

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDIVIS, INC.
Petitioner

v.

NOVARAD CORP.
Patent Owner

US Patent No. 11,004,271

Inter Partes Review No. IPR2023-00042

**PETITION FOR *INTER PARTES* REVIEW
OF US PATENT NO. 11,004,271
UNDER 35 USC §§ 311-319 AND CFR § 42.100, *et. seq.***

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Exhibit	Description
Ex. 1001	US Patent No. 11,004,271, claiming priority to March 30, 2017 (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, through which the ‘271 Patent claims priority
Ex. 1004	Excerpts of File history of Application No. 15/474,702, filed on March 30, 2017, and now U.S. Patent No. 9,892,564, through which the ‘271 Patent claims priority
Ex. 1005	Excerpt of Amira 5 User’s Guide title through Chapter 2 (Visual Imaging 2009) (“ <i>Amira</i> ”)
Ex. 1006	US Patent Application Publication No. US 2016/0191887 A1 to Casas, published on June 30, 2016 (“ <i>Casas</i> ”)
Ex. 1007	S. Pujol, Ph.D. et al., 3D Visualization of DICOM Images for Radiological Applications (Surgical Planning Laboratory, Brigham and Women’s Hospital, Boston, Massachusetts 2014) (“ <i>3D Visualization</i> ”)
Ex. 1008	International Publication No. WO 2015/164402 A1 to Doo et al., published on October 29, 2015 (“ <i>Doo</i> ”)
Ex. 1009	X. Chen et al., “Development of a 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> ”)

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Ex. 1010	Main Application GUI for 3D Slicer < https://www.slicer.org/wiki/Documentation/4.6/Slicer/Application/MainApplicationGUI > (last edited 7 November 2016) (“ <i>3D Slicer</i> ”)
Ex. 1011	E. Azimi et al., “Augmented 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.
Ex. 1014	Email message entitled “Novarad v. Medivis” and dated August 3, 2022, from counsel for Novarad, Brett Davis, to counsel for Medivis, Brian Lemon and others.

I. INTRODUCTION

U.S. Patent No. 11,004,271 (the ‘271 Patent), entitled “Augmenting Real-Time Views of a Patient with Three-Dimensional Data,” claims methods for augmenting real-time non image actual views of a patient with three-dimensional data using an augmented reality (AR) headset. In simplified terms, the claimed methods take conventional medical image data of a patient’s anatomy of interest (*e.g.*, from MRIs, CT scans, X-rays, etc.) and, via a conventional AR headset (such as the Microsoft HoloLens®), project that medical image (*e.g.*, in the form of a hologram) onto the patient. The ‘271 Patent claims priority to March 30, 2017. But by then, the claimed methods were known in the art. The Office issued the ‘271 Patent because it did not consider the best prior art. Without the best prior art, the Office could not appreciate that the ‘271 Patent claimed known or obvious methods. Claims 1-6 and 12-20 should be cancelled as unpatentable over prior art that the Office had not considered when it issued the ‘271 Patent.

A. The Parties

Petitioner Medivis, Inc., was founded in 2016 by two young doctors in New York City—a neurosurgeon and a radiologist. Medivis immediately began developing an augmented reality (“AR”) surgical navigation system that enables 3D medical images to be overlaid onto a view of a patient. This system uses the Microsoft HoloLens® AR headset. As soon as the HoloLens AR headset became

commercially available to developers in early 2016, Medivis and several other companies began developing AR surgical applications based on it. Medivis won FDA 510(k) approval for the SurgicalAR® system in May 2019, and began selling it to hospitals soon thereafter. As discussed further below, Medivis's system built on the medical community's research into AR-assisted surgery.

Patent Owner Novarad Corp. sued Medivis for infringement of the '271 Patent. That suit (described below) is currently pending.

B. Mandatory Notices And Certifications

1. Real Party-in-Interest

The real party in interest for this petition for *inter partes* review (IPR) is Medivis, Inc., of 174 5th Avenue, Suite 505, New York, NY, 10010.

