

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 CRAIG ROSENBERG, Ph.D.

TABLE OF CONTENTS

I.	QUALIFACTIONS.....	7
II.	MY EXPERTISE AND THE PERSON OF ORDINARY SKILL IN THE ART.....	15
III.	LEGAL STANDARDS	17
IV.	OVERVIEW OF THE USE OF AUGMENTED REALITY (AR) AT THE TIME OF THE '271 PATENT (MARCH 2017).....	20
V.	THE '271 PATENT AND THE CHALLENGED CLAIMS.....	22
A.	The '271 Patent Provides a Novel Virtual Control for Navigating 3D Medical Data Projected in an Augmented Reality (AR) Environment.	22
B.	Virtual Controls in an AR Environment Are Very Different From Using a Mouse, Keyboard, and Conventional Computer Monitor.	25
VI.	CONSTRUCTION OF CERTAIN CLAIM TERMS	27
1.	“three-dimensional (3D) data ... including an outer layer of the patient and multiple inner layers of the patient”	29
2.	“inner layer(s) of the patient”	30
3.	“being confined within a virtual 3D shape”	31
4.	“being having”	35
5.	Summary Table of Claim Interpretation.....	35
VII.	ANALYSIS OF THE PRIOR ART	36
A.	Doo (Ex. 1008).....	36
B.	Chen (Ex. 1009)	39
C.	3D Slicer (Ex. 1010).....	41
D.	3D Visualization (Ex. 1007).....	44
E.	Amira (Ex. 1005).....	45
VIII.	GROUND OF PATENTABILITY	49
A.	Ground 1: <i>Doo</i> Does Not Disclose All of the Elements of Claims 1, 5, and 6.....	49
1.	<i>Doo</i> does not disclose all of the elements of independent claim 1.....	49
2.	<i>Doo</i> does not disclose all of the elements of dependent claims 5 and 6.....	53
B.	Ground 2: <i>Doo</i> Alone or in View of <i>Amira</i> Does Not Render Claims 1-6 Obvious.	54
1.	Non-disclosure with respect to claims 1-6	54

2.	Non-disclosure with respect to independent claim 11	59
3.	Non-Disclosure with respect to claims 12-20.....	62
4.	No motive to combine <i>Doo</i> and <i>Amira</i>	63
C.	Ground 3: <i>Chen</i> in View of <i>3D Visualization</i> and <i>3D Slicer</i> Does Not Render Claim 1-6 and 11-20 Obvious.....	65
1.	<i>Chen</i> 's, <i>3D Slicer</i> 's, and <i>3D Visualization</i> 's non-disclosure with respect to independent claim 1.....	65
2.	<i>Disclosures of Chen, 3D Slicer, and 3D Visualization</i> with respect to dependent claims 2-6	68
3.	<i>Chen</i> 's disclosure with respect to independent claim 11	73
4.	Non-disclosure with respect to dependent claims 12-20	74
5.	No motive to combine <i>Chen</i> and <i>3D Slicer</i> or <i>3D Visualization</i>	75

I, Craig Rosenberg, Ph.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 specifications 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 ¶¶ 121-188.

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 Kazanzides, Ph.D.
Ex. 1013	Curriculum Vitae of Peter Kazanzides 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. QUALIFICATIONS

13. I believe I am qualified to serve as a technical expert in this proceeding based on my educational and work experience, including my 30+ years of experience in human factors, user interface design, user interaction design, human-computer interaction, and software engineering from 1988 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 Science degree in Industrial Engineering, my Master of Science degree in Human Factors, and Doctor of Philosophy in Human

Factors from the University of Washington School of Engineering. For 30 years, I have worked in human factors, user interface design, software development, software architecture, systems engineering, and modeling and simulation across various application areas, including aerospace, communications, entertainment, and healthcare.

17. I graduated from the University of Washington in 1988 with a Bachelor of Science in Industrial Engineering. After graduation, I continued my studies at the University of Washington College of Engineering. In 1990, I obtained a Master of Science degree in Human Factors. Human Factors is an engineering discipline that studies the design of products, processes, equipment, and systems to work more efficiently with humans. Human factors is concerned with reducing human error, increasing productivity and efficiency, and enhancing safety and comfort with a specific focus on the interactions and interfaces between humans and the products, processes, or systems with which they interact. In 1994, I graduated with a Doctor of Philosophy in Human Factors, focusing on advanced interface design. My Bachelor of Science, Master of Science, and Doctor of Philosophy degrees were all obtained at the University of Washington College of Engineering.

18. During my doctoral studies, I worked as an Associate Assistant Human Factors Professor at the University of Washington Industrial Engineering

Department. My duties included teaching, writing research proposals, designing and conducting funded human factors experiments for the National Science Foundation, and hiring and supervising students. While studying at the University of Washington, I also worked as a human factors researcher. I designed and performed advanced human factors experiments relating to virtual environments and interface design, stereoscopic displays, and advanced visualization research, which the National Science Foundation funded. My duties included user interface design, systems design, software development, graphics programming, experimental design, and hardware and software interfacing.

19. I have published twenty-one research papers in professional journals and proceedings in user interface design, computer graphics, and the design of spatial, stereographic, and auditory displays. I also authored a book chapter on augmented reality displays in the book “Virtual Environments and Advanced Interface Design” (Oxford University Press, 1995). In addition, I created one of the first virtual spatial musical instruments called the MIDIBIRD that, utilized the MIDI protocol, two six-dimensional spatial trackers, a music synthesizer, and a computer graphics workstation to create an advanced and novel musical instrument.

20. For the past 21 years, I have been a consultant for Global Technica, Sunny Day Software, Stanley Associates, Tchrizon, CDI Corporation, and the

Barr Group. In this capacity, I have provided advanced engineering services for many companies.

21. I consulted for the Boeing Company for 15 years as a senior human factors engineer, user interface designer, and software architect for various advanced commercial and military programs. Many of the projects that I was involved with at Boeing involved advanced software development, user interface design, agent-based software, and modeling and simulations in the areas of missile defense, homeland security, battle command management, computer-aided design, networking and communications, air traffic control, location-based services, and Unmanned Aerial Vehicle (“UAV”) command and control. Additionally, I was the lead system architect developing advanced air traffic controller workstations and air traffic control analysis applications, toolsets, and trade study simulations for Boeing Air Traffic Management.

22. I was also the architect of the Boeing Human Agent Model. The Boeing Human Agent Model is an advanced model for the simulation of human sensory, cognitive, and motor performance as applied to the roles of air traffic controllers, pilots, and UAV operators. In another project, I was the lead human factors engineer and user interface designer for Boeing’s primary vector and raster computer-aided drafting and editing system that produces the maintenance manuals, shop floor illustrations, and service bulletins for aircraft produced by the

Boeing Commercial Aircraft Company. Additional responsibilities in my time as a consultant include system engineering, requirements analysis, functional specification, use case development, user stories, application prototyping, modeling and simulation, object-oriented software architecture, graphical user interface analysis, and design, as well as UML, C++, C#, and Java software development.

23. In 1995 and 1996, I was hired as the lead human factors engineer and user interface designer for the first two-way pager produced by AT&T. Before this technology, individuals could receive pages but had no way to respond utilizing their pager. This new technology allowed users to use a small handheld device to receive and send canned or custom text messages, access and update an address book, and access and update a personal calendar. This high-profile project involved designing the entire feature set, user interface/user interaction design and specification, and all graphical design standards.

24. From 1999 to 2001, I was the lead human factors engineer and user interface designer for a company called Eyematic Interfaces, where I was responsible for all user interface design and development activities associated with real-time mobile handheld 3D facial tracking, animation, avatar creation, and editing software for a product for Mattel. My work involved user interface design,

human factors analysis, requirements gathering and analysis, and functional specifications.

25. I was the lead user interface designer for a company called ObjectSpeed, which developed a portable handheld telephone for use in homes and businesses with many of the same capabilities we take for granted in mobile cellular phones. This portable multifunction device supports voice, email, chat, video conferencing, internet radio, streaming media, Microsoft Outlook integration, photo taking, sharing, etc. The ObjectSpeed device was specifically designed and developed as a portable handheld device.

26. I was the lead user interface designer for Ahaza, which was building IPv6 routers. I designed the user interfaces to configure and control these advanced network hardware devices. My responsibilities included requirements analysis, functional specification, user interface design, user experience design, and human factors analysis.

27. I am the founder, inventor, user interface designer, and software architect of WhereWuz. WhereWuz is a company that produces advanced mobile software running on GPS-enabled smartphones and handheld devices. WhereWuz allows users to record exactly where they have been and query this data for subsequent retrieval based on time or location. WhereWuz was specifically designed and developed to run on small handheld devices.

28. I am the co-founder of a medical technology company called Healium. Healium developed advanced wearable and handheld user interface technology to allow physicians to interact more effectively with electronic medical records.

29. I am the co-founder of a medical technology company called StratoScientific. StratoScientific is developing an innovative case for a smartphone that turns a standard handheld smartphone into a full-featured digital stethoscope that incorporates visualization and machine learning for telemedicine and automated diagnosis.

30. I designed and developed a large software project for Disney World called xVR that allowed the operational employees of Disney World to utilize a handheld device to view the current and historical status of all of the guests of Disney World within multiple attractions and one of their restaurants. The application could run in a real-time/live mode where it would display data collected from sensors that showed the location and status of all guests within the attraction; the application could also be run in a fast-time/simulated mode. The application was developed on a laptop computer and designed to run on various devices, including laptops, personal computers, smartphones, and tablets.

