data of the patient 106 may be viewed by the user 104 from any angle”). The “multiple inner layers may be layers that go all the way through the patient 106, or may be layers that only go to a certain partial depth into the patient.” Ex. 1001: 12:13-16.

60. In view of the foregoing, a POSITA understands that the ’271 Patent describes direct volume rendered 3D data because only a DVR image is 3D, includes an outer layer and multiple inner layers of the patient, and can be cut

along any axis and viewed from any angle in real-time. A POSITA understands that only DVR provides the comprehensiveness, detail, and flexibility to visualize and navigate the internal layers of a projected 3D volume of a patient in real-time: “all the way through the patient,” at a “certain partial depth into the patient,” and along multiple axes, as described and claimed in the '271 Patent.

61. A POSITA understands that this cannot be done using any of the other known methods. For example, as mentioned above, “slice-by-slice viewing” and “multiplanar reconstruction (MPR)” do not provide a full 3D view. They also cannot be viewed or navigated in real-time along multiple axes. Conventional “slice-by-slice viewing” is limited to the axis of the original scan (e.g., axial, sagittal, or coronal). Similarly, MPR is limited to the plane selected for “re-slicing.” Additionally, anatomical structures do not always align themselves along the conventionally defined axial planes (e.g., axial, sagittal, or coronal). A POSITA appreciates that anatomical structures are very unique to each patient and tend to traverse in and out of conventional planes as they course through the human body.

62. A POSITA understands that “surface rendering” is also limited. For example, surface rendering only provides a view of a surface model, *i.e.*, shell, of a specific feature of interest and nothing else. A surface model does not include any of the surrounding anatomical structure. Moreover, with surface rendering, the modeled feature is identified prior to segmentation and generation of the surface

model. Thus, a POSITA understands that there would be less of a need for a navigational tool for a surface model, like the “virtual 3D shape” of claim 1. Because a DVR image includes the full 3D dataset of the patient’s anatomy, including external surfaces and internal structures, a “virtual 3D shape” is particularly useful, as described in more detail below.

B. The '271 Patent Provides a Novel Method for Navigating, in Real-Time, Direct Volume Rendered Data While It is Projected onto Non-Image Actual Views of a Patient.

63. The '271 Patent provides a novel method—a “virtual 3D shape”—for navigating, in real-time, direct volume rendered data while it is projected onto non-image actual views of a patient in an augmented reality environment. The '271 Patent discloses that a “virtual spatial difference box 116 may be generated by the AR headset 108 *to confine within a volume* of the virtual spatial difference box 116 the projected inner layer of the patient 106 from the 3D data.” Ex. 1001, 6:5-8 (emphasis added). The “virtual spatial difference box 116 *may ... assist the user when navigating the projected 3D data....*” Ex. 1001, 6:11-13 (emphasis added). The virtual spatial difference box “may assist the user when moving axial slices, coronal slices, sagittal slices, or oblique slices of the 3D data within the virtual spatial difference box 116.” Ex. 1001, 6:14-17. The “3D slices may include curved slices, such as curved slices that follow the natural curve of an anatomical feature, or slices that have depth as well as height and width.” Ex. 1001, 6:18-21.

The “virtual 3D shape is *configured to be controlled to reposition ... slices of the projected inner layer of the patient* from the 3D data.” Ex. 1001, Claim 3. The ’271 Patent further discloses that the “user 104 may move these slices using hand gestures....” Ex. 1001, 6:21-22 (emphasis added).

64. A POSITA understands that this “virtual spatial difference box” is a navigational tool and it is not limited to a “box” shape. A POSITA understands that the purpose of the “virtual 3D shape,” as recited in claims 1-5, is to assist the user in navigating the projected volume rendered 3D data by *confining* the visible portion of the 3D data within the 3D virtual shape. For example, the boundaries of the 3D virtual shape may be moved by the user to reveal more or less of the projected 3D data. A user may use the 3D virtual shape to move between 3D slices or segments and along any axis. Thus, the boundaries and orientation of the virtual 3D shape determine which 3D slices, or internal layers, of the projected 3D data are visible to the user. This “navigation” occurs in real-time, while the 3D data is projected on and registered to non-image actual views of the patient.

65. A POSITA would appreciate that a navigational tool like the “virtual 3D shape” of claim 1 is particularly useful for navigating a projected 3D DVR image in an augmented reality (AR) environment for at least the following reasons: As mentioned above, a DVR image includes both external surfaces and internal

structures. DVR allows for real-time interaction with the data, including slicing and other modifications. DVR also allows for detailed exploration of complex three-dimensional structures without the need for physical dissection or manipulation.

VI. CONSTRUCTION OF CERTAIN CLAIM TERMS

66. The following is a listing of the challenged claims in the '271 Patent:

1(a)	A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:
1(b)	identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient; and
1(c)	displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient
1(d)	the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.
2	The method as recited in claim 1, wherein: the virtual 3D shape is a virtual box; and the virtual box includes a top side, a bottom side, a left side, a right side, a front side, and a back side.
3	The method of claim 1, wherein: the virtual 3D shape is configured to be controlled to toggle between displaying and hiding lines of the virtual 3D shape; and the virtual 3D shape is configured to be controlled to reposition two-dimensional (2D) slices and/or 3D slices of the projected inner layer of the patient from the 3D data.
4	The method of claim 1, wherein lines of the virtual 3D shape are displayed.
5	The method of claim 1, wherein lines of the virtual 3D shape are hidden.

6	One or more non-transitory computer-readable media storing one or more programs that are configured, when executed, to cause one or more processors to perform the method as recited in claim 1.
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11(a)	A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:
11(b)	identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient, the multiple inner layers of the patient having an original color gradient;
11(c)	altering the original color gradient of the multiple inner layers to be lighter than the original color gradient in order to be better visible when projected onto real-time, non-image actual views of the outer layer of the patient; and
11(d)	displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient, the projected inner layer of the patient from the 3D data being having the altered color gradient.
12-19	The method as recited in claim 11, wherein the altered color gradient represents a tissue [hardness/relaxivity/echogenicity/enhancement amount/enhancement speed/density/radioactivity/water content] property of the multiple inner layers of the patient.
20	One or more non-transitory computer-readable media storing one or more programs that are configured, when executed, to cause one or more processors to perform the method as recited in claim 11.

1. “three-dimensional (3D) data ... including an outer layer of the patient and multiple inner layers of the patient”

Claim Term	Petitioner’s Construction	Patent Owner’s Construction
“three-dimensional (3D) data ... including an outer layer of the patient and multiple inner layers of the patient” (claims 1 and 11)	“one or more of MRI images, Computerized Tomography (CT) scan images, X-ray images, Positron Emission Tomography (PET) images, ultrasound images, fluorescence, Infrared Thermography (IRT) images, and Single-Photon Emission Computer Tomography (SPECT) scan image”	“Direct-volume-rendered CT, MRI, PET, and SPECT imaging (and also ultrasound and fluorescence imaging, depending on the methods used.”

67. The ’271 Patent acknowledges “[c]onventional medical imaging systems may create three-dimensional (3D) data for a patient and then display that 3D data as an image or images on a computer display.” Ex. 1001, 2:49-51. The ’271 Patent states “3D data of the patient ... may include, but is not limited to, MRI images, Computerized Tomography (CT) scan images, X-ray images, Positron Emission Tomography (PET) images, ultrasound images, fluorescence images, Infrared Thermography (IRT) images, and Single-Photon Emission Computer Tomography (SPECT) scan image, or some combination thereof.” Ex. 1001, 11:45-51. Dr. Kazanzides opines that “the person of ordinary skill in the art understands that ‘3D data’ may be one or more of the foregoing types of images.”

Ex. 1012, ¶ 32. However, it is unclear what Dr. Kazanzides means by “‘3D data’ may be one or more of the foregoing types of images.”

68. A POSITA understands, and Dr. Kazanzides admitted, that “something is three-dimensional if it has the dimension of depth as well as width and height.” K Depo, 58:11-15. Or, put another way, a 3D volume has x-, y-, and z-data in a Cartesian coordinate system. A POSITA would also understand that the conventional medical imaging systems listed in the ’271 Patent generally generate 2D images or a series of 2D images taken along a particular axis of the patient anatomy (e.g., axial, sagittal, or coronal). As Dr. Kazanzides, admits each 2D image has no “z information” other than that “common to the slice.” K Depo, 64:1-7.

69. After review of the specification and the claims, a POSITA understands that “3D data” means direct volume rendered medical imaging because direct volume rendering is the only visualization method that is consistent with the language of the ’271 Patent and the claims. For example, claim 1 requires “real-time” augmentation of “non-image actual views of a patient with three-dimensional (3D) data.” A POSITA understands that this 3D data must have height, width, and depth. Claim 1 also requires “3D data including an outer layer of the patient and multiple inner layers of the patient.” According to the specification, the inner layers of the patient “have depth as well as height and

width” Ex. 1001, 6:17-21. Claim 1 further requires that the projected 3D data is “confined within a volume of a virtual 3D shape.” DVR is the only visualization method that is: three-dimensional (3D), includes an outer layer of the patient and multiple inner layers of the patient (where the layers also have depth as well as height and width), and is capable of being confined with a virtual 3D shape. Also, with DVR, the inner layers of the patient may be viewed as continuous structures and not just as slices, which is essential for navigation and precise localization in the patients’ body.

70. In view of the foregoing, the term “3D data ... including an outer layer ... and multiple inner layers of the patient” requires direct volume rendering. More specifically, in view of the claims 1-6 and the specification, a POSITA understands that “3D data including an outer layer of the patient and multiple inner layers of the patient” means direct-volume-rendered three-dimensional (3D) imaging of the anatomy of a patient, including an outer layer of the patient and multiple inner layers of the patient.

2. “inner layer(s) of the patient”

Claim Term	Petitioner’s Construction	Patent Owner’s Construction
“inner layer(s) of the patient” (claims 1 and 11)		“A 3D direct volume rendering of the anatomy of the patient at a certain depth below the outer layer, or skin, of the patient.”

71. In the context of the claims and the specification of the '271 Patent, a POSITA understands that “inner layer” means a three-dimensional inner layer of the anatomy of the patient. More specifically, “inner layer” means a volume rendering of the anatomy of the patient viewed at a certain depth below the outer layer, or skin, of the patient. The '271 Patent is titled, “Augmenting Real-Time Views of a Patient with *Three-Dimensional Data*” (emphasis added). The preambles to claims 1 and 11 state, “A method for augmenting real-time, non-image actual views of a patient with *three-dimensional (3D) data*” (emphasis added). Thus, a POSITA understands that the element projected and augmenting the real-time, non-image actual views of the patient, *i.e.*, “one of the inner layers of the patient,” is three-dimensional.