2. Related Matters

On October 13, 2021, Novarad filed a complaint alleging that Medivis infringes the '271 Patent and U.S. Patent No. 10,945,807 (the '807 Patent). Novarad served the complaint on Medivis on October 14, 2021. The case is pending in the District of Delaware, C.A. No. 21-1447-GBW. Medivis moved to dismiss the case because the '271 Patent (as well as the '807 Patent) claims ineligible subject matter in violation of 35 U.S.C. § 101. That motion has not yet been heard and remains pending. Given the pending motion to dismiss, Medivis has not answered Novarad's complaint. Discovery is in its early stages. Claim

construction has not been briefed, let alone argued or decided. In short, the case remains in its early stages.

Along with this petition, Medivis also filed a petition for IPR of the ‘807 Patent. The ‘807 patent is also owned by Novarad, lists the same two inventors, is generally directed to similar AR-assisted surgical navigation methods, but is not part of the ‘271 Patent family.

The ‘271 Patent results from a continuation of an application that matured into U.S. Patent 10,010,379. The ‘271 Patent appears to have two continuations: (1) Application No. 17/201,983 (now U.S. Patent 11,266,480); and (2) Application No. 17,687,114, filed on March 4, 2022, and is currently pending.

3. Counsel and Service Information

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All of the foregoing counsel are attorneys at McCarter & English, LLP, 265 Franklin Street, Boston, MA 02110. Medivis consents to service by email at all of the foregoing email addresses.

4. Standing

Pursuant to 37 CFR § 42.104(a), Medivis certifies that the ‘271 Patent is available for *inter partes* review and that Medivis is not estopped nor barred from requesting *inter partes* review of the ‘271 Patent based on the grounds in this petition.

II. THE ‘271 PATENT AND ITS PROSECUTION

A. The Challenged ‘271 Patent

The ‘271 Patent claims priority from March 30, 2017, through two parent applications. The ‘271 Patent includes three independent claims—Claims 1, 7, and 11—and a total of 20 claims. All of the claims of the ‘271 Patent are directed to methods for augmenting real-time non image actual views of a patient with three-dimensional data using an AR headset. At a high level, the ‘271 Patent describes feeding three dimensional (3D) data (*e.g.*, X-rays, MRIs, CT scans, etc.) of the patient’s anatomy (*e.g.*, organs, bones, viscera) to an AR headset to be overlaid onto the view of a patient. To the wearer, the AR headset can project an AR image associated with the patient.

As a starting point, it is important to recognize what the inventors of the ‘271 Patent do not claim to have invented. For example, the inventors do not claim to have invented any new mode of medical imaging. Instead, the ‘271 Patent relies on long-known imaging techniques, such as X-rays, MRI, CT scans, PET scans,

fluoroscopy, etc. Ex. 1001, ‘271 Patent, 2:49-51 (“conventional medical imaging systems may create three-dimensional (3D) data for a patient”); 11:45-59 (the 3D data may include MRI, CT scans, X-ray, and PET images, among others). Nor do the inventors claim to have invented AR systems. *Id.*, 17:11-16 (referencing “conventional AR systems”). Nor do the inventors claim to have invented AR headsets or any particular improvements to the headsets, such as circuitry, lenses, or sensors. Rather, the claimed inventions can use a commercially-available AR headset. *Id.*, 4:39-42 (“the AR headset 108 may be any computer system in the form of an AR headset that is capable of augmenting real-time views of the patient 106 with 3D data) and 4:60-61 (“the AR headset 108 may be a modified version of the Microsoft HoloLens”).

Other aspects of the claimed inventions were also known in the art at the relevant time. For example, and as detailed below, the use of AR headsets to display medical imaging data and the display of medical image data within a virtual 3D shape such as a bounding box were known. Similarly, altering of color gradients in image data as also known before the ‘271 Patent’s priority date.

B. Summary of the Challenged Claims

Medivis challenges Claims 1-6 and 11-20. The challenged claims include two of the three independent claims—Claims 1 and 11—and all of their related dependent claims. All of the challenged claims of the ‘271 Patent are directed to

methods for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data. Claim 1, for example, recites the following method:

1. A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:
identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient; and
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 confined within a volume of a virtual 3D shape.

The other challenged independent claim—Claim 11—includes all of the limitations of Claim 1 except the requirement that “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.”