31. I have received several awards for my engineering work relating to interface design, computer graphics, and the design of spatial, stereographic, and

auditory displays, including a \$10,000 scholarship from the I/ITSEC for advancing the field of interactive computer graphics for flight simulation and a Link Foundation award for furthering the field of flight simulation and virtual interface design. I have also created computer graphic illustrations for several popular book covers and animations for a movie produced by MIRAMAR.

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

33. The combination of my education, research, training, and work experience in software development, human factors, user interface design, user interaction design, and human-computer interaction enables me to provide analysis and opinions on the subject matter of this litigation.

34. 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 in this case. I have worked on a significant number of patent litigation cases, several of which were related to virtual and augmented reality. These include the following cases:

- ARCzar v. Nintendo (Artificial Reality Patent Case)
- Glasses.com v. Ditto (Artificial Reality Patent Case)
- Lennon v. Sephora (Artificial Reality Patent Case)

- RPX v. Virtual Immersion Technologies (VR Patent Case)
- Princeton Digital Image Corporation v. Harmonix Music Systems (VR Patent Case)
- Princeton Digital Image Corporation v. Konami Digital Entertainment (VR Patent Case).
- Barbaro v. Niantic (VR Patent Case)
- Worlds, Inc v. Linden Labs (VR Patent Case)
- Utherville v. Epic Games (VR Patent Case)

35. I have been retained over 100 times, been deposed 46 times, and have testified seven times at trial. And I have written many expert reports and declarations.

36. 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

37. My opinions in this declaration are based on my experience in this technical field. More specifically, my over 30 years of experience designing and

implementing virtual reality (VR) and augmented reality (AR) environments.

38. I am certainly 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.

39. 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.

40. 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.

41. 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.

42. A POSITA at the time of the '271 Patent would include someone with a degree in human factors or human-computer interaction. Human factors professionals play a crucial role in the design and development of AR systems to

ensure they are user friendly, effective, and safe. AR combines virtual elements with the real world, overlaying computer-generated information onto the user's view of the physical environment. It involves the integration of various technologies, including hardware, software, and user interfaces. Human factors considerations become essential in optimizing the usability, interaction, and overall user experience of AR applications.

43. 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

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

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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.

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

52. 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.

53. 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.

54. 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.

55. 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.

56. 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 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.

57. 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) AT THE TIME OF THE '271 PATENT (MARCH 2017)

58. The concept of Augmented Reality (AR) has been around for several

decades. The earliest forms of AR can be traced back to the 1960s and 1970s. However, the term “Augmented Reality” was not coined until 1990 by Tom Caudell, a researcher at Boeing. The 2000s and 2010s saw a significant increase in AR development, spurred by advances in technology and the increasing ubiquity of smartphones.

59. In terms of AR head-mounted displays (HMDs), the field is still relatively new. Google introduced Google Glass, an early example of an AR head-mounted display, in 2013. In 2015, Microsoft introduced its HoloLens, a more advanced AR headset. A development edition of the HoloLens wasn’t available until 2016. The first generation of commercial VR/AR headsets from Oculus, HTC, and others also launched in 2016. Despite these developments in hardware, AR in March 2017 was still facing significant hurdles, particularly in surgical applications.

60. While AR was showing considerable potential in areas such as surgical planning, intraoperative guidance, training, and patient education, several significant challenges were limiting widespread adoption and usage in 2017, including by way of example:

61. **Technological Limitations:** To be effective in surgical applications, AR had to provide accurate, real-time information. This required significant

computing power and advanced imaging technology. Issues like latency, resolution, and field of view were major concerns.

62. **Registration and Tracking:** Accurate alignment of virtual data (like preoperative imaging) with the actual patient anatomy is critical in AR. Imperfect registration can lead to significant errors, which can have severe consequences in a surgical context.

63. **Usability:** Surgeons needed to feel comfortable with the technology and trust it enough to rely on it during procedures. There were also ergonomic considerations, such as how the technology would fit into the surgical workflow without disrupting or slowing it.

64. While solutions to these problems have been pursued in the years following 2017, many of these challenges still exist today.

V. THE '271 PATENT AND THE CHALLENGED CLAIMS

A. The '271 Patent Provides a Novel Virtual Control for Navigating 3D Medical Data Projected in an Augmented Reality (AR) Environment.

65. The '271 Patent explains that a “common problem faced by AR systems is proper placement of virtual controls for managing virtual elements.” Ex. 1001, 1:29-30. The '271 Patent further explains that “[v]irtual controls, while intended to aide a user in interacting with virtual elements, are often placed in positions in the live view that render them more of a hinderance than a help to the

user.” Ex. 1001, 1:31-34. The ’271 Patent provides methods for “augment[ing] real-time views of a patient with 3D data.” Ex. 1001, 3:23. The 3D data “may be automatically aligned, or registered, with [and projected onto] a real-time view of the actual patient.” Ex. 1001, 3:24-27. The “augmenting of real-time views of a patient with 3D data may include the display of a virtual user interface and other virtual controls for altering the [3D data] projected onto the real-time view of the patient.” Ex. 1001, 3:50-54. The “virtual user interface and ... virtual controls may be projected to avoid obstructing the medical professional’s field of view when viewing the patient....” Ex. 1001, 3:54-56. The virtual user interface and virtual controls “allow the medical professional to quickly and easily alter the [3D data] projected onto the real-time view of the patient.” Ex. 1001, 3:60-62.

66. The ’271 Patent explains that an “augmented reality (AR) environment 100 ... may include a 3D space 102, a user 104, a patient 106, and an AR headset 108,” (Ex. 1001, 3:63-66), as illustrated in Figure 1 copied below.

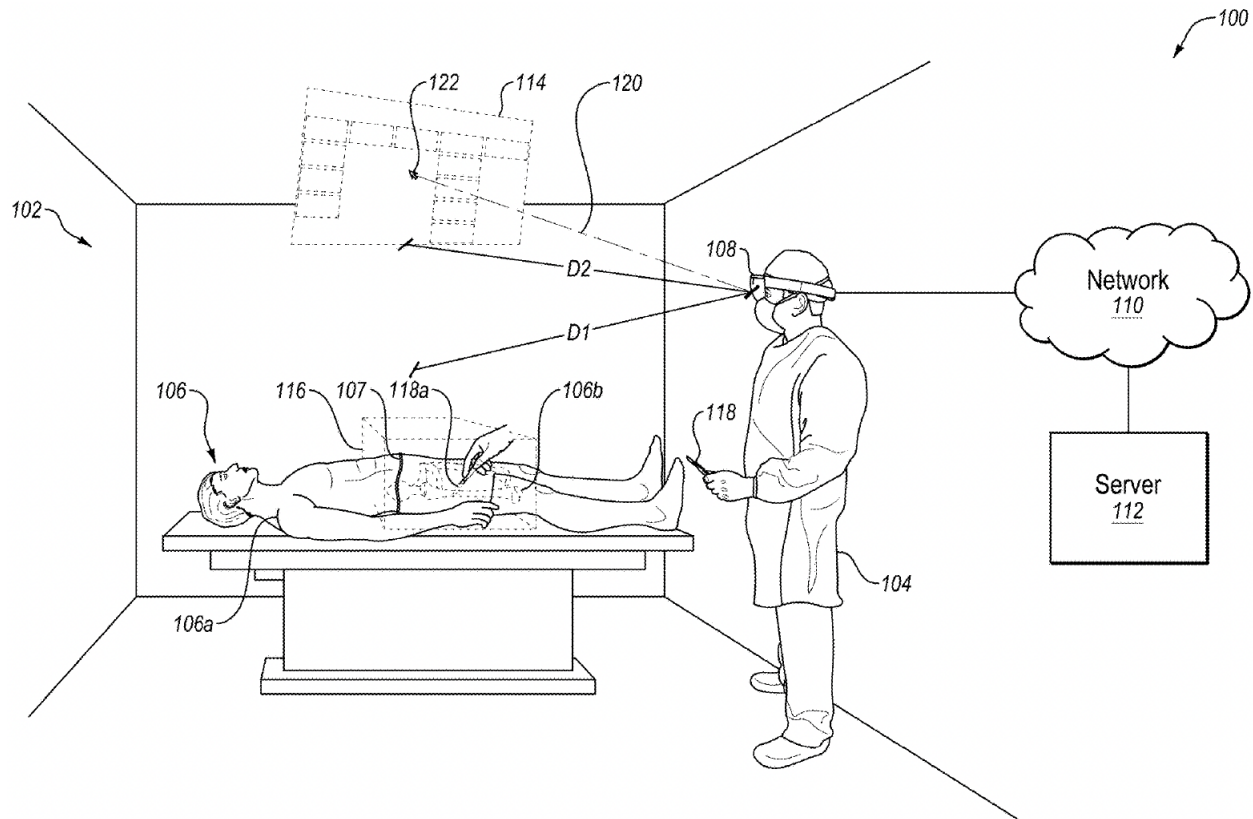


FIG. 1

The '271 Patent further explains that the AR environment “may also include a virtual user interface 114” and “a virtual spatial difference box 116.” Ex. 1001, 4:1-3.

67. The “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. It may also “assist the user when navigating the projected 3D data by providing a frame of reference for the user 104.” Ex. 1001, 6:11-13. 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.” Ex. 1001, 6:14-17. The slices may be three-dimensional (3D), including “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, 6:17-21. The “user 104 may move [the] slices using hand gestures that require the user 104 to generally move his hand in the directions of the lines of the virtual spatial difference box 116...” Ex. 1001, 6:21-25.

B. Virtual Controls in an AR Environment Are Very Different From Using a Mouse, Keyboard, and Conventional Computer Monitor.