72. The '271 Patent explains that the “multiple inner layers may be layers that go all the way through the patient 106, or may be layers that only go to a certain partial depth into the patient.” Ex. 1001, 12:13-16. The '271 Patent also explains that “[s]lices may be ... 3D slices” and “may include ... slices that have depth as well as height and width.” Ex. 1001, 6:16-21. For at least these reasons, a POSITA understands that the “one of the inner layers of the patient” in claims 1 and 11 is three-dimensional. And, more specifically, it means a 3D volume

rendering of some anatomy of the patient at a certain depth below the outer layer, or skin, of the patient.

3. “confined within a virtual 3D shape”

Claim Term	Petitioner’s Construction	Patent Owner’s Construction
“confined within a virtual 3D shape”		“The virtual 3D shape controls what portion of the projected inner layer(s) are visible the user. The virtual 3D shape confines the projected inner layer(s), it does not merely surround them.”

73. In view of the claims and the specification of the ’271 Patent, a POSITA understands “being confined within a virtual 3D shape” means that the virtual 3D shape determines what portion of the projected inner layer(s) are visible to the user. In other words, the virtual 3D shape does more than merely surround the projected inner layer(s). As discussed above, the “virtual 3D shape” is a navigational tool. *Supra* at ¶¶ 63-65. Claim 3 requires that “virtual 3D shape” be “configured to be controlled to reposition ... slices of the projected inner layer of the patient from the 3D data.” The ’271 Patent further explains that “[t]he user ... may move these slices using hand gestures that require the user ... to generally move his hand in the directions of the lines of the virtual spatial difference box ... so the display of the virtual spatial difference box ... may make these hand

movements easier for the user.” Ex. 1001, 6:21-26. A POSITA understands that a user may also use the “virtual 3D shape” to view the anatomical structure, i.e., “inner layers”, of the patient as one continuous structural slice as it moves in and out of a defined plane without being confined to any axial plane.

74. Since the “virtual 3D shape” confines the projected 3D data, a POSITA understands that the boundaries of the “virtual 3D shape” determine which slices, or inner layers, of the projected 3D data are visible to the user. This “navigation” and augmentation occurs in “real-time,” while the 3D data is projected on and registered to non-image actual views of the patient. *Supra* at ¶¶ 63-65; *see also* Claim 1 (“A method for augmenting ***real-time***, non-image actual views of a patient with three-dimensional (3D) data”) (emphasis added).

75. Dr. Kazanzides opines that “the ’271 patent discloses virtual 3D shapes as simple as a box and as complex as the outer layer of the patient, all of which would confine a projected inner layer of the patient.” Ex. 1012, ¶ 33. While I agree that the “virtual 3D shape” can be any shape, I disagree with Dr. Kazanzides’ reasoning.

76. As support for his opinion, Dr. Kazanzides relies, in part, on the following language from the specification: “the AR headset 108 [may] analyz[e] the 3D data in order to determine the size and shape of the outer layer of the patient [and] may ... generat[e] a point cloud of the outer layer of the patient that

represents the size and shape of the outer layer. For example, where the outer layer is represented by triangles or other polygonal shapes, the point cloud may include some or all of the vertices of the polygonal shapes.” Ex. 1012, ¶ 33 (citing Ex. 1001, 12:39-48).

77. However, this language is clearly describing an embodiment of the ’271 Patent for “determin[ing] virtual morphometric measurements of the outer layer of the patient from the 3D data” (Ex. 1001, 12:34-36) as a step to “automatically register the position of the outer layer of the patient from the 3D data to align with the registered real-time position of the outer layer of the patient in the 3D space.” Ex. 1001, 13:6-9. In other words, it is completely unrelated to any description of “virtual 3D shape” or “virtual spatial difference box” in the specification or the claims of the ’271 Patent.

78. A POSITA would understand that “virtual 3D shape”, in the context of the ’271 patent, is more than a 3D appearance of an object. The “virtual 3D shape” is derived from direct volume rendering the detail of the object and may extend beyond the outer layer or a any inner layer defining the course of anatomical structures confined within it. This definition is of importance when a surgeon or a proceduralist is operating on a patient’s anatomy allowing for precision and proper positiong of required surgical instruments in relation to the surrounding structures.

79. A POSITA would understand that the ordinary and customary meaning of “virtual 3D shape” is a 3D “spatial form or contour”³ capable of confining within its boundaries a 3D volume.

4. “being having”

Claim Term	Petitioner’s Construction	Patent Owner’s Construction
“being having”	“being or having”	“having”

80. I agree with Dr. Kazanzides. To a person of ordinary skill in the art, the term “being having” appears to be a clerical error. *See* Ex. 1012, ¶ 34. For purpose of this IPR, I interpret the term “being having” as “having.”

5. Summary Table of Claim Interpretation

Claim Term	Petitioner’s Construction	Patent Owner’s Construction
“three-dimensional (3D) data”	“one or more of MRI images, Computerized Tomography (CT) scan images, X-ray images, Positron Emission Tomography (PET) images, ultrasound images, fluorescence, Infrared Thermography (IRT) images, and Single-Photon Emission Computer Tomography (SPECT) scan image”	“Direct volume rendered CT, MRI, PET, and SPECT imaging (and also ultrasound and fluorescence imaging, depending on the methods used).”
“inner layer of the patient”		“A volume rendering of the anatomy of the patient at a

³ <https://www.merriam-webster.com/dictionary/shape>

		certain depth below the outer layer, or skin, of the patient.”
“being confined within a virtual 3D shape”		“The virtual 3D shape controls what portion of the projected inner layer(s) are visible the user. The virtual 3D shape confines the projected inner layer(s), it does not merely surround them.”
“being having”	“being or having”	“having”

VII. ANALYSIS OF THE PRIOR ART

81. Of the cited references relied upon by Petitioner and Dr. Kazanzides, only two discuss virtual elements projected on a patient using an augmented reality (AR) headset. Those are *Doo* (Ex. 1008) and *Chen* (Ex. 1009). The other cited references relied upon discuss only displaying elements on a computer monitor. These are *3D Slicer* (Ex. 1010), *3D Visualization* (Ex. 1007), and *Amira* (Ex. 1005).⁴

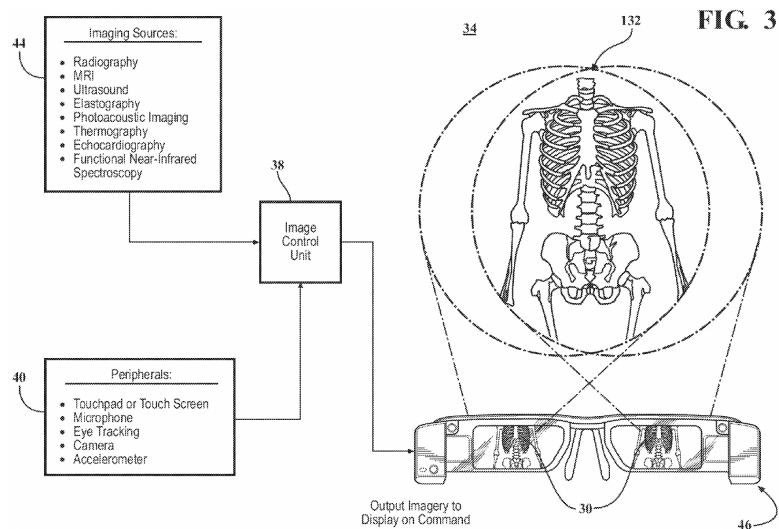
A. Doo (Ex. 1008)

82. *Doo* discloses an “intra-operative medical image viewing system [that] can allow a surgeon to maintain a view perspective on the patient while calling-up visual images on-the-fly.” Ex. 1008, *Abstract*. *Doo*’s medical image

⁴ *Casas* (Ex. 1006) and *Azimi* (Ex. 1011) were cited by Dr. Kazanzides and Petitioner. However, Petitioner relies on neither as a basis for invalidating the challenged claims.

viewing system is meant to allow a “surgeon to maintain a proper viewing perspective on the patient while concurrently obtaining relevant information about the patient.” Ex. 1008, ¶ [0011]. Thereby, “lowering distraction, cognitive load, and concomitant fatigue.” Ex. 1008, ¶ [0014].

83. *Doo* describes “a plurality of different two-dimensional, 2-1/2 dimensional, or three-dimensional modalit[ies]” for displaying medical imaging to the surgeon. Ex. 1008, ¶ [0073]. In *Doo*, “Figure 3 illustrates the application of a first three-dimensional modality, displaying a stereoscopic feed through a binocular viewer. The head mountable unit 46 displays the image 132 to the left and right eye such that the fields of view for each eye partially overlap to create binocular vision.” Ex. 1008, ¶ [0073]. Figure 3 of *Doo* is shown below:



84. Figure 6 of *Doo* “illustrates the application of a second three-dimensional modality, ‘holographic 3D’ in which three-dimensional tomography

(or other suitable form) data can be used to create a feature specific three-dimensional anatomical view.” Ex. 1008, ¶ [0074]. *Doo* provides an example of a heart 332 that “can be an amalgam or fusion of several tomographic slices that have been stitched together so as to create a 3D image.” Ex. 1008, ¶ [0074].

Figure 6 of *Doo* is shown below:

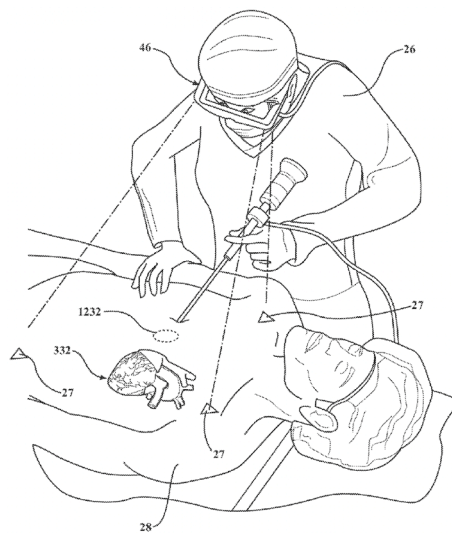


FIG. 6

85. As I explained previously, there are a variety of ways by which “several tomographic slices [can be] stitched together to create a 3D image.” *Supra* at ¶¶ 50-58. It is unclear how *Doo* is “stitching” slices together to create its “feature specific three-dimensional anatomical view.” However, because *Doo* describes only a “feature-specific three-dimensional anatomical view,” a POSITA would understand that *Doo* likely proposes using the surface rendering method to create a “feature specific” surface model of a heart or other previously identified anatomical structure. *Supra* at ¶¶ 52-53. A POSITA would assume that *Doo*’s

heart image 332 is likely only a shell of the patient's heart because it does not appear to include either internal or surrounding anatomical structure. *Doo's* image 332, therefore, does not disclose "3D data including an outer layer and multiple inner layers of the patient," i.e., a direct volume rendering of the patient's anatomy. For example, *Doo* cannot navigate through the inner layers of the heart image 332 or view or navigate through the surrounding anatomy in three dimensions.

86. A POSITA also understands that "stitching" conventional slices together to create a 3D shape introduces stepping artifacts—especially when the organs in the body (e.g., heart, lungs and other structures) beat or move to perform their physiological functions. Such movement makes the "stitching" of conventional slices both inaccurate and unusable.