Instead, the method of Claim 11 requires the step of “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.” Claim 11 also requires “the projected inner layer of the patient from the 3D data being having the altered color

gradient.” Most of the method claims that depend from Claim 11 limit what the altered color gradient represents.

C. Reasons for Allowance of the Challenged Claims

According to the Notice of Allowability, “Reasons for allowance remain the same as discussed in the non-final office action dated 8/06/2020.” Ex. 1002, 9. That office action only provides reasons for allowance of Claims 1-6 and 11-20.

The office action finds allowable subject matter in Claims 1-6 because none of three cited references “suggest projection onto real-time actual views of the patient, layers confined to a 3D shape.” Ex. 1002, 37. But as discussed below, a virtual bounding box, which inner layers are confined within, was well known in the art at the relevant time. Ex. 1012, Kazanzides Decl., ¶ 54.

The office action finds allowable subject matter in Claims 11-20 because none of the cited references “suggest application to projection on to real-time actual views by lightening the layer to improve visibility.” Ex. 1002, 38. But as discussed below, adjusting the color of an overlaid virtual image was known in the art at the relevant time. Ex. 1012, ¶ 56.

As seen below, both of the supposedly missing steps in the challenged independent claims were disclosed in prior art that the Office did not consider.

III. CLAIM CONSTRUCTION

A. Legal Standard for Construction

The claims “shall ... be construed using the same claim construction standard that is used to construe the claim in a civil action in district court” because this petition was filed after November 13, 2018. 83 FED. REG. 51340. Thus, claim terms should be given their ordinary meaning to one of ordinary skill in the art. 37 C.F.R. § 42.100; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). That meaning is always informed by the specification. *Phillips*, 415 F.3d at 1315. Indeed, the specification is “usually dispositive; it is the single best guide to the meaning of a disputed term.” *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (citation omitted). In addition, the tribunal “should also consider the patent’s prosecution history, if it is in evidence” *Phillips*, 415 F.3d at 1317.

B. The Field of the Invention and Person of Ordinary Skill in the Art

The ‘271 Patent states that “[a]ugmented reality (AR) systems generally take a user’s live view with computer-generated virtual elements such as video, sound, or graphics,” and thus “enhance a user’s current perception of reality.” Ex. 1001, ‘271 Patent, 1:17-21 (Background section). The ‘271 Patent then asserts that “[o]ne common problem faced by AR systems is accurately aligning the position of a virtual elements with a live view of a real-world environment.” *Id.*, 1:22-24.

The '271 Patent states that “[c]onventional medical imaging systems may create three-dimensional (3D) data for a patient and then display that 3D data as an image or images on a computer display.” Ex. 1001, 2:49-51. Further, “viewing images of a patient on a computer display ... may be useful in training, research, diagnosis, and treatment” *Id.*, 2:51-55.

The challenged claims of the '271 Patent are directed to “augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data.” *Id.*, Claims 1 and 11. “FIG. 1 illustrates an example augmented reality (AR) environment in which real-time views of a patient may be augmented with the three-dimensional (3D) data.” *Id.*, 2:25-27. Figure 1 illustrates “an operating room with an operative table 103.” *Id.*, 4:8-11. Figure 1 illustrates the patient as “a living human adult” on the operative table. *Id.*, 4:28-31. The '271 Patent states “the patient 106 may ... ha[ve] been rendered unconscious in order to undergo a medical procedure” *Id.*, 4:28-31.

Peter Kazanzides, Ph.D., is a Research Professor of Computer Science at The Johns Hopkins University and has been teaching, researching, and working in the field of computer-assisted surgery for nearly 20 years. Professor Kazanzides has developed and patented various AR-assisted surgical systems and has several patents to his name, including, for example, US Patent 11,244,508, entitled “Augmented Reality Display for Surgical Procedures.” Professor Kazanzides has

co-authored numerous research papers, journal articles, and conference proceedings on computer-assisted surgery, including, for example, a paper entitled “Augmented Reality Goggles with an Integrated Tracking System for Navigation in Neurosurgery,” published in 2012. He also advises graduate students on their Ph.D. theses in the field of AR-assisted surgical systems. *See* Ex. 1012, Declaration of Peter Kazanzides, ¶¶ 2-13; Ex. 1013, Kazanzides *Curriculum Vitae*.