68. Virtual controls in an augmented reality (AR) environment are very different from using a mouse and keyboard and a conventional computer monitor. When designing virtual controls in an AR environment, several factors are considered, including:

69. **Cognitive Load:** AR environments are often filled with a lot of information which can cause cognitive overload. Therefore the design must be such that it presents the right amount of information at the right time to the user, aiding in decision-making and reducing mental effort.

70. **Physical Ergonomics:** Even though the controls are virtual, they are operated by people in the physical world. This means that the positioning and manipulation of these controls must take into account the physical abilities and

constraints of the user. For instance, controls should be within comfortable reach and not require awkward or strenuous movements to manipulate.

71. **Sensory Feedback:** In the absence of tangible feedback (like feeling a button click on a mouse), AR controls may need to provide other forms of feedback (e.g., visual or auditory feedback) to let the user know that their actions have been successful.

72. **Learnability and Usability:** Virtual controls should be designed such that they are easy to learn and use.

73. **Visual Clarity and Contrast:** AR often involves overlaying digital information onto the real world. It's important that virtual controls are distinct and clear, ensuring they stand out from the real-world backdrop.

74. **Context-Sensitive Design:** The AR controls should be adaptable to the context of the intended use. For example, controls used by a surgeon in an operating room might need to be voice-activated or gesture-based in order to maintain sterility, while controls used by an engineer may be hand-operated.

75. **Safety Considerations:** Especially in professional or industrial settings, it is important that the design of virtual controls doesn't increase the risk of accidents. They should not be distracting or misleading, and should always provide a clear way to return to a 'safe' state.

76. Designing virtual controls for AR is an interdisciplinary task that requires knowledge in psychology, physiology, design principles, and user experience methodologies. While user interface design is highly complex, often the best user interface designs seem the most obvious in hindsight.

VI. CONSTRUCTION OF CERTAIN CLAIM TERMS

77. 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.

78. As an expert in user interface design in augmented reality (AR) environments, I comment on the interpretation of claim terms related to that expertise.

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 3D CT, MRI, PET, and SPECT imaging (and also ultrasound and fluorescence imaging, depending on the methods used).”

79. Claim 1 is a “method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data.” The “3D data” includes “an outer layer and multiple inner layers of the patient.” I am not an expert in the specifics of medical imaging. However, based on the plain and ordinary meaning of “three-dimensional (3D),” a POSITA would understand that the image projected onto the patient in an AR environment must at least appear to the user to have height, width, and depth.

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.”

80. Claim 1 requires “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.” Again, based on the plain language of the claim, a POSITA would understand that the image projected onto the patient in an AR environment, whether the complete 3D dataset or some subset, appears to the user to have height, width, and depth. The ’271 Patent explains that the inner layers, i.e., slices, may be 3D and 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, 6:17-21.

3. “being confined within a virtual 3D shape”

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

81. Claim 1 requires that the projected 3D image “be[] confined within a volume of a virtual 3D shape.” Claim 2 states that “virtual 3D shape” may be a “virtual box.” Claim 3 states that the “virtual 3D shape is configured to be controlled to reposition ... 3D slices of the projected inner layer of the patient.”

82. The '271 Patent explains that the “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. The “virtual spatial difference box 116 may “assist the user when navigating the projected 3D data by providing a frame of reference for the user 104.” Ex. 1001, 6:11-13. 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.” Ex. 1001, 6:14-17. The slices may be 3D and 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, 6:17-21. And the “user 104 may move [the] slices using hand gestures that requires the user 104 to generally move his hand in the directions of the lines of the virtual spatial difference box 116...” Ex. 1001, 6:21-25.

83. A POSITA would understand that the “virtual spatial difference box,” described in the ’271 Patent, is an example of the “virtual 3D shape” of claim 1. A POSITA would also understand that the “virtual 3D shape,” like the “virtual spatial difference box” is an example of a “virtual user interface” or “virtual control[] for altering the [3D data] projected onto the real-time view of the patient.” Ex. 1001, 3:50-54. Based on the language of the ’271 Patent, a POSITA would understand that the “virtual 3D shape” may “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. A POSITA would also understand that the user can use “hand gestures” to use the “virtual 3D shape” to adjust the viewable volume of the projected 3D dataset or 3D slice.

84. Dr. Kazanzides contends 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, Kazanzides, ¶ 33. While I agree that the ’271 Patent discloses virtual 3D shapes as simple as a

box and as complex as the outer layer of the patient, I disagree with Dr.

Kazanzides' interpretation of the word "confine".

85. A POSITA would understand that the virtual 3D shape could be the shape of the outer layer of a patient. The '271 Patent explains that 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, 6:17-21. A POSITA would also understand that a user could use the virtual 3D shape to navigate through "curved slices that follow the natural curve" of the patient's outer layer.

86. However, Dr. Kazanzides interprets "confine" as merely an outline. He relies on boxes in the prior art that are not used in an augmented reality (AR) environment. The boxes referenced by Kazanzides in *Amira* and *3D Visualization*, which are discussed in detail below, are displayed on computer monitors, not in AR. A POSITA would understand that a static outline alone does not satisfy the "virtual 3D shape" of claim 1, which a POSITA would understand is a "virtual control" that is "generated by the AR headset 108 to confine within a volume of the virtual [3D shape] the projected inner layer of the patient 106 from the 3D data." Ex. 1001, 6:5-8.

87. A POSITA would understand that the "virtual 3D shape" is a "virtual control" for a number of reasons. First, at the outset, the '271 Patent states that a

“common problem faced by AR systems is proper placement of virtual controls for managing virtual elements.” Ex. 1001, 1:29-30. Second, the ’271 Patent offers “a virtual user interface and other virtual controls for altering the images projected onto the real-time view of the patient” as a solution to the poor virtual control problem identified at the outset. Ex. 1001, 3:50-54. Third, in the following paragraph, the ’271 Patent describes “an example augmented reality (AR) environment 100” with the proposed improved controls, including “a virtual user interface 114” and “a virtual spatial difference box 116.” Ex. 1001, 3:63-67; 4:1-7. The ’271 Patent explains that the “virtual 3D shape” may “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17.

88. A POSITA would understand that the ordinary and customary meaning of the term “virtual,” consistent with the specification of the ’271 Patent, is an element that appears to a user superimposed onto or integrated into the user’s real-world view.

89. A POSITA would understand that the ordinary and customary meaning of “virtual 3D shape”, in view of the ’271 Patent, is a 3D “spatial form or contour”², which is a “virtual control” capable of confining within its boundaries the 3D data that is project, i.e., superimposed, onto a patient in an augmented reality environment.

² <https://www.merriam-webster.com/dictionary/shape>

90. Based on the forgoing, a POSITA would understand “being confined within a virtual 3D shape” means that the virtual 3D shape is a “virtual control” that “controls” what portion of the volume of the projected 3D layer(s) are visible to the user. In other words, the virtual 3D shape does more than merely outline an image projected in a 3D space.

4. “being having”

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

91. 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 the 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 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 to 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

92. *Doo* (Ex. 1008) and *Chen* (Ex. 1009) are the only references cited by Petitioner that disclose an augmented reality (AR) environment. The other references cited by Petitioner (*3D Slicer* (Ex. 1010), *3D Visualization* (Ex. 1007), and *Amira* (Ex. 1005)) are computer software and generally cannot be used in an AR environment.

A. *Doo* (Ex. 1008)

93. *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*. Dr. Kazanzides argues that *Doo*’s Figure 7, copied below, “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, Kazanzides, ¶ [0075]. I disagree.

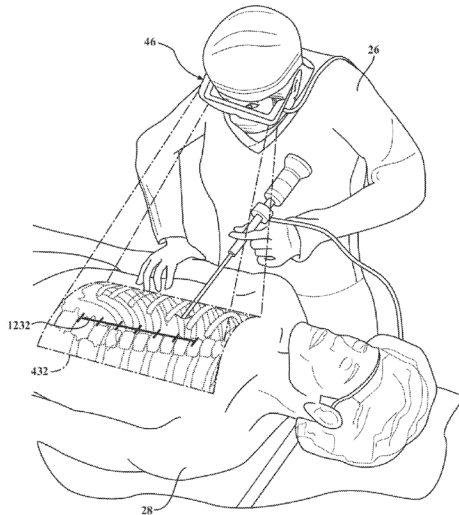


FIG. 7

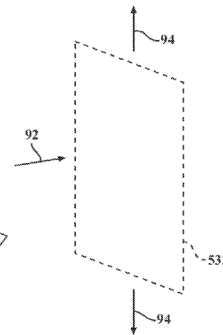


FIG. 8

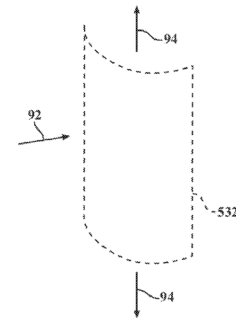


FIG. 9

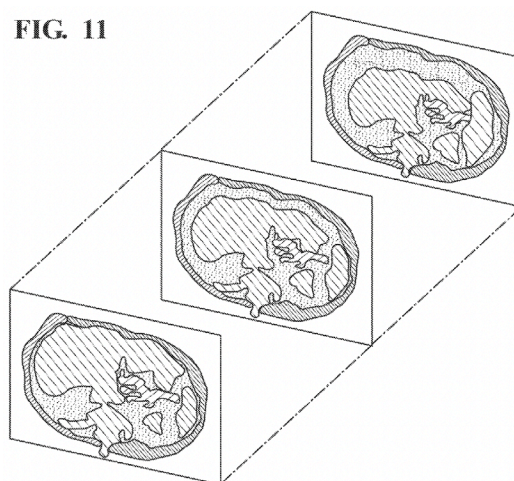
94. Figures 7 and 9, shown above, illustrate a curved “two-dimensional image ... rendered by the system as having been wrapped over the chest of the patient,” like a curved piece of paper. Ex. 1008, ¶ [0075]. This is quite different from projecting a virtual control—a virtual 3D shape that confines, on all sides, the projected 3D data and “assist[s] the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. The curved plane of Figure 9 is not a shape that confines a volume, or as recited in claim 1 of the ’271 Patent, it is not a shape that allows for “confined within a volume of a virtual 3D shape.”