87. 3D volume rendering, on the other hand, can "freeze" an entire section of the body that is imaged in any given moment in time. DVR allows the operator to slice and view the "virtual solid image block" as needed for the surgery that is being performed. The process of "stitching" conventional slices versus rendering an entire volume or block and slicing are very different techniques. With 3D volume rendering, a surgeon has the ability to freeze a moving organ and the obtained image in slices in any direction needed to obtain the necessary anatomic detail.

88. Figure 7 of *Doo* “illustrates the application of a third three-dimensional modality, sometimes referred to as ‘false 3D’ or ‘2.5D’ in which a two-dimensional image can be wrapped around a three dimensional structure, namely the body surface of the patient 28 ... yielding the appearance of a three-dimensional image.” Ex. 1008, ¶ [0075]. Figure 7 of *Doo* is shown below:

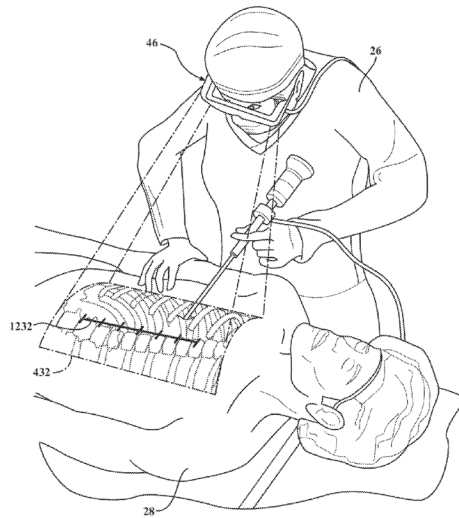


FIG. 7

89. “Figures 8 and 9 further illustrate the concept of image wrapping as introduced in ... Figure 7.” Ex. 1008, ¶ [0075]. “Figure 8 is a perspective view of two-dimensional image 532 in a planar configuration.” *Id.*, ¶ [0075]. “Figure 9 is a perspective view of the two-dimensional image 532 shown in Figure 8 but rendered in a warped configuration to mimic the surface curvature of the patient’s body.” *Id.*, ¶ [0076]. Figures 8 and 9 of *Doo* are shown below:

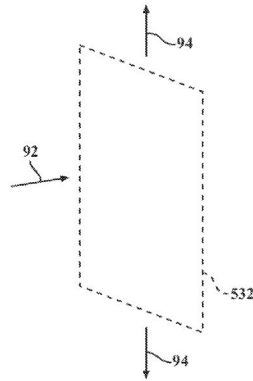


FIG. 8

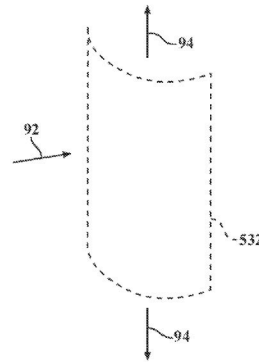


FIG. 9

90. Dr. Kazantzides contends, “[a]s illustrated in *Doo*’s Figure 7, the resulting image of the projected inner layer of the patient from the 3D data is confined within the volume of the virtual 3D shape illustrated in Figure 9.” Ex. 1012, ¶ [0075]. Dr. Kazantzides argues, “*Doo*’s Figure 7, for example, illustrates the projection of bones of the patient from the 3D data being confined within the volume of the virtual 3D shape illustrated in Figure 9.” Ex. 1012, ¶ [0075]. However, the Figures 7 and 9 clearly show only a “two-dimensional image” that was “rendered by the system as having been wrapped over the chest of the patient.” Ex. 1008, ¶ [0075]. This is vastly different from projecting a 3D direct volume rendering of the anatomy of the patient, which is navigable in real-time. *Doo*’s “wrapped” 2D plane, illustrated in Figures 7 and 9, has no volume and therefore incapable of confining “the projected inner layer fo the patient,” as recited in claim 1. Thus, a POSITA understands that neither Figures 7 nor 9

disclose “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape,” as recited in claim 1 of the ’271 Patent.

B. Chen (Ex. 1009)

91. *Chen* discloses “an AR-based surgical navigation system (AR-SNS) ... using an optical see-through HMD (head-mounted display), aiming at improving the safety and reliability of surgery.” Ex. 1009, *Abstract*. *Chen* acknowledges that “developing a surgical navigation system based on AR is a significant challenge for the next generation.” Ex. 1009 at 1. *Chen* used surface modeling to reconstruct models of “a 3D bladder and some blood vessels and nerves.” Ex. 1009 at 6. The surface-rendered models are shown in Fig. 3 of *Chen* below. The models were then registered to and projected onto a real non-virtual pelvis model. Ex. 1009 at 6.

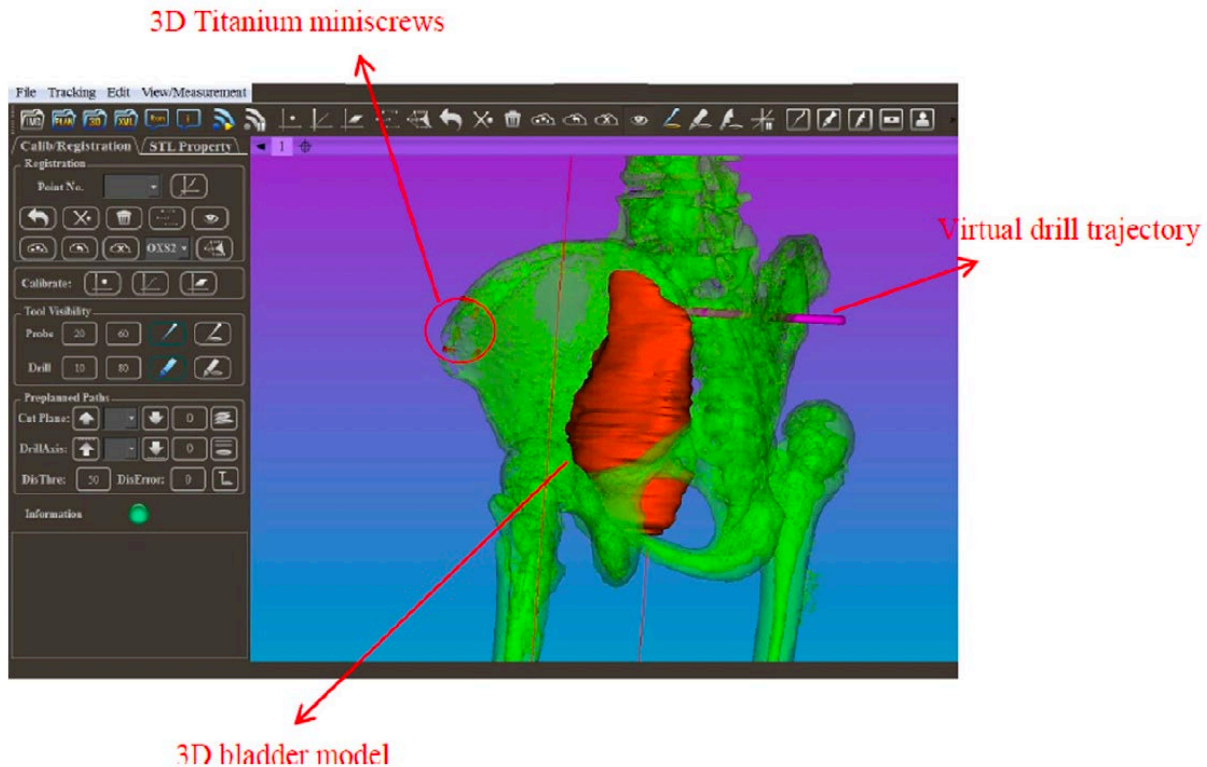


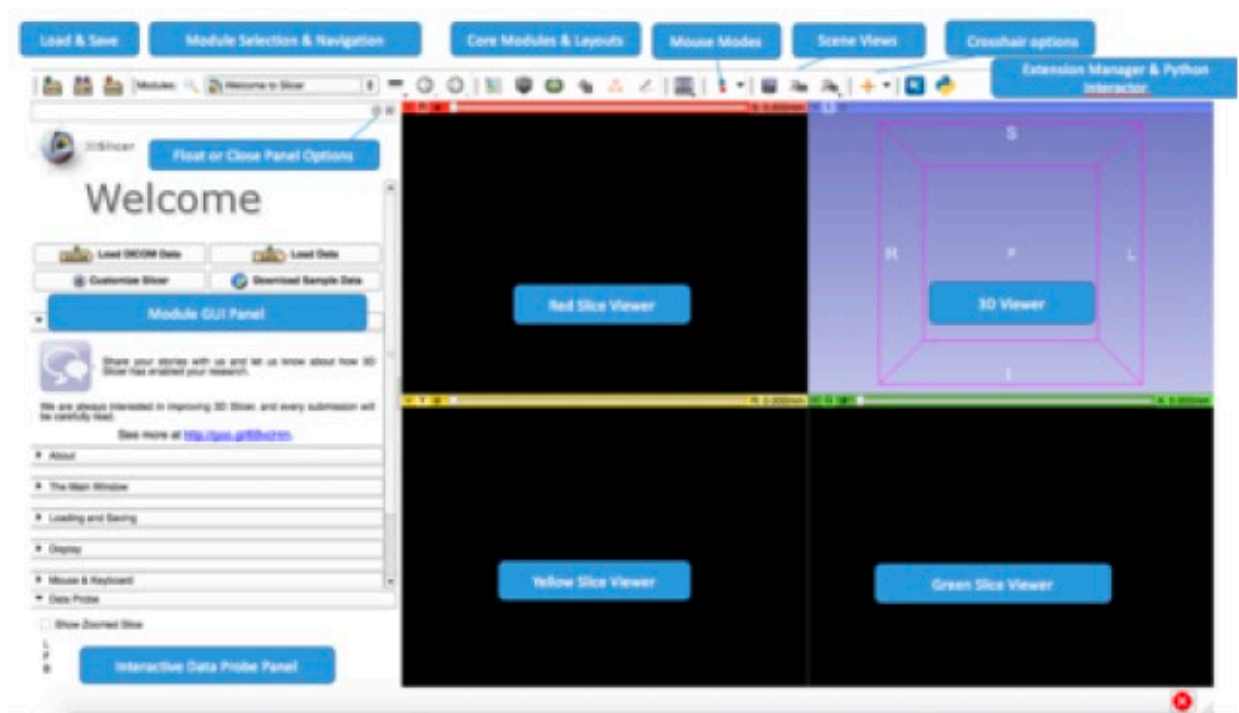
Fig. 3. A 3D pelvis model and a bladder imported into the AR-SNS.

92. Again, as described *Chen* is vastly different from projecting a 3D direct volume rendering of the anatomy of the patient, which is navigable in real-time. A POSITA understands that *Chen*'s pelvis and bladder surface models are merely shells and do not include any internal or surrounding anatomic structure. *Chen*'s models are not direct volume rendered and are not navigable. For example, *Chen* cannot navigate through the inner layers and contours of its pelvis and bladder models or view or navigate through the surrounding anatomy.