Based on his reading of the ‘271 Patent and the prior art discussed below, Professor Kazanzides concludes that the relevant art is “systems and methods for using augmented reality during medical procedures.” Ex. 1012, ¶ 23.

For purposes of this IPR, Medivis does not challenge the priority date claimed in the ‘271 Patent. Accordingly, the relevant date for considering the patentability of the challenged claims is on or before March 30, 2017.

Based on his reading of the ‘271 Patent and experience, Professor Kazanzides concludes that the hypothetical person of ordinary skill in the art at the time of the relevant date (POSA) would be “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.

C. Claim Terms

On August 3, 2022, during the litigation pending in the District of Delaware, the patent owner asserted that “all of the claims terms ... should be given their plain and ordinary meaning as understood by one having ordinary skill in the art” and that “no court claim construction is necessary.” Exhibit 1014, Email.

1. “three-dimensional (3D) data” and “3D data”

The phrases “three-dimensional (3D) data” and “3D data” appear in each of the independent claims of the ‘271 Patent. The ‘271 Patent states that “[c]onventional medical imaging systems may create three-dimensional (3D) data for a patient and then display that 3D data as an image or images on a computer display.” Ex. 1001, 2:49-51. Prof. Kazantzides concluded that “the person of ordinary skill in the art would understand ‘three-dimensional (3D) data’ and ‘3D data’ to be synonymous because the ‘271 Patent uses those terms synonymously.” Ex. 1012, ¶ 29.

The ‘271 Patent states that “3D data of the patient 106 may include, but is not limited to, MRI images, Computerized Tomography (CT) scan images, X-ray images, Positron Emission Tomography (PET) images, ultrasound images, fluorescence images, Infrared Thermography (IRT) images, and Single-Photon Emission Computer Tomography (SPECT) scan image, or some combination thereof.” Ex. 1001, 11:45-51. The patent further states that “Any of these images

may be in the form of still images or video images.” *Id.*, 11:51-53.

Review of the parent application sheds some light on the applicants’ interpretation of claim terms as of the assumed priority date. Like Claim 1 of the ‘271 Patent, Claim 1 of the original parent application (Application No. 15/474,702, filed on March 30, 2017) introduces “three-dimensional (3D) data” in the preamble. Ex. 1004, Excerpts of Application No. 15/474,702 File History, 136. Like Claim 1 of the ‘271 Patent, Claim 1 of the original parent application is directed to “[a] method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data.” Ex. 1004, 136. Also like Claim 1 of the ‘271 Patent, Claim 1 of the original parent application includes recites the step of “identifying 3D data for a patient, the 3D data including an outer layer of the patient and multiple inner layers of the patent.” Ex. 1004, 136.

Claim 6 of the original parent application (Application No. 15/474,702) depends directly from original parent application Claim 1. Ex. 1004, 37. Original parent application Claim 6 recites “the 3D data includes one or more of MRI images, Computerized Tomography (CT) scan images, X-ray images, Positron Emission Tomography (PET) images, ultrasound images, fluorescence images, Infrared Thermography (IRT) images, and Single-Photon Emission Computer Tomography (SPECT) scan image.” Ex. 1004, 37. Based on the foregoing, Professor Kazazides concluded that “the person of ordinary skill in the art would

understand that ‘3D data’ may be one or more of any of the foregoing types of images.” Ex. 1012, ¶ 32.

2. “virtual 3D shape”

The phrase “virtual 3D shape” appears only in Claim 1 and its dependent claims. Figure 1 illustrates element 116, which the specification describes as “a virtual spatial difference box.” Ex. 1001, FIG. 1 and 3:63-4:7. The ‘271 Patent states that element 116 is “generated by the AR headset 108 and only viewable by the user 104 through the AR headset 108.” Ex. 1001, 4:1-7. Further, “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. For example, the projected bones 106b of the patient 106 may be confined within the virtual spatial difference box 116 in FIG. 1.” *Id.*, 6:5-11. But the ‘271