95. *Doo* does not disclose that the “wrapped” 2D plane of Figure 9 can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. *Doo* does not disclose that the “wrapped” 2D plane can be “configured to be

controlled,” as recited in claim 3 of the ’271 Patent. *Doo* also does not disclose that the “wrapped” 2D plane can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3.

96. For at least these reasons, a POSITA would understand that neither Figures 7 nor 9 of *Doo* 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. For the same reasons, a POSITA would understand that Figures 7 and 9 of *Doo* also do not disclose a “virtual 3D shape” that is “configured to be controlled” or that can “reposition ... 3D slices,” as recited in claim 3 of the ’271 Patent.

97. Dr. Kazanzides also contends that “[a] person of ordinary skill in the art would understand that *Doo*’s Figure 11 illustrates a collection of medical images forming a virtual 3D shape.” Ex. 1012, Kazanzides, ¶ 76. Figure 11 is shown below.



98. 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]. Dr. Kazanzides argues that a stack of 2D images, like a stack of paper, forms the “virtual 3D shape” of claim 1. I disagree.

99. Assuming for a moment that Fig. 11 shows a stack of 2D pictures, the resultant box would be static and not controllable by a user. *Doo* does not disclose that the box can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. *Doo* also does not disclose that the box can be “configured to be controlled,” as recited in claim 3 of the ’271 Patent. *Doo* does not disclose that the box can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3.

100. For at least these reasons, a POSITA would understand that Figure 11 of *Doo* does not 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. For the same reasons, a POSITA would understand that Figure 11 of *Doo* also do not disclose a “virtual 3D shape” that is “configured to be controlled” or that can “reposition ... 3D slices,” as recited in claim 3 of the ’271 Patent.

B. Chen (Ex. 1009)

101. *Chen* discloses “an AR-based surgical navigation system (AR-SNS)”

that uses an “optical see-through HMD (head-mounted display), aiming at improving the safety and reliability of surgery.” Ex. 1009, *Abstract*. *Chen* discloses the projection of surface models, e.g., “a 3D bladder and some blood vessels and nerves”) onto a plastic pelvis model. Ex. 1009 at 6; *see* Figure 5 copied below.

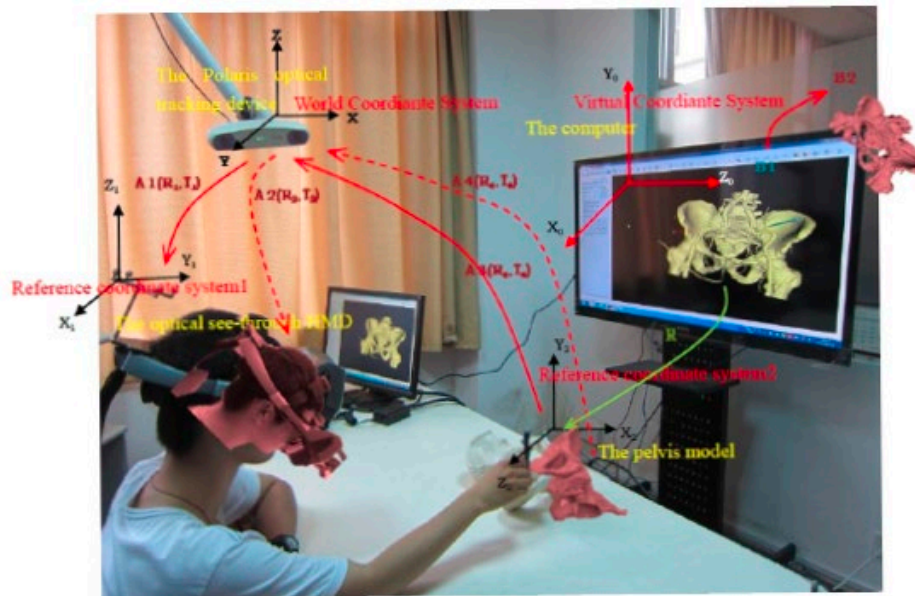


Fig. 5. The establishment of coordinate systems in AR-SNS.

102. *Chen* also discloses the projection of a pelvis model, a bladder model, and titanium miniscrews models onto a cadaver. Ex. 1009 at 6; *see* Figure 9 copied below.



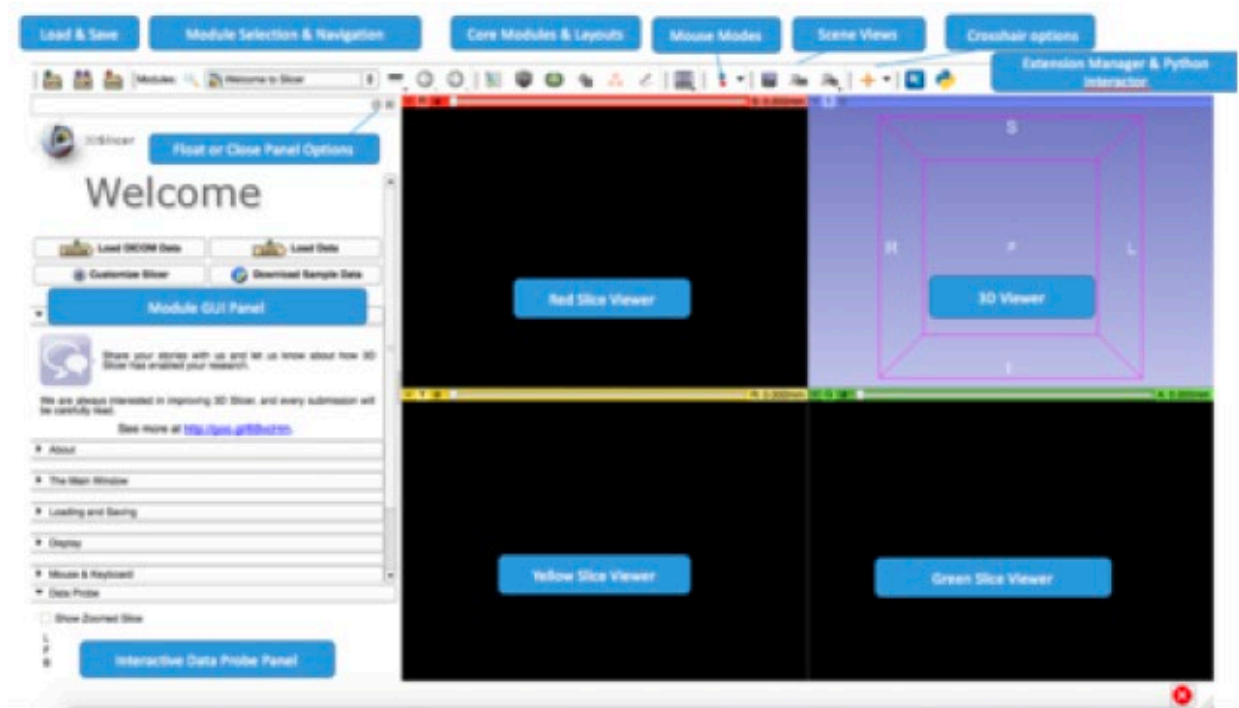
Fig. 9. The panoramic view of the operating room for a cadaver experiment.

103. Dr. Kazanzides does not contend, and thereby tacitly admits, that *Chen* does not 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. *Chen* also does not disclose a “virtual 3D shape” that is “configured to be controlled” or that can “reposition ... 3D slices,” as recited in claim 3 of the ’271 Patent. I agree.

C. 3D Slicer (Ex. 1010)

104. Ex. 1010 (“3D Slicer”) is a seven-page document that purports to be online documentation 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 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 or that it can be used to project 3D medical imaging data onto non-

image actual views of a patient. On page one, it appears to show a screenshot of a two-dimensional (2D) display, copied below.



105. Ex. 1010 at 1. Based on the limited content in the document, it appears Slicer4 can only be used to view “jpg, tif, or png files” on a conventional “desktop” computer monitor. Ex. 1010 at 2.

106. There are significant differences between rendering a 3D image for a computer monitor and rendering for augmented reality (AR). Both involve translating 3D data sets into 2D images, but the way this is done is quite different due to the nature of the display technology and the viewing environment. I discuss several of those differences below:

107. Real World Integration: AR headsets overlay digital content onto the real-world view, which requires careful alignment and tracking to ensure that the digital content is correctly registered with the real world and then stays correctly positioned as the user moves their head or walks around. This requires real-time six degree-of-freedom tracking (position and orientation) and can also utilize environment mapping or surface detection. Rendering for a computer monitor typically involves a straightforward rectangular projection and does not need to take into account the user's head position.

108. Transparency and Occlusion: Rendering for AR also needs to handle transparency and occlusion between the real and digital worlds. The digital content might need to appear semi-transparent, or it might need to occlude real-world objects or be occluded by real-world objects, which requires depth sensing and real-time compositing.

109. Latency and Performance: Frame rate is important in both cases, but it's particularly crucial in AR. Low frame rates on a computer monitor can make a data set look choppy, but low frame rates in AR can make the user feel nauseous and/or dizzy.