C. 3D Slicer (Ex. 1010)

93. Ex. 1010 ("3D Slicer") purports to be a seven-page document that professes to be online documentation from "Slicer Wiki" for "Slicer4." Ex. 1010

at 1-2. 3D Slicer purports to explain “Slicer4’s main desktop interface,” (Ex. 1010 at 2) but provides very little information, if any, about what “Slicer4” actually is or what its capabilities are. The document does not disclose that it can be used in an augmented reality (AR) environment. It does not disclose that it can be used to project 3D medical imaging data onto non-image actual views of a patient. 3D Slicer does not explicitly disclose what imaging can be loaded into Slicer 4. In its “User FAQ: User Interface” section, it says, “How to load data from a sequence of jpg, tif, or png files?” Ex. 1010 at 7. The document also does not explicitly state how a user can use “Slicer4” to view medical imaging. On page one, 3D Slicer appears to show a screenshot of a two-dimensional (2D) display, copied below.

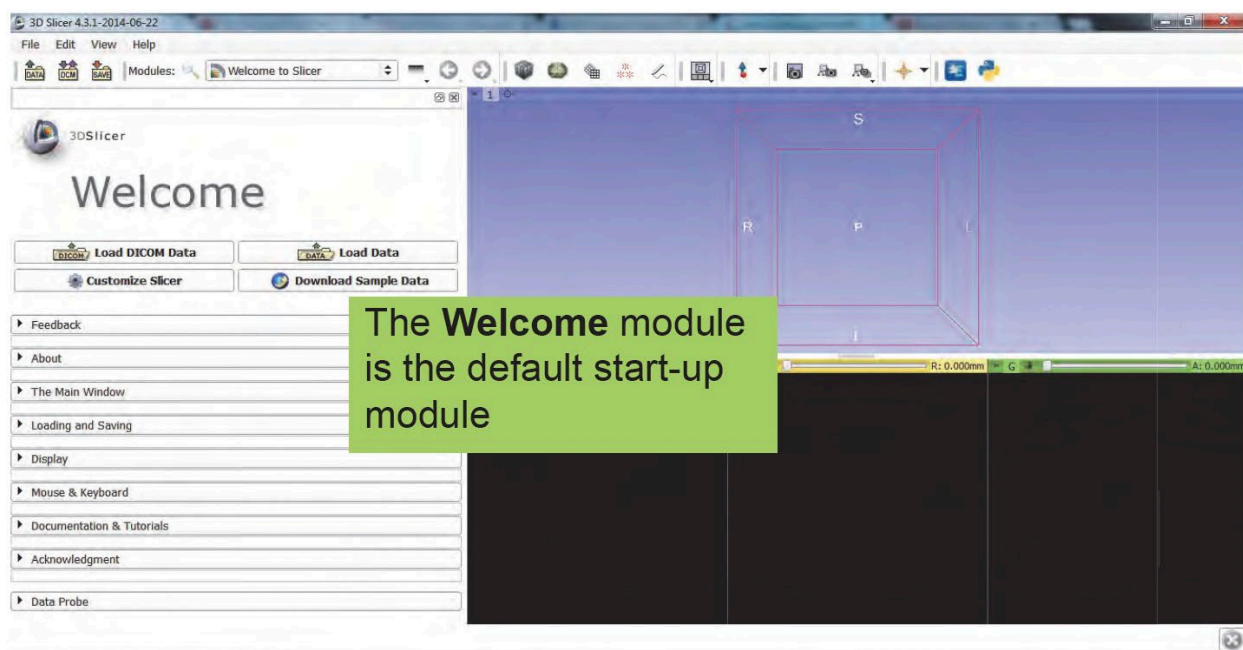


Ex. 1010 at 1. Based on 3D Slicer's disclosure, presumably Slicer4 can only be used to view "jpg, tif, or png files" on a conventional "desktop" computer monitor.

Ex. 1010 at 2.

D. 3D Visualization (Ex. 1007)

94. 3D Visualization purports to be a presentation entitled, "3D Visualization of DICOM Images for Radiological Applications." Ex. 1007. It provides a tutorial on "3D Slicer version 4.0." Ex. 1007, slide 6. 3D Visualization does not disclose that "3D Slicer version 4.0" can be used in an augmented reality (AR) environment. 3D Visualization also does not disclose that "3D Slicer version 4.0" can be used to project 3D medical imaging data onto non-image actual views of patient. 3D Visualization appears to show screenshots of a two-dimensional (2D) display, copied below.



Ex. 1007, Slide 17. Presumably, “3D Slicer version 4.0” can only be used to view images on a conventional computer monitor. *Id.*

E. Amira (Ex. 1005)

95. Ex. 1005 purports to be the first two chapters of a user guide for *Amira* 5. Ex. 1005 at 1. According to Ex. 1005, *Amira* is a “3D data visualization, analysis and modeling system,” which “allows you to visualize scientific data sets from various applications areas....” It appears that *Amira*, like *3D Slicer*, is a computer software package for medical image visualization and analysis. Ex. 1005 states that *Amira* is “intended for research only” and “is not a medical device.” Ex. 1005 at 4.

96. Like *3D Slicer*, *Amira*'s images cannot be visualized in AR. Nor can *Amira* be used to project medical imaging onto non-image actual views of a patient. For the most part, *Amira*'s images, like *3D Slicer*, generally can only be viewed in 2D on a computer monitor. At the time of the invention, *Amira* did not support visualization in AR environments.

VIII. GROUNDS OF PATENTABILITY

A. Ground 1: *Doo* Does Not Anticipate Claims 1, 5, and 6.

97. *Doo* does not disclose “displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient” or “the projected

inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape,” as recited in claim 1.

1. *Doo* does not anticipate independent claim 1.

- (a) “A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data”
(preamble of claims 1 and 11)

98. Dr. Kazanzides alleges that “[t]o a person of ordinary skill in the art, *Doo* discloses a ‘method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data.’” Ex. 1012, ¶ 64. However, as support, Dr. Kazanzides cites only *Doo*’s selectively transparent “display worn by the surgeon” that “exhibits to the surgeon an image derived from the image file.” Ex. 1012, ¶ 63 (citing Ex. 1008, *Abstract*). Dr. Kazanzides also includes FIG. 2 of *Doo*, which shows a surgeon viewing a 2D image hovering above a patient.

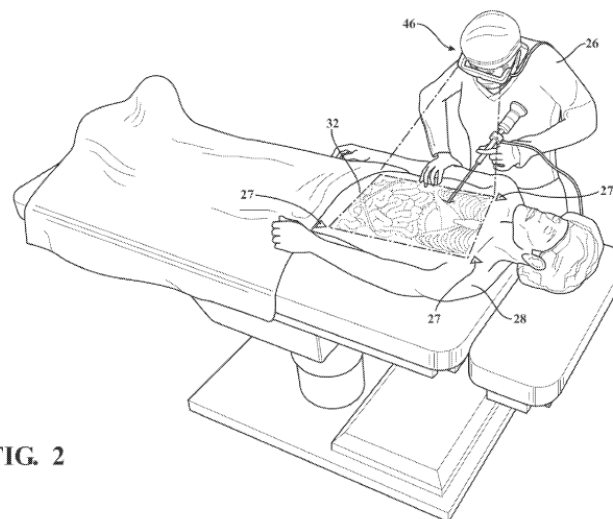


FIG. 2

Doo explains that “[i]n Figure 2, the exemplary image 32 is suggested as an x-ray of the chest of the patient 28.... Figure 2 illustrates how the image 32 can be perceived by the surgeon 26 as hovering directly over the body of the patient.” Ex. 1008, [0039].

99. These references in *Doo*, cited by Dr. Kazanzides, do not support his allegation at least because the image projected in FIG. 2 is two-dimensional (2D) and not three-dimensional (3D). Moreover, in Figure 2, *Doo*’s 2D image is “hovering ... over the body of the patient.” Ex. 1008, [0039]. Thus, a POSITA would not interpret these references in *Doo* as teaching a method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data,” as recited in the preambles of claims 1, 7, and 11, because the projected image 32 is two-dimensional (2D) and does not include “an outer layer ... and multiple inner layers of the patient,” i.e., it is not direct volume rendered.

- (b) “identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient” (“identifying” step of claims 1 and 11)

100. Dr. Kazanzides alleges that “[t]o a person of ordinary skill in the art, *Doo* discloses the step of ‘identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient.’” Ex. 1012 at ¶ 68. As support, Dr. Kazanzides points to “images generated by radiography,

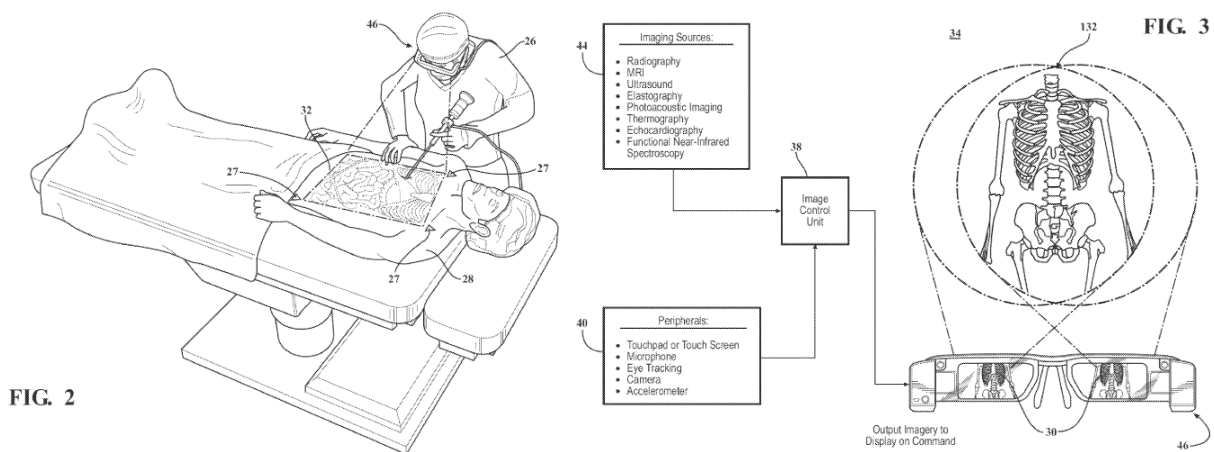
computer-aided tomography, positron emission tomography, single phase emission tomography, magnetic resonance imaging (MRI), ultrasound, elastography, photo-acoustic imaging, thermography, echocardiography, functional near infrared, and spectroscopy.” Ex. 1008, ¶ 65.

101. A POSITA understands that the imaging modalities mentioned in *Doo* conventionally produce two-dimensional (2D) images or a series of 2D images. While *Doo* identifies potential sources of 3D patient data, including “computer-aided tomography” (CT) and “magnetic resonance imaging (MRI)” (Ex. 1008, [0040]), *Doo* does not identify direct volume rendered data including an outer layer and multiple inner layers of the patient. *Supra* at ¶¶ 82-90. More specifically, *Doo* does not disclose 3D “inner layers” that can be confined (i.e., navigated) and viewed along any axis.