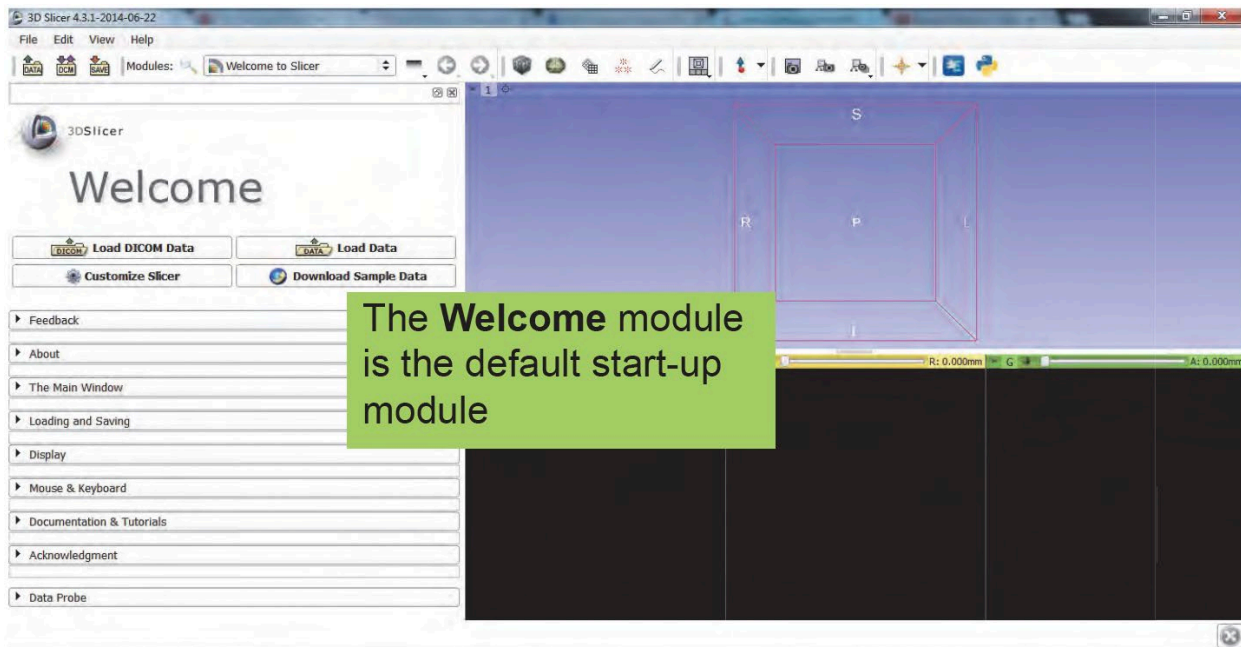
110. Stereoscopic Rendering: AR headsets are typically stereo devices, meaning they have separate displays (or views) for each eye to create a sense of depth and 3D perception. This requires rendering two different perspectives of the

scene, one for each eye. In contrast, a computer monitor usually only requires a single view to be rendered.

111. Thus, a POSITA would understand that *3D Slicer*'s 2D solutions are not solutions to the challenges of projecting in AR medical imaging of a patient onto non-image actual views of the patient. Nor does *3D Slicer* provide solutions to a POSTIA for assisting a user "when navigating the projected 3D data" in an augmented reality (AR) environment. Ex. 1001, 6:14-17.

D. 3D Visualization (Ex. 1007)

112. 3D Visualization appears to be a presentation/tutorial for Slicer4 entitled, "3D Visualization of DICOM Images for Radiological Applications." Ex. 1007, slide 6. The document does not disclose that "Slicer4" can be used in an augmented reality (AR) environment. It also does not disclose that "Slicer4" can be used to project 3D medical imaging data onto non-image actual views of a patient. It does appear to show screenshots from a typical computer monitor, copied below.



Ex. 1007, Slide 17. Based on 3D Visualization’s disclosure, it looks like “Slicer4” can only be used to view images on a typical computer monitor. *Id.*

E. Amira (Ex. 1005)

113. Ex. 1005 purports to be the first two chapters (out of 12 total chapters) of a user guide for computer software titled “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, e.g., medicine, biology, bio-chemistry, microscopy, biomed, bioengineering.” Ex. 1005 at 15.

114. Like *3D Slicer*, *Amira*, it appears cannot be used in an augmented reality (AR) environment. *Amira* cannot be used to project imaging onto non-image actual views of a patient. Generally, *Amira*’s images are viewed on a

computer monitor. *Amira* does appear to have a virtual reality option “designed to enable the use of *Amira*’s advanced data visualization and analysis features on immersive VR systems and tiled screen configurations.” Ex. 1005 at 26.

However, virtual reality (VR) and augmented reality (AR) are not the same.

115. In virtual reality, the user is fully immersed in a completely digital environment. When using a VR headset, the user’s real-world surroundings are completely replaced by the simulated environment. The virtual environment can be a simulation of the real world or an entirely imagined world.

116. On the other hand, augmented reality overlays digital content onto the user’s direct perception of the real world. When using AR, the real world is still visible, but it is augmented by additional information, such as text, images, or 3D models. This additional information appears to be present in the real world, and it can provide useful context or additional details about the real environment.

117. Virtual reality and augmented reality also have their own unique challenges. Some of the challenges of VR include:

- Immersion & Realism: The virtual world needs to be convincingly real to fully engage the user. Achieving high levels of visual realism, fine details, realistic physics, and high frame rates can be resource intensive;

- Motion Sickness: VR can cause discomfort or motion sickness in some people, often due to a mismatch between what the user's eyes see and what their body feels; and
- Isolation: By design, VR is a largely isolating experience. It cuts the user off from actual physical surroundings, which can be disorienting or even unsafe if not managed carefully.

118. One of the main goals of augmented reality (AR) is the seamless integration of digital content into the real world. This poses several significant challenges unique to AR, for example:

- Tracking and Registration: For digital content to appear as if it's part of the real world, it needs to stay in the correct position and orientation even as the user moves their viewpoint. This requires tracking and position orientation of the user's device (e.g., headset) with high accuracy and low latency. The process of aligning the digital content with the real world is known as registration;
- Environment Understanding: For a more convincing and interactive AR experience, the AR system should understand the real-world environment. This includes recognizing objects and surfaces in the real world, understanding lighting conditions, and even understanding semantic information (like knowing that a certain object is a chair). This

- information can be used to make the digital content interact realistically with the environment, like casting correct shadows or being occluded by real-world objects;
- Lighting and Rendering: In the real world, the appearance of objects is affected by lighting conditions, material properties, and the viewer's perspective. For digital content to blend seamlessly into a real-world environment, the same factors need to be taken into account. This requires sophisticated rendering techniques, possibly including real-time ray tracing, global illumination, and physically based rendering; and
 - User Perception and Comfort: AR experiences should be designed to be comfortable and easy to understand for the user. This can involve managing issues like visual fatigue and ensuring that the digital content doesn't interfere with the user's perception of the real world. It also involves designing intuitive interfaces and interactions that leverage the user's existing knowledge and expectations about the real world.

119. Thus, a POSITA would understand that *Amira*'s 2D and VR solutions are not solutions to the challenges of projecting in medical imaging onto a real patient in an AR environment or assisting a user "when navigating the projected 3D data" in an AR environment.

VIII. GROUNDS OF PATENTABILITY

A. Ground 1: *Doo* Does Not Disclose All of the Elements of Claims 1, 5, and 6.

120. For the reasons provided below, *Doo* at least does not 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 independent claim 1.

1. *Doo* does not disclose all of the elements of independent claim 1.

121. Dr. Kazanzides argues that, to a POSITA, “*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, Kazanzides, ¶ 77. I disagree.

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

122. Dr. Kazanzides argues that *Doo*’s “‘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” satisfies this claim element. Ex. 1012, Kazanzides, ¶ 75.

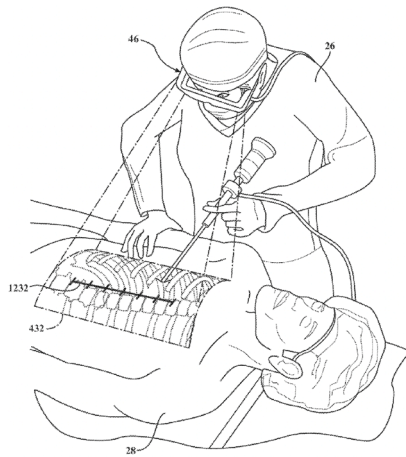


FIG. 7

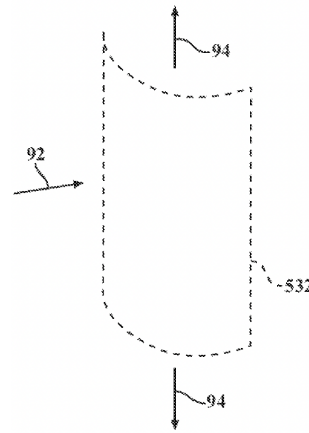


FIG. 9

123. Dr. Kazanzides concludes, “[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, Kazanzides, ¶ 75. However, a POSITA would understand that Figures 7 and 9 show only a curved two-dimensional (2D) image. *Doo* explains that the 2D image in Figures 7 and 9 was “rendered by the system as having been wrapped over the chest of the patient.” Ex. 1012, Kazanzides, ¶ 75. Thus, *Doo*’s “wrapped” 2D plane is clearly not 3D data. It is also vastly different from projecting a virtual control—a “virtual 3D shape” that confines, on all sides, the projected 3D data and “assist[s] the user when navigating the projected 3D data.” Ex. 1001, 6:14-17.

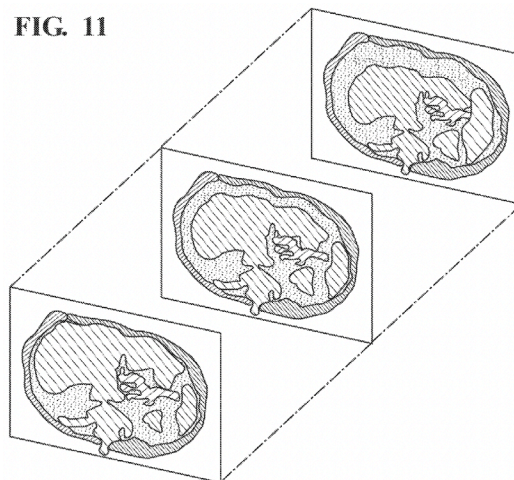
124. *Doo* does not disclose that the curved 2D plane of Figure 9 can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. *Doo* also does not disclose that the curved 2D plane can be “configured to be

controlled,” as recited in claim 3 of the ’271 Patent. *Doo* does not disclose that the curved 2D plane can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3.

125. For at least these reasons, a POSITA would understand that neither Figures 7 nor 9 of *Doo* 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) *Doo*’s Heart (Figures 6 and 11) Does Not and Cannot Confine a 3D Volume.

126. Dr. Kazanzides also contends that “[a] person of ordinary skill in the art would understand that *Doo*’s Figure 11 illustrates a collection of medical images forming a virtual 3D shape.” Ex. 1012, Kazanzides, ¶ 76. Figure 11 is shown below.



127. According to *Doo*, Figure 11 illustrates “several tomographic slices [that] can be stitched together to create a 3D image.” Ex. 1008, ¶ [0078]. Dr. Kazanzides argues that a stack of 2D images, like a stack of paper, forms the “virtual 3D shape” of claim 1. I disagree.

128. Again, assuming that Fig. 11 shows a stack of 2D pictures, even if the projection of the stack created a box, it seems the content of the images would only be visible to the user if the white space surrounding the image on each page were invisible. And, in any case, the resultant box would be static. Nowhere does *Doo* disclose that the box can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. *Doo* also does not disclose that the box can be “configured to be controlled,” as recited in claim 3 of the ’271 Patent. *Doo* does not disclose that the box can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3.

129. For at least these reasons, a POSITA would understand that Figure 11 of *Doo* does not 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. For the same reasons, a POSITA would understand that Figure 11 of *Doo* also do not disclose a “virtual 3D shape” that is “configured to be controlled” or that can “reposition ... 3D slices,” as recited in claim 3 of the ’271 Patent.

2. *Doo* does not disclose all of the elements of dependent claims 5 and 6.

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

130. 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 would understand 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, Kazanzides, ¶ 78. I disagree. As discussed above, *Doo* does not disclose a “virtual 3D shape,” as recited in claim 1. *Supra* at ¶¶ 112-120. 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.

131. 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.

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

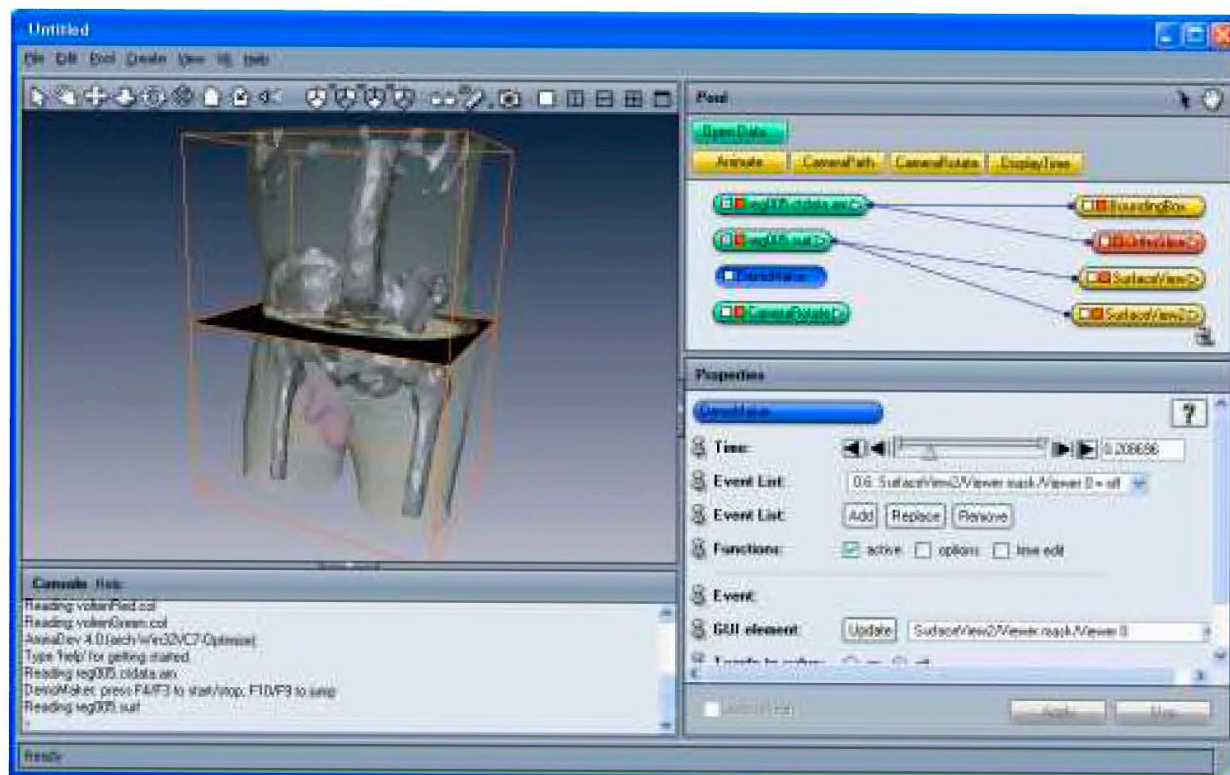
133. Dr. Kazanzides opines that “claims 1-6 and 11-20 would have been obvious over *Doo* in view of *Amira* at the relevant time to a person of ordinary skill in the art.” Ex. 1012, Kazanzides, ¶ 81.

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.”

134. Dr. Kazanzides contends 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, Kazanzides, ¶ 83. I disagree. *Amira* does not “project” an inner layer of the patient from the 3D data. Dr. Kazanzides relies on a description of an optional module (“Amira Virtual Reality Option”) from the introduction provided in Ex. 1005. However, a POSITA would understand that in a virtual reality (VR) environment objects are not projected on to the real world. In VR the entire environment is virtual.

135. *Amira* also does not disclose “the 3D data being ***confined*** within a volume of a ***virtual*** 3D shape,” as recited in claim 1. Dr. Kazanzides relies on a screenshot provided on page 80 of *Amira* (Ex. 1005 at 92), shown below:



136. Dr. Kazanzides contends that *Amira*'s skin model satisfies the "virtual 3D shape" of claim 1. Ex. 1012, Kazanzides, ¶ 83. I disagree. A POSITA would understand that the "virtual 3D shape" of claims 1-5 is a tool for navigating the projected 3D data. *See supra* ¶¶ 54-55. *Amira* does not disclose such a "virtual 3D shape," as required by claims 1-5. *Amira* shows only non-virtual bounding box that is not used in a AR environment at all.

137. *Amira* does not disclose that its skin model can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. *Amira* also does not disclose that its skin model can be “configured to be controlled,” as recited in claim 3 of the ’271 Patent. *Doo* does not disclose that its skin model can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3. For at least these reasons, a POSITA would understand that *Amira*’s skin model does not 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.

138. Dr. Kazanzides also contends that *Amira*’s bounding box satisfies the “virtual 3D shape” of claim 1. However, *Amira* explains that “[i]n *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. *Amira* does not disclose that its bounding box can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. For at least these reasons, a POSITA would understand that *Amira*’s bounding box does not 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) 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.”

139. 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.”

140. 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.

Supra at ¶¶ 136-139.

141. 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, Kazanzides, ¶ 86. Dr. Kazanzides relies on the following from *Amira*:

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 on *Amira*’s “3D Rotate icon” that can be used “to rotate the object in the 3D viewer.” Ex. 1005 at 100.

142. Dr. Kazanzides admits that *Amira* discloses using a conventional mouse and a user interface displayed on a conventional computer monitor to rotate an object also displayed on a the computer monitor. This is vastly different from a virtual control or virtual user interface in an augmented reality (AR) environment. As mentioned above, virtual controls in an augmented reality (AR) environment are very different from using a mouse and keyboard in front of a computer monitor.

143. A POSITA would understand that the “virtual 3D shape” of claim 1 of the ’271 Patent is a “virtual control” designed for a AR environment. The user uses hand gestures to move 3D slices “confined within a volume of a virtual 3D space.” Because it is a virtual control, a POSITA would understand that the “virtual 3D shape” is meant to reduce cognitive load, be convenient and easy to use, be comfortable, provide visual feedback to the user, and maintain sterility in an operating room. Perhaps, to a lay person, it may seem obvious to combine *Amira*’s bounding box with *Doo*’s medical image viewing system to arrive at the “virtual 3D shape” of claim 1, but a POSITA understands that it is not because the combination would fundamentally change how *Amira*’s box works.

144. For example, *Amira* cannot be used in an AR environment. *Amira* does not disclose that its bounding box can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. *Amira* also does not

disclose that its bounding box can be “configured to be controlled,” as recited in claim 3 of the ’271 Patent. *Amira* does not disclose that its bounding box can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3. For at least these reasons, a POSITA would understand that *Amira*’s bounding box does not disclose all of the elements of claim 3 of the ’271 Patent.