- (c) “displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient” (“displaying ... inner layer[]” step of claims 1, 7, and 11)

102. Dr. Kazanzides contends that “[t]o a person of ordinary skill in the art, *Doo* discloses ‘displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient.’” Ex. 1012 at ¶ 73. I disagree.

103. As support, Dr. Kazanzides cites *Doo*'s "head mountable unit" (Ex. 1012, ¶ 69 (citing Ex. 1008, [0044])) that can be "configured to exhibit at least one medical image 32 to the surgeon 226 that is overlaid on the patient." Ex. 1012, ¶ 70 (citing Ex. 1008, [0038]). Dr. Kazanzides argues, "[a]s illustrated by Figures 2 and 3," that "*Doo* discloses that the projected display may be inner layers of the patient from the 3D data." Ex. 1012, ¶ 72. However, Figures 2 and 3 do not disclose "displaying ... one of the inner layers of the patient from the 3D data projected onto real-time non-image actual views of the out layer of the patient," as recited in claim 1. Rather, Figure 2 shows only a two-dimensional "x-ray of the chest of the patient 28.... hovering directly over the body of the patient." Ex. 1008, [0039]. Also, according to *Doo*, Figure 3 shows only a bone model "overlaid on the patient 28 by at least one of panning, zooming and rotating the image 132, as well as tilting, key-stoning, half-toning, texturing, wrapping or other image manipulation techniques." Ex. 1008, [0041].



104. A POSITA would understand that neither Figure 2 nor Figure 3 discloses “displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient,” as recited in claim 1, because neither Figure 2 nor Figure 3 discloses a projected volume of the anatomy of the patient displaying the anatomical structure of the patient at a certain depth below the outer layer, or skin, of the patient. Moreover, *Doo* does not disclose “inner layers” that can be confined (i.e., navigated) and viewed along any axis.

- (d) “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape” (“confined” limitation of claim 1)

105. Dr. Kazanzides opines that “[t]o a person of ordinary skill in the art, *Doo* discloses ‘the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.’” Ex. 1012 at ¶ 77. I disagree.

- (i) *Doo*’s 2D Wrap (Figures 7 and 9) is Not 3D and Cannot Confine a 3D Volume.

106. Dr. Kazanzides contends that *Doo*’s “‘false 3D’ or ‘2.D’ in which a two-dimensional image can be wrapped around a three dimensional structure, namely the body surface of the patient” satisfies this claim element. Ex. 1012, ¶ 75. Dr. Kazanzides directs the Board to Figures 7 and 9, shown below:

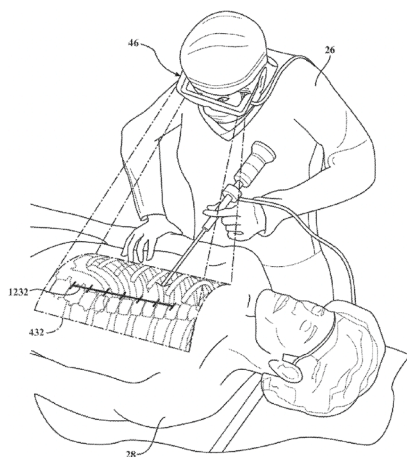


FIG. 7

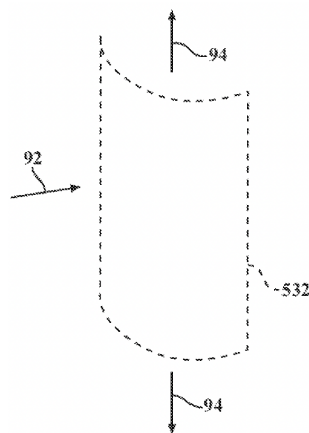


FIG. 9

107. Dr. Kazanzides concludes, “As illustrated in *Doo*’s Figure 7, the resulting image of the projected inner layer of the patient from the 3D data is confined within the volume of the virtual 3D shape illustrated in Figure 9.” Ex. 1012, ¶ 75. However, the Figures 7 and 9 show a “two-dimensional image” that was “rendered by the system as having been wrapped over the chest of the patient.” Ex. 1008, ¶ [0075]. On its face, this is not 3D data. And it is certainly not navigable direct volume rendered 3D data. In other words, *Doo*’s 2D wrap is not viewable or navigable through multiple inner layers the projected 3D data or along any axis.

108. As such, a POSITA would understand that neither Figures 7 nor 9 disclose “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape,” as recited in claim 1.

(ii) *Doo's Heart* (Figures 6 and 11) Does Not and Cannot Confine a 3D Volume.

109. Dr. Kazanzides opines, “A person of ordinary skill in the art understands that *Doo's* Figure 11 illustrates a collection of medical images forming a virtual 3D shape.” I disagree. According to *Doo*, Figure 11 “is a series of three-dimensional tomographic slices of an anatomical feature of a patient” (Ex. 1008, ¶ [0026]) that “can be stitched together to create a 3D image.” Ex. 1008, ¶ [0078]. *Doo* explains further, Figure 6 illustrates the application of a second three-dimensional modality, “holographic 3D” in which three-dimensional tomography (or other suitable form) data can be used to create a *feature-specific* three-dimensional anatomical view.” Ex. 1008, ¶ [0074] (emphasis added).

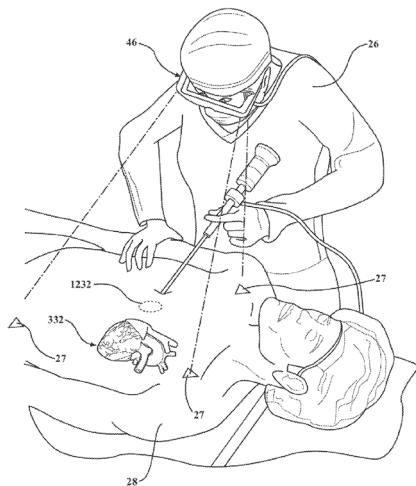


FIG. 6

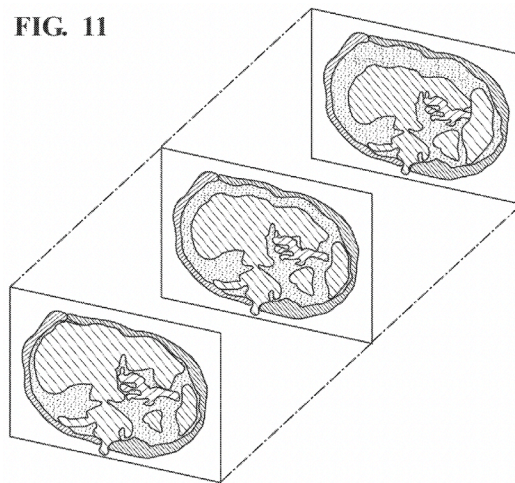


FIG. 11

110. A POSITA would understand that FIG. 11 shows only a graphical representation of a series of three two-dimensional (2D) tomographic slices of an anatomical feature of a patient. A POSITA would further understand that the

rectangles surrounding and the dashed lines connecting each slice are only meant to illustrate an alignment of the representative slices. A POSITA could not reasonably interpret FIG. 11 as a disclosure of “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape,” as recited in claim 1.

111. A POSITA would understand that the “3D virtual shape,” recited in claim 1, does not merely show where the projected volume data ends, but it is a tool for navigating, in real time, direct volume rendered 3D data, while it is projected onto non-image actual views of a patient. *Supra* ¶¶63-65. *Doo* does not disclose a virtual 3D shape at all. Moreover, *Doo* does not disclose a virtual 3D shape **confining** the heart (image 332) of *Doo*.

112. Moreover, a POSITA would understand that *Doo*’s heart (image 332) is not navigable at all. There is no indication in *Doo* that image 332 is a navigational tool. For example, the boundaries of *Doo*’s heart cannot be moved by a surgeon to reveal more or less of the internal structure of the heart or any of the surrounding anatomy. Also, a user cannot use *Doo*’s heart to move between slices along any axis. And the boundaries of *Doo*’s heart do not determine which slices, or internal layers, of the heart or surrounding anatomy are visible to the surgeon.

2. *Doo* does not anticipate dependent claims 5 and 6.

- (a) Claim 5: “The method of claim 1, wherein lines of the virtual 3D shape are hidden.”

113. Dr. Kazanzides opines that “in view of what was known in the art at the relevant time, a person of ordinary skill in the art understands that *Doo* discloses a projected inner layer of a patient confined within a volume of a virtual 3D shape, wherein the lines of the virtual 3D shape are hidden.” Ex. 1012 at ¶ 78. I disagree. As discussed above, *Doo* does not disclose a “virtual 3D shape,” as recited in claim 1. *See supra* at ¶¶ 105-112. Because *Doo* does not disclose “a virtual 3D shape” or “a projected inner layer of a patient confined within a volume of a virtual 3D shape,” as recited in claim 1, *Doo* also does not disclose “wherein lines of the virtual 3D shape are hidden,” as recited in claim 5.

- (b) Claim 6: “One or more non-transitory computer-readable media storing one or more programs that are configured, when executed, to cause one or more processors to perform the method as recited in claim 1.

114. Because *Doo* does not disclose the method as recited in claim 1, it also does not disclose “one or more non-transitory computer-readable media storing one or more programs that are configured, when executed, to cause one or more processors to perform the method as recited in claim 1,” as recited in claim 6.

B. Ground 2: *Doo* Alone or in View of *Amira* Does Not Render Claims 1-6 Obvious.

115. I incorporate by reference my discussion of the disclosure, or rather nondisclosure, of *Doo* as it related to the challenged claims above.

116. Dr. Kazanzides opines that “claims 1-6 and 11-20 would have been obvious over *Doo* in view of *Amira* at the relevant time to a person of ordinary skill in the art.” Ex. 1012 at ¶ 81.