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

145. 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.”

146. 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.”

147. As discussed above, *Amira* 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

148. As discussed above, *Amira* generally displays images and objects on 2D computer monitors. *Amira* does not disclose projecting a 3D data on to non-

image actual views of the patient. *See supra* at ¶¶45-52.

- (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)

149. Dr. Kazanzides contends 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.

150. Augmented reality (AR) adds extra layers of complexity to the processes of rendering and visualizing 3D medical data, including the adjustment of color gradients. The challenges associated with adjusting color gradients in medical imaging can be amplified in AR applications, in ways that a POSITA, looking at Amira, would not appreciate. For example:

151. **Lighting Conditions.** In AR, the lighting conditions of the real-world environment, including an operating room can affect the visibility and perceived colors of the projected 3D data. This means that the same color gradient often look different under different lighting conditions, potentially leading to inconsistent interpretations.

152. **Display Technology Limitations.** AR display technologies, especially those used in wearable devices, may have limitations in terms of color

accuracy, contrast ratio, brightness, and resolution. These limitations could affect the quality of the color gradients and the ability to make fine adjustments.

153. **Subjective Perception.** The perception of color can be affected by the surrounding colors (a phenomenon known as color constancy). In AR, where the 3D data is registered to and projected onto non-image actual views of a patient, the surrounding colors are much more variable than in a controlled screen environment, potentially leading to inconsistent color perceptions and inaccurate interpretations of the projected 3D data.

154. Thus, in view of these challenges, a POSITA would understand that changes to color gradients on a computer monitor and within an AR environment are not substitutes for each other. A POSITA would understand that *Amira*'s color adjustment on a computer monitor, or even in VR, is much different from altering the color gradient of a direct volume 3D rendering projected on to non-image actual views of a patient presented to the user 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)

155. 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.

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

156. 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, Kazanzides, ¶ 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] property of the multiple inner layers of the patient.”

157. 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.

158. 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.”

159. 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*

160. 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, Kazanzides, ¶ 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.

161. The ‘271 Patent discloses the projection of 3D data onto non-image actual views of a patient in AR. That projected 3D data is confined within a volume of a virtual 3D shape. The virtual 3D shape is a virtual tool that “assist[s] the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. It can be

“configured to be controlled” and to “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3.

162. Certainly, Dr. Kazanzides has not explained why a POSITA would have been motivated or had success combining the medical image viewing system of *Doo* with the *Amira* computer software to arrive at the claims of the '271 Patent. In my opinion, such a conclusion is unsupportable and unreasonable.

163. Neither *Doo* nor *Amira* disclose navigating 3D data while it is projected onto non-image actual views of a patient, as required by claims 1-6. Neither *Doo* nor *Amira* disclose any virtual tool that can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. Neither *Doo* nor *Amira* disclose a virtual tool “configured to be controlled,” or that can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3. Moreover, neither *Doo* nor *Amira* adjust the color gradient of direct volumed rendered 3D data “to better visible when projected onto real-time, non-image actual views of the outer layer of a patient,” as recited in claims 11-20. Based on the forgoing, it stands to reason that the combination of *Doo* and *Amira* would not result in the challenged claims. In my opinion, a POSITA would have not have been motivated to so combine *Doo* and *Amira*, nor do I believe that they would have had a reasonable expectation of success.

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

164. Dr. Kazanzides opines 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, Kazanzides, ¶ 106. Dr. Kazanzides contends that “[a] person of ordinary skill in the art would understand that *Chen* expressly suggests combination of the systems and methods disclosed therein with the features and capabilities described in *3D Slicer* and *3D Visualization*. Dr. Kazanzides further contends that “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, Kazanzides, ¶ 106. I disagree. For the reasons provided below, a POSITA would not be motivated to combine *Chen*, *3D Slicer*, and *3D Visualization*, in the manner proposed by Dr. Kazanzides. See *infra* at ¶¶ 159-182.

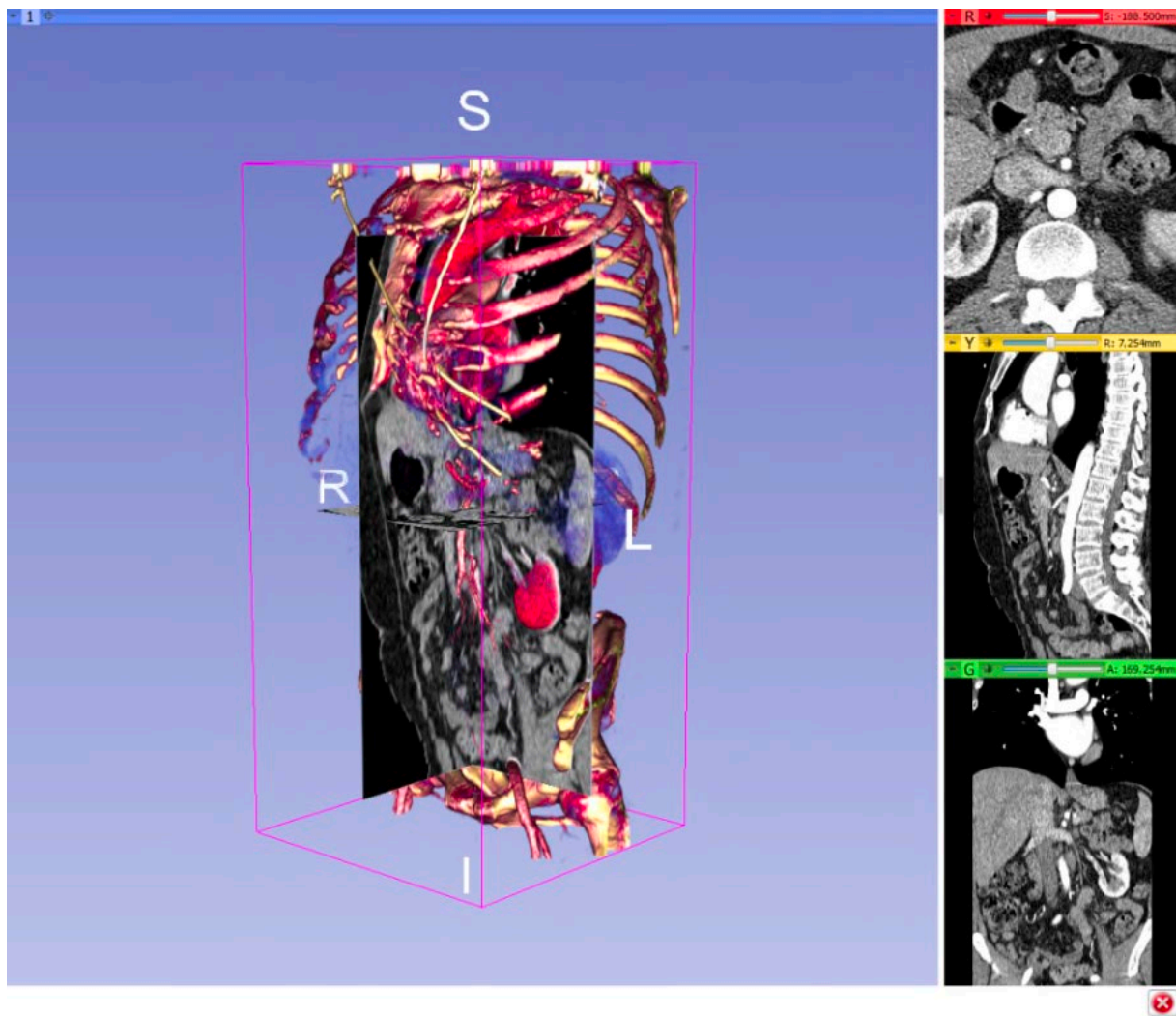
165. Dr. Kazanzides claims that “claims 1-6 and 11-20 would have been obvious over *Chen* in view of *3D Slicer* and *3D Visualization* at the relevant time to a person of ordinary skill in the art.” Ex. 1012, Kazanzides, ¶ 108. Again, for the reasons provided below, I disagree.

1. *Chen*’s, *3D Slicer*’s, and *3D Visualization*’s non-disclosure with respect to independent claim 1

(a) “confined” limitation of claim 1

166. By providing no opinion, Dr. Kazanzides tacitly acknowledges that *Chen* does not disclose the “confined” limitation of claim 1. Dr. Kazanzides contends that “*3D Visualization* discloses the display of an inner layer of the patient image data in both two and three dimensional form within a volume of a virtual 3D shape.” Ex. 1012, Kazanzides, ¶ 118. However, *3D Visualization* and *3D Slicer* do not disclose “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape,” first because *3D Slicer* and *3D Visualization* do not “**project** an inner layer of the patient from the 3D data,” as required by claim 1. *3D Slicer* only displays images and objects on 2D computer monitors.

167. *3D Slicer* and *3D Visualization* also do not disclose “the 3D data being **confined** within a volume of a **virtual** 3D shape,” as recited in claim 1. Dr. Kazanzides relies on a screenshot from slide 44 of *3D Visualization*, shown below:



168. Dr. Kazanzides contends that *3D Visualization*'s magenta box satisfies the “virtual 3D shape” of claim 1. Ex. 1012, Kazanzides, ¶ 118. I disagree. A POSITA would understand that the “virtual 3D shape” of claims 1-5 is a tool for navigating the projected 3D data. *See supra* ¶¶85-90. *3D Slicer* and *3D Visualization* do not disclose such a “virtual 3D shape,” as required by claims 1-5. *3D Slicer* and *3D Visualization* show only a non-virtual bounding box that is not used in a AR environment at all.