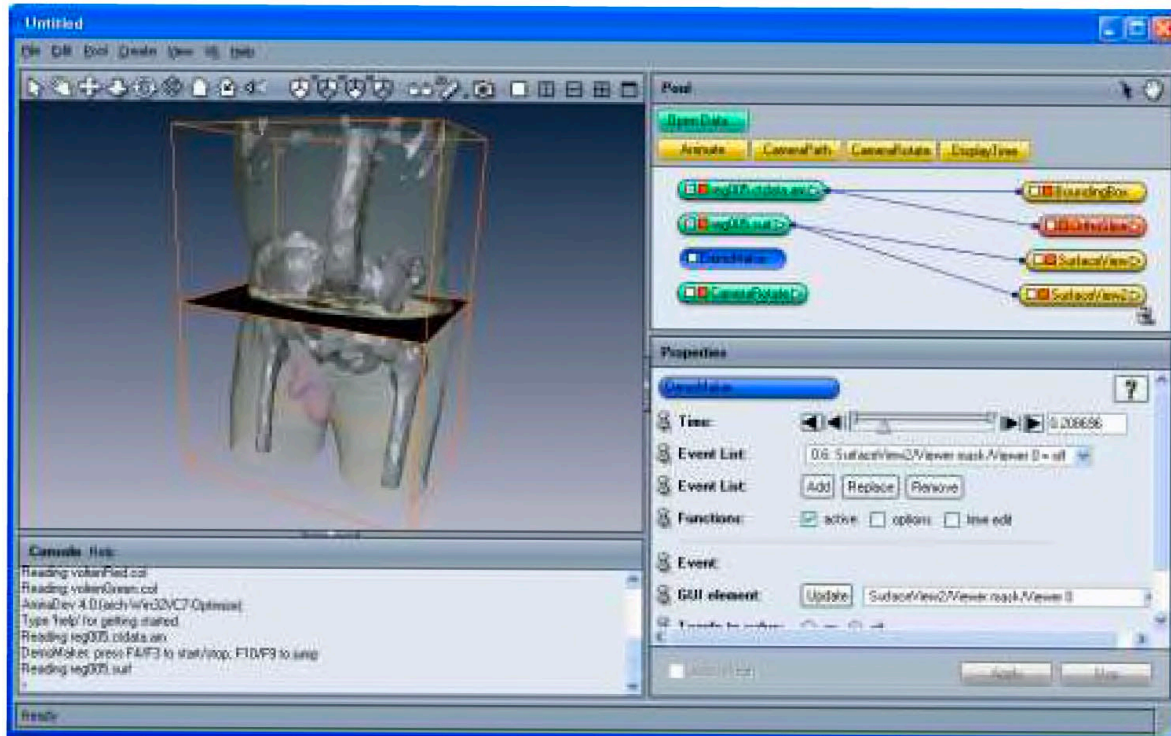
1. Non-disclosure with respect to claims 1-6

- (a) Claim 1 limitations including “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.”

117. Dr. Kazanzides opines that “*Amira* discloses ‘the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.’” Ex. 1012 at ¶ 83. I disagree. *Amira* does not disclose “the projected inner layer of the patient from the 3D Data being confined within a volume of a virtual 3D shape,” foremost because *Amira* does not disclose a projection “onto real-time, non-image actual views of the outer layer of the patient.” But it also does not disclose “3D data being **confined** within a volume of a virtual 3D shape.” *See supra* at ¶ 63. Dr. Kazanzides relies on a description of an optional module (“*Amira* Virtual Reality Option”) from the introduction provided in Ex. 1005, but

the Ex. 1005 provides no discussion or *Amira*'s VR capabilities. Furthermore, *Amira* does not mention any augmented reality (AR) capability at all.

118. Dr. Kazanzides relies on a screenshot from provided on page 80 of *Amira* (Ex. 1005 at 92), shown below:



119. Dr. Kazanzides contends that *Amira*'s 2D bone model satisfies “displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data.” Ex. 1012, ¶ X. However, the *Amira*'s bone model is a “polygonal surface model” (“data/medical/reg005.surf”) generated only after segmentation of the 3D image volume. Ex. 1005 at 89. In contrast, a POSITA understands, for the reasons provided above (*supra* at ¶¶59-62), that the “3D data” of claim 1 is direct-volume-rendered and can be viewed at any angle and cut along

any plane. This is not what *Amira* shows. There is no disclosure in *Amira* related to being able to navigate through the displayed 3D data at along any axis.

120. A POSITA would further understand, for the reasons provided above (*supra* at ¶¶ 71-72), that the projected “at least one inner layer” of claim 1 is a volume rendering of the anatomy of the patient at a certain depth below the outer layer, or skin, of the patient without segmentation and without constructing intermediate polygonal models. *Supra* at ¶ 71. This is not what *Amira* discloses.

121. Dr. Kazanzides further contends that *Amira*’s 3D bone model satisfies the “virtual 3D shape” of claim 1. Ex. 1012, ¶ 83. I disagree. A POSITA understands that the “virtual 3D shape” of claims 1-5 is a tool for navigating, in real time, direct volume rendered 3D data, while it is projected onto non-image actual views of a patient. *See supra* ¶¶ 71-72. *Amira* does not disclose such a “virtual 3D shape,” as required by claims 1-5. *Amira* shows only polygonal surface models (bones and skin) confined within a bounding box. *Amira* does not show the volumized 3D data confined within a virtual 3D shape. A POSITA would also understand that the skin model, i.e. “outer layer of the patient,” cannot also satisfy the “virtual 3D shape” of claim 1 at least because it is not a navigational tool. A user cannot adjust the boundaries of *Amira*’s skin model to navigate the displayed data at any angle.

122. Dr. Kazanzides also contends that the bounding box satisfies the “virtual 3D shape” of claim 1. Again, a POSITA understands that the “virtual 3D shape” of claims 1-5 is a tool for navigating, in real time, direct volume rendered 3D data, while it is projected onto non-image actual views of a patient. *See supra* ¶¶71-72. *Amira* shows only polygonal surface models (bones and skin) confined within a bounding box. *Amira* does not show direct volume rendered 3D data confined within a virtual 3D shape. *Amira* also does not indicate that its bounding box actually **confines** the models. *See supra* at ¶¶ 71-72. It appears that *Amira*’s bounding box merely represents the space in which the data set exists. “In *Amira* the bounding box of an object is the smallest rectangular, axis-aligned volume in 3D space that encompasses the object.” Ex. 1005 at 40. Based on the foregoing, *Amira* does not disclose the “virtual 3D shape” of claim 1.

- (b) Claim 2: “The method of claim 1, wherein: the virtual 3D shape is a virtual box; and the virtual box includes a top side, a bottom side, a left side, a right side, a front side, and a back side.”

123. As discussed above, *Amira* does not disclose the “virtual 3D shape” of claim 1. For the same reasons, *Amira* does not disclose the elements of claim 2.

- (c) Claim 3: “The method of claim 1, [3a] wherein: the virtual 3D shape is configured to be controlled to toggle between displaying and hiding lines of the virtual 3D shape; and [3b] the virtual 3D shape is configured to be controlled to reposition two-dimensional (2D) slices and/or 3D slices of the projected inner layer of the patient from the 3D data.”

124. As discussed above, *Amira* does not disclose the “virtual 3D shape” of claim 1. For the same reasons, *Amira* does not disclose the elements of claim 3.

125. Dr. Kazanzides contends that *Amira* discloses control of the display so that the virtual 3D shape, and any 2D or 3D slices contained within, is repositioned using the 3D viewer. Ex. 1012, ¶ 86. As support, Dr. Kazanzides cites, “The 3D view lets you look at the model from different positions. If you click on the Trackball button in the viewer tool bar, moving the mouse inside the viewer window with the left mouse button pressed lets you rotate the object.” Ex. 1005 at 24. Dr. Kazanzides further cites, “the 3D Rotate icon [can be used] to rotate the object in the 3D viewer.” Ex. 1005 at 100. However, “rotation” is not the same as “navigation.”

126. The “virtual 3D shape” of claims 1-5 is a tool for navigating, in real time, direct volume rendered 3D data, while it is projected onto non-image actual views of a patient. *See supra* ¶¶71-72. Thus, a POSITA understands that “configured to be controlled to reposition two-dimensional (2D) slices and/or 3D slices of the projected inner layer of the patient from the 3D data” means that the

boundaries of the 3D virtual shape may be moved by the user to reveal more or less of the projected 3D data to navigate all the way through the 3D data at any angle. A POISTA would further understand that a user may use the 3D virtual shape to move all the way through the projected 3D data along any axis. The boundaries of the virtual 3D shape determine which slices, or internal layers, of the projected 3D data are visible to the user. This “navigation” occurs in real-time, while the 3D data is projected on and registered to non-image actual views of the patient. *See supra* ¶¶71-72. Based on the forgoing, *Amira* does not disclose the elements of claim 3.

- (d) Claim 4: “The method of claim 1, wherein lines of the virtual 3D shape are displayed.”

127. As discussed above, *Amira* does not disclose the “virtual 3D shape” of claim 1. For the same reasons, *Amira* does not disclose the elements of claim 4.

- (e) Claim 5: “The method of claim 1, wherein lines of the virtual 3D shape are hidden.”

128. As discussed above, *Amira* does not disclose the “virtual 3D shape” of claim 1. For the same reasons, *Amira* does not disclose the elements of claim 5.

- (f) Claim 6: “One or more transitory computer-readable media storing one or more programs that are configured when executed, to cause one or more processors to perform the method as recited in claim 1.”

129. As discussed above, *Doo* does not disclose the method as recited in

claim 1. For the same reasons, *Amira* does not disclose the elements of claim 6.

2. Non-disclosure with respect to independent claim 11

130. As discussed above, *Amira* displays 3D models on 2D computer monitors. *Amira* does not disclose projecting a 3D direct volume rendering of the anatomy of the patient on to non-image actual views of the patient. *See supra* at ¶¶118-123.

- (a) “altering the original color gradient of the multiple inner layers to be lighter than the original color gradient in order to be better visible when projected onto real-time, non-image actual views of the outer layer of the patient” (altering” step of claim 11)

131. Dr. Kazanzides opines that “the person of ordinary skill in the art at the relevant time would have appreciated that the same color adjustment technology applies to improving visibility of a virtual image overlaid on the actual patient view.” Ex. 1012, Kazanzides, at ¶ 96. I disagree.

132. As support, Dr. Kazanzides argues that “*Doo* discloses ‘adjusting the transparency of the overlaid image.’” Ex. 1012, Kazanzides, ¶ 91 (citing Ex. 1008, pg. 28, claim 5). However, a POSITA understands that changing transparency or opacity of an image is different from “altering the original color gradient of the multiple inner layers to be lighter than the original color gradient in order to be better visible when projected onto real-time, non-image actual views of the patient,” as recited in claim 1. Opacity refers to the transparency or translucency

of an object or element. It determines how much light can pass through an object. On the other hand, color refers to the specific hue or shade of an object or element. Changing the color of an object modifies its visual hue or shade.

133. Dr. Kazanzides also argues that *Amira*'s use of a color map to control visualization of the overlay image discloses "altering the original color gradient" element of claim 11. Ex. 1012, ¶ 96. However, a POSITA would understand that *Amira*'s color maps and image overlays are quite different from changing the original color gradient of a DVR image projected onto a real patient in an AR environment. *Amira* does not disclose "altering the original color gradient of the multiple inner layers to be lighter than the original color gradient in order to be better visible when projected onto real-time, non-image actual views of the outer layer of the patient" at least because *Amira* cannot be used in an AR environment.

- (b) "the projected inner layer of the patient from the 3D data being having the altered color gradient" ("altered color" limitation of claim 11)

134. As discussed above, *Amira* does not disclose "the projected inner layer of the patient from the 3D data ... having the altered color gradient," as recited in claim 11, because *Amira* is limited to displaying images on a computer monitor or in VR. *Amira* does not project inner layers of a patient with an altered color gradient directly onto the outer surface of a patient.

3. Non-Disclosure with respect to claims 12-20

135. Dr. Kazanzides opines, “the person of ordinary skill in the art at the relevant time would have understood that a color gradient could be applied to represent any parameter that a user could identify or define based on the available 3D data.” Ex. 1012, ¶ 101.

- (a) Claim [12/13/14/15/16/17/18/19/]: “The method as recited in claim 11, wherein the altered color gradient represents a tissue [hardness/relaxivity/echogenicity/enhancement amount/enhancement speed/density/radioactivity/water content] tissue property of the multiple inner layers of the patient.”

136. As discussed above, *Amira* does not disclose “the projected inner layer of the patient from the 3D data ... having the altered color gradient,” as recited in claim 11, because *Amira* is limited to displaying images on a computer monitor or in VR. *Amira* does not project images onto real-world environments in AR. For at least this reason, *Amira* does not disclose the elements of claims 12-19.

137. Petitioner contends that “*Amira* discloses coloring based on a detected property in a 3D data set.” Petition at 48. But the only properties Petitioner identifies in *Amira* are “a surface colored according to its curvature” (Ex. 1005, 17) and “blood flow.” Petition at 49, 53. *Amira*’s blood flow visualization requires “[l]oad[ing] the surface model of the carotids *bloodFlow.ruf.am* from the tutorial directory *data/tutorials/vector*; Attach[ing] an

SurfaceView module to this data object; Load[ing] the data set called *bloodFlow.vector.am* from the tutorial directory;” and “Connect[ing] a *Vectors* module to the vector field *bloodFlow.vector.am*.” Ex. 1005 at 81. *Amira*’s labeling of surface models is very different from identifying tissue properties within the direct volume rendered 3D data. Moreover, *Amira* does not disclose altering a color gradient to identify any of the characteristics specifically identified in claims 12-19, e.g., tissue [hardness/relaxivity/echogenicity/enhancement amount/enhancement speed/ density/ radioactivity/water content].

- (b) Claim 20: “One or more non-transitory computer-readable media storing one or more programs that are configured, when executed, to cause one or more processors to perform the method as described in claim 11.”

138. As discussed above, *Amira* and *Doo* do not disclose the method as recited in claim 11. For the same reasons, *Amira* does not disclose the elements of claim 20.

4. No motive to combine *Doo* and *Amira*

139. Dr. Kazanzides concludes that a POSITA “would have been motivated to combine *Amira* with *Doo* to enable the intra-operative medical image viewing system and method disclosed in *Doo* to take advantage of the visualization technology disclosed in *Amira*” and “would have had a reasonable expectation of success” Ex. 1012 at ¶ 103. However, Dr. Kazanzides provides no support for his

conclusion. He says only that a POSITA “would have been motivated” and “would have had a reasonable expectation of success,” but Dr. Kazanzides does not explain “why” a POSITA would have been motivated and would have had success.

140. The ‘271 Patent discloses the projection of direct volume rendered 3D data onto non-image actual views of a patient in AR. That projected 3D data is navigable, in real-time, using a “virtual 3D shape.” The boundaries of the virtual 3D shape determine which slices, or internal layers, of the projected 3D data are visible to the user.

141. Certainly, Dr. Kazanzides has not explained why a POSITA would have been motivated or had success combining the medical image viewing system of *Doo*, which includes 2D images and surface models, with the *Amira* computer software to arrive at the claims of the ’271 Patent. In my opinion, such a conclusion is unreasonable. Neither *Doo* nor *Amira* disclose navigating, in real-time, direct volume rendered 3D data while it is projected onto non-image actual views of a patient, as required by claims 1-6. Moreover, *Doo* does not mention color gradient adjustment at all. And *Amira* cannot be used in an AR environment. Thus, neither *Doo* nor *Amira* adjust the color gradient of direct volumed rendered 3D data “to be better visible when projected onto real-time, non-image actual views of the outer layer of a patient,” as recited in claim 11. Furthermore, neither

Doo nor *Amira* disclose altering a color gradient to identify any of the tissue properties specifically identified in claims 12-19, e.g., tissue [hardness/relaxivity/echogenicity/enhancement amount/enhancement speed/density/ radioactivity/water content].

142. In my opinion a POSITA would not have been motivated to so combine *Doo* and *Amira* to achieve the challenged claims, nor do I believe that they would have had a reasonable expectation of success. This is because neither *Doo* nor *Amira* identify problems or provide solutions to navigating 3D medical imaging while it is projected onto a patient in an AR environment. Furthermore, neither *Doo* nor *Amira* identify problems or provide solutions to adjusting the color gradient of the 3D medical imaging to improve visibility of the projected 3D imaging or to represent the specific tissue properties of the 3D imaging recited in claims 12-19.

C. Ground 3: *Chen* in View of *3D Visualization* and *3D Slicer* Does Not Render Claim 1-6 and 11-20 Obvious.

143. Dr. Kazanzides claims that “claims 1-6 and 11-20 would have been obvious over *Chen* in view of *3D Slicer* and *3D Visualization* at the relevant time to a person of ordinary skill in the art.” Ex. 1012 at ¶ 108. Again, for the reasons provided below, I disagree.

1. *Chen*'s non-disclosure with respect to independent claim 1

(a) preamble of claim 1

144. Dr. Kazanzides opines “[t]o a person of ordinary skill in the art, *Chen* discloses ‘[a] method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data,’ as recited in the preamble of each of the independent claims.” Ex. 1012 at ¶ 110. However, *Chen* only used surface modelling to reconstruct 3D models of a pelvis, bladder, and miniscrews, shown below:

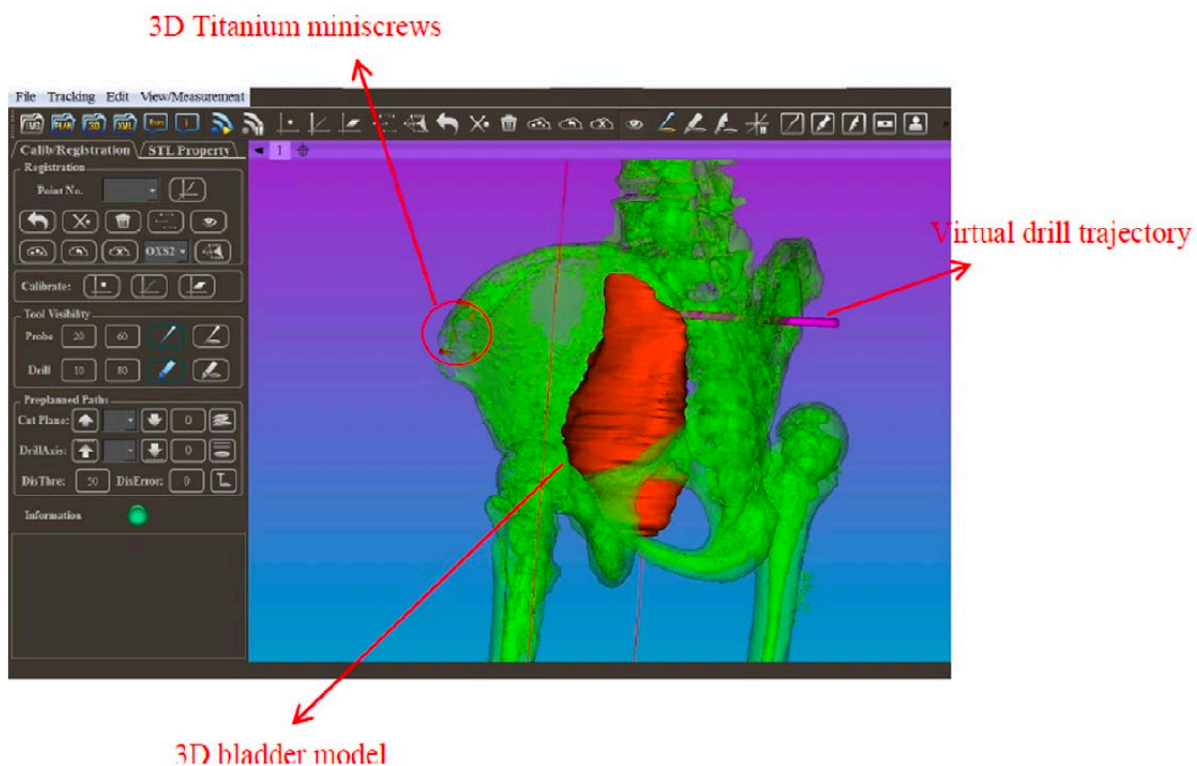


Fig. 3. A 3D pelvis model and a bladder imported into the AR-SNS.

Ex. 1009 at 3. As with the other surface modelling references relied upon by Dr. Kazanzides, *Chen*'s imaging is different from the claimed invention. *Chen*

explains, “[O]n the basis of the preoperative CT data of a patient, imaging segmentation is conducted, so that 3D models including hard and soft tissues, especially critical anatomical structures such as blood vessels and nerves can be reconstructed.” Ex. 1009 at 2. *Chen*’s “feature specific” models were created using the surface rendering technique and then “imported into the AR-SNS system.” *Id.*

145. As discussed above, in view of the claims 1-6 and the specification, a POSITA understands that “3D data including an outer layer of the patient and multiple inner layers of the patient” requires direct-volume-rendered imaging. *See supra* at ¶¶ 67-72. *Chen* discloses only surface models. *Chen* does not disclose use of the actual 3D data. Thus, *Chen* does not disclose the “3D data” limitation of claim 1.

(b) “identifying” step of claim 1

146. Dr. Kazanzides opines “[t]o a person of ordinary skill in the art, *Chen* discloses the step of ‘identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient.’” Ex. 1012, ¶ 112.

147. *Chen* identifies potential sources of data for the patient, including “CT data.” Ex. 1009, Figure 2. However, *Chen* converts the data into a feature-specific surface model. This is different from the 3D data used in the claimed invention.

Also, *Chen* does not disclose “inner layers” that can be navigated all the way through the projected 3D data and viewed along any axis.

(c) “displaying ... inner layer[]” step of claim 1

148. Dr. Kazanzides opines “[t]o a person of ordinary skill in the art, *Chen* discloses the step of ‘displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient.’” Ex. 1012 at ¶ 117. Again, in view of the claims 1-6 and the specification, a POSITA understands that “3D data including an outer layer of the patient and multiple inner layers of the patient” requires direct-volume-rendered imaging. *See supra* at ¶¶ 67-72. Thus, *Chen*’s models do not disclose an inner layer of the “3D data” of claim 1. Moreover, *Chen* does not disclose “inner layers” that can be navigated all the way through the projected 3D data and viewed from any angle.

(d) “confined” limitation of claim 1

149. By providing no opinion, Dr. Kazanzides tacitly acknowledges that *Chen* does not disclose the “confined” limitation of claim 1. Dr. Kazanzides argues that *3D Visualization* discloses the “confined” limitation of claim 1. Ex. 1012, Kazanzides, ¶ 18. I disagree. *3D Visualization*’s magenta box (*see* Ex. 1007, slide 44) is not a “virtual 3D shape,” as Dr. Kazanzides contends at least because *3D Visualization* does not disclose that “3D Slicer version 4.0” can be

used in an augmented reality (AR) environment. *Supra* at ¶ 94. *3D Visualization* also does not disclose that “3D Slicer version 4.0” can be used to project 3D medical imaging data onto non-image actual views of patient. *Id.* For at least these reasons, a POSITA would understand that *3D Visualization*’s box does not disclose the “confined” limitation of claim 1.