169. *3D Visualization* does not disclose that its box can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. *3D Visualization* also does not disclose that its box can be “configured to be controlled,” as recited in claim 3 of the ’271 Patent. *3D Visualization* does not disclose that its box can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3. For at least these reasons, a POSITA would understand that *3D Visualization*’s box does not 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.

2. Disclosures of *Chen*, *3D Slicer*, and *3D Visualization* 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.”

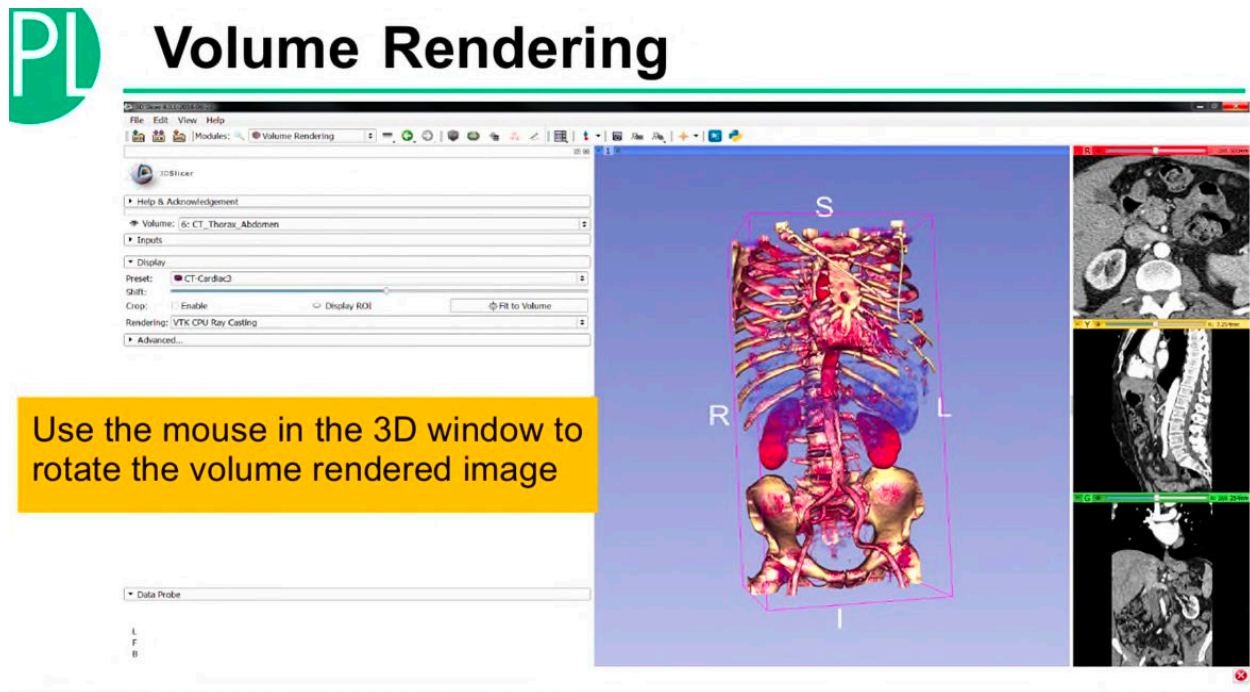
170. By providing no opinion, Dr. Kazanzides tacitly provides acknowledges that *Chen* does not disclose the limitations of claim 2. As discussed above, *3D Slicer* and *3D Visualization* do not disclose the “confined within a virtual 3D shape” limitation of claim 1 and, therefore, does not cure the deficiencies of *Chen*. See *supra* at ¶¶ 113-114.

- (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.”

171. 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, does not cure the deficiencies of *Chen*. See *supra* at ¶¶ 113-114.

172. Dr. Kazanzides contends that *3D Slicer*’s box “is configured to be controlled to reposition ... 3D slices of the projected inner layer of the patient.” Ex. 1012, Kazanzides, ¶ 121. As support, Dr. Kazanzides provides only slide 46 from *3D Visualization*, shown below.



173. As shown above, the slide states, “Use the mouse in the 3D window to rotate the volume rendered image.” Ex. 1007, slide 46. Dr. Kazanzides admits that *3D Visualization* discloses using a conventional mouse and a user interface displayed on a conventional computer monitor to rotate an object also displayed on a the computer monitor. As stated previously, this is vastly different from a virtual control or virtual user interface in an augmented reality (AR) environment. As mentioned above, virtual controls in an augmented reality (AR) environment are very different from using a mouse and keyboard in front of a computer monitor.

174. Also, claim 3 requires that 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.” The ’271 Patent concerns “[a]ugmenting real-time views of a patient with three-dimensional (3D) data” and “automatically registering 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, *Abstract*. A POSITA would therefore understand that the projected 3D data is not rotated because it’s registered to the patient. In fact, the ’271 Patent actually does not even mention the word “rotate.” Thus, a POSITA would understand that “configure to be controlled to reposition ... slices” means “navigating the projected 3D data” by repositioning slices registered to the patient within the virtual 3D shape—not rotation.

175. A POSITA would understand that the “virtual 3D shape” of claim 1 of the ’271 Patent is a “virtual control” designed for a AR environment. The user uses hand gestures to move 3D slices “confined within a volume of a virtual 3D space.” Because it is a virtual control, a POSITA would understand that the “virtual 3D shape” is meant to reduce cognitive load, be convenient and easy to use, be comfortable, provide visual feedback to the user, and maintain sterility in an operating room. Perhaps, to a typical person, it may seem simple to combine *Amira*’s bounding box with *Doo*’s medical image viewing system at arrive at the “virtual 3D shape” of claim 1, but a POSITA understands that it is not.

176. *3D Visualization* does not disclose that its box can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. *3D Visualization* also does not disclose that its box can be “configured to be controlled,” as recited in claim 3 of the ’271 Patent. *3D Visualization* does not disclose that its box can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3. For at least these reasons, a POSITA would understand that *3D Visualization*’s box does not disclose all of the elements of claim 3 of the ’271 Patent.

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

177. 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, does not cure the deficiencies of *Chen*. See *supra* at ¶¶ 113-114.

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

178. 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, does not cure the deficiencies of *Chen*. See *supra* at ¶¶ 113-114.

- (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.”

179. Because *Chen*, *3D Slicer*, and *3D Visualization* fail to disclose the method of claim 1, they also fails to disclose the limitations of claim 6.

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

(a) “altering “ step of claim 11

180. Dr. Kazanzides opines that “*3D Visualization* teaches altering color values for different inner layers.” Ex. 1012, Kazanzides, ¶ 128. A support, Dr. Kazanzides provides slides 53 and slide 73 as examples. However, as mentioned above, augmented reality (AR) adds extra layers of complexity to the processes of rendering and visualizing 3D medical data, including the adjustment of color gradients. The challenges associated with adjusting color gradients in medical imaging can be amplified in AR applications, in ways that a POSITA, looking at *3D Slicer* or *3D Visualization*, would not appreciate. As mentioned above, these challenges include at least lighting conditions, alignment and tracking, display technology limitations, and subjective perception. *See supra* at ¶¶ 151-154. In view of these challenges, a POSITA would understand that changes to color gradients on a computer monitor and within an AR environment are not substitutes for each other. A POSITA would understand that *3D Slicer's* color adjustment on a computer monitor is much different from altering the color gradient of 3D data projected on to non-image actual views of a patient in an AR environment.

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

11

181. Dr. Kazanzides opines that “a person of ordinary skill in the art would

understand 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, Kazanzides, ¶ 130. As discussed above, *3D Visualization* and *3D Slicer* do not disclose “the projected inner layer of the patient from the 3D data ... having the altered color gradient,” as recited in claim 11, because *3D Slicer* and *3D Visualization* are limited to displaying images on a computer monitor. *3D Slicer* and *3D Visualization* do not project images onto real-world environments in AR.

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]

182. 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, Kazanzides, ¶ 132. However, 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.”

183. As discussed above, neither *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* and *3D Slicer* or *3D Visualization*

184. Dr. Kazanzides contends that a POSITA “would understand that *Chen* expressly suggests combination of the systems of methods disclosed therein with the features and capabilities described in *3D Slicer* and *3D Visualization*.” Ex. 1012, Kazanzides, ¶ 106. However, Dr. Kazanzides provides no support for his contention.

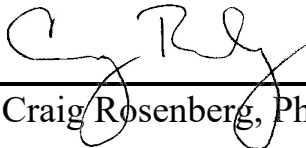
185. The ‘271 Patent discloses the projection of 3D data onto non-image actual views of a patient in AR. That projected 3D data is confined within a volume of a virtual 3D shape. The virtual 3D shape is a virtual tool that “assist[s] the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. It can be “configured to be controlled” and to “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3.

186. Certainly, Dr. Kazanzides has not explained why a POSITA would have been motivated or had success combining the medical image viewing system of *Chen* with the *3D Slicer* computer software to arrive at the claims of the '271 Patent. In my opinion, such a conclusion is unsupportable and unreasonable. Neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose navigating 3D data while it is projected onto non-image actual views of a patient, as required by claims 1-6. Neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose any virtual tool that can be used to “assist the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. Neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose a virtual tool “configured to be controlled,” or that can “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3.

187. Moreover, neither *3D Slicer* nor *3D Visualization* adjusts the color gradient of 3D data “to better visible when projected onto real-time, non-image actual views of the outer layer of a patient,” as recited in claims 11-20. In my opinion, a POSITA would have not have been motivated to so combine *Chen*, *3D Slicer*, and *3D Visualization*, nor do I believe that they would have had a reasonable expectation of success.

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.

Date: July 17, 2023



Craig Rosenberg, Ph.D.