2. *Chen*’s disclosure with respect to dependent claims 2-6

- (a) Claim 2: “The method of claim 1, wherein: the virtual 3D shape is a virtual box; and the virtual box includes a top side, a bottom side, a left side, a right side, a front side, and a back side.”

150. By providing no opinion, Dr. Kazanzides tacitly provides acknowledges that *Chen* does not disclose the limitations of claim 2. As discussed above, *3D Slicer* and *3D Visualization* do not disclose the “confined within a virtual 3D shape” limitation of claim 1 and, therefore, do not cure the deficiencies of *Chen*. *Supra* at ¶ 149.

- (b) Claim 3: “The method of claim 1, [3a] wherein: the virtual 3D shape is configured to be controlled to toggle between displaying and hiding lines of the virtual 3D shape; and [3b] the virtual 3D shape is configured to be controlled to reposition two-dimensional (2D) slices and/or 3D slices of the projected inner layer of the patient from the 3D data.”

151. By providing no opinion, Dr. Kazanzides tacitly provides acknowledges that *Chen* does not disclose the limitations of claim 3. As discussed

above, *3D Slicer* and *3D Visualization* do not disclose the “confined within a virtual 3D shape” limitation of claim 1 and, therefore, do not cure the deficiencies of *Chen*. *Supra* at ¶ 149.

- (c) Claim 4: “The method of claim 1, wherein lines of the virtual 3D shape are displayed.”

152. By providing no opinion, Dr. Kazanzides tacitly provides acknowledges that *Chen* does not disclose the limitations of claim 4. As discussed above, *3D Slicer* and *3D Visualization* do not disclose the “confined within a virtual 3D shape” limitation of claim 1 and, therefore, do not cure the deficiencies of *Chen*. *Supra* at ¶ 149.

- (d) Claim 5: “The method of claim 1, wherein lines of the virtual 3D shape are hidden.”

153. By providing no opinion, Dr. Kazanzides tacitly provides acknowledges that *Chen* does not disclose the limitations of claim 5. As discussed above, *3D Slicer* and *3D Visualization* do not disclose the “confined within a virtual 3D shape” limitation of claim 1 and, therefore, do not cure the deficiencies of *Chen*. *Supra* at ¶ 149.

- (e) Claim 6: “One or more non-transitory computer-readable media storing one or more programs that are configured, when executed, to cause one or more processors to perform the method as recited in claim 1.”

154. Dr. Kazanzides opines that “a person of ordinary skill in the art at the

assumed relevant time understands that *Chen* teaches a non-transitory computer-readable media storing one or more programs that are configured to cause one or more processors to perform the method as recited in claim 1, when executed.

However, because *Chen* fails to disclose the method as recited in claim 1, it also fails to disclose the limitations of claim 6. *3D Slicer* and *3D Visualization* do not cure the deficiencies of *Chen*.

3. *Chen*'s disclosure with respect to independent claim 11

155. I incorporate by reference my discussion of the disclosure, or rather nondisclosure, of *Chen* as it related to the challenged claims above.

- (a) “identifying” and “displaying ... inner layer[s] steps of claim 11

156. As discussed above, in view of claims 1-6 and the specification, a POSITA understands that “3D data including an outer layer of the patient and multiple inner layers of the patient” requires direct-volume-rendered imaging. *Supra* at ¶¶ 67-70. *Chen*'s surface model is not direct volume rendered 3D imaging and does not include “multiple inner layers of the patient,” as recited in claim 11. It is a surface model and does not include any other internal or surrounding external anatomy. *Chen*'s surface model was not created to be “sliced” or “repositioned” or navigated. Nor could *Chen*'s surface model be

modified as required by claim 11. Thus, *Chen* does not disclose the “identifying” and displaying ... inner layer[s]” limitations of claim 11.

(b) “altering” step of claim 11

157. Dr. Kazanzides opines “[t]o a person of ordinary skill in the art, *Chen* discloses the ‘altering’ step of claim 11, ‘altering the original color gradient of the multiple inner layers to be lighter than the original color gradient in order to be better visible when projected onto real-time, non-image actual views of the outer layer of the patient.’” Ex. 1012, Kazanzides, ¶ 127. Dr. Kazanzides further opines “a person of ordinary skill in the art understands that *Chen* illustrates and discloses the results of experimentation with altering the original color gradient to be better visible.” *Id.* For the reasons provided below, I disagree.

158. A POSITA understands that “3D data including an outer layer of the patient and multiple inner layers of the patient” requires direct-volume-rendered imaging. *Supra* at ¶¶ 67-70. *Chen* does not alter the color gradient direct-volume-rendered CT data. *Chen* only alters the color gradient of surface-rendered models. This is different from altering the color gradient of direct volume rendering. In surface rendering, the colors are typically determined by the segmentation step, where different structures are labeled with different colors. The colors can then be adjusted manually, or they can be mapped to the surface curvature or other geometric properties to highlight certain features. Also, *Chen*’s method of using a

black background in the HMD would not work for projecting a 3D DVR image onto a real patient in an operating room, because the black background would mask data in the projected 3D image. For at least these reasons, a POSITA understands that *Chen* does not disclose the “altering” step of claim 11.

(c) “displaying ... the altered color gradient” step of claim 11

159. Dr. Kazanzides opines “[t]o a person of ordinary skill in the art, *Chen* discloses the ‘altered color’ limitation of claim 11, ‘the projected inner layer of the patient from the 3D data ... having the altered color gradient.’” Ex. 1012 at ¶ 129. Dr. Kazanzides further opines “a person of ordinary skill in the art understands that *Chen* teaches displaying the projected inner layer of the patient in an altered color gradient for a better effect.” Ex. 1012 at ¶ 129. However, because *Chen* does not disclose the “altering step” of claim 11, as discussed above (*supra* at ¶¶ 157-158), *Chen* also does not disclose the “displaying ... the altered color gradient” step of claim 11.

160. Dr. Kazanzides opines that “a person of ordinary skill in the art understands from *3D Visualization* that *3D Slicer* teaches displaying the projected inner layer of the patient in an altered color gradient for better visibility.” Ex. 1012 at ¶ 130. But *3D Visualization* and *3D Slicer* only disclose images displayed on 2D computer monitors. They do not disclose altering the color gradient “to be

better visible when projected onto real-time, non-image actual views of the outer layer of the patient,” as recited in claim 11.

4. Non-disclosure with respect to dependent claims 12-20

- (a) Claim [12/13/14/15/16/17/18/19]: “The method as recited in claim 11, wherein the altered color gradient represents a tissue [hardness/relaxivity/echogenicity/enhancement amount/enhancement speed/density/radioactivity/water content]

161. Dr. Kazanzides opines “the person of ordinary skill in the art at the relevant time would have understood that 3D Slicer enabled a user to apply a color gradient to represent a variety of parameters that a user could identify or define based on the available 3D data.” Ex. 1012 at ¶ 132. As discussed above, neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose “the projected inner layer of the patient from the 3D data ... having the altered color gradient,” as recited in claim 11. For the same reasons, neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose the limitations of claims 12-19.

162. Moreover, neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose altering a color gradient to identify any of the characteristics specifically identified in claims 12-19, e.g., tissue [hardness/relaxivity/echogenicity/enhancement amount/enhancement speed/ density/ radioactivity/water content].

- (b) Claim 20: “One or more non-transitory computer-readable media storing one or more programs that are configured, when executed, to cause one or more processors to perform the method as recited in claim 11.”

163. As discussed above, neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose “the projected inner layer of the patient from the 3D data ... having the altered color gradient,” as recited in claim 11. For the same reasons, neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose the limitations of claim 20.

5. No motive to combine *Chen*, *3D Visualization*, and *3D Slicer*.

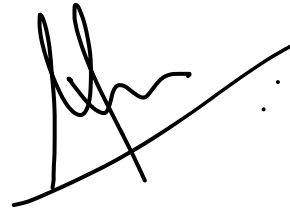
164. Dr. Kazanzides concludes that “*Chen* expressly suggests combination of the systems and methods disclosed therein with the ‘well-known, free and open-sourced package named 3D Slicer (<http://www.slicer.org/>) for visualization and medical image computing.” Ex. 1012 at ¶ 106. Dr. Kazanzides also opines that “[a] person of ordinary skill in the art understands that *Chen* expressly suggests combination of the systems and methods disclosed therein with the features and capabilities described in *3D Slicer* and *3D Visualization*. According to Dr. Kazanzides, “at the relevant time a person of ordinary skill in the art would have looked to *3D Slicer* and *3D Visualization* to understand what the suggested combination would encompass.” Ex. 1012 at ¶ 106. I disagree.

165. The ‘271 Patent discloses the projection of direct volume rendered 3D data onto non-image actual views of a patient in AR. That projected 3D data is navigable, in real-time, using a “virtual 3D shape.” The boundaries of the virtual 3D shape determine which slices, or internal layers, of the projected 3D data are visible to the user.

166. Dr. Kazanzides has not explained why a POSITA would have been motivated or had success combining the system of *Chen*, which includes surface models, with the *3D Visualization* presentation or the seven-page *3D Slicer* documentation. In my opinion, such a conclusion is unreasonable. *3D Visualization* and *3D Slicer* cannot be used in an AR environment at all. And *Chen* does not disclose real-time navigation of 3D direct volume rendered imaging while it is projected onto non-image actual views of a patient, as required by claims 1-6. Moreover, neither *Chen*, *3D Visualization*, nor *3D Slicer* adjust the color gradient of direct volume rendered medical imaging to be better visible when projected onto real-time, non-image actual views of the outer layer of a patient,” as recited in claim 11. Furthermore, neither *Chen*, *3D Visualization*, nor *3D Slicer* disclose altering a color gradient to identify any of the tissue properties specifically identified in claims 12-19, e.g., tissue [hardness/relaxivity/echogenicity/enhancement amount/enhancement speed/ density/ radioactivity/water content].

167. In my opinion a POSITA would not have been motivated to so combine *Chen*, *3D Visualization*, nor *3D Slicer* to achieve the challenged claims, nor do I believe that they would have had a reasonable expectation of success. This is because neither *Chen*, *3D Visualization*, nor *3D Slicer* identify problems or provide solutions to navigating 3D medical imaging while it is projected onto a patient in an AR environment. Furthermore, neither *Chen*, *3D Visualization*, nor *3D Slicer* identify problems or provide solutions to adjusting the color gradient of the 3D medical imaging to improve visibility of the projected 3D imaging or to represent the specific tissue properties of the 3D imaging recited in claims 12-19.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.

A handwritten signature in black ink, consisting of stylized, overlapping loops and a long horizontal stroke extending to the right.

Date:7/18/2023

Mahesh Mulumudi, M.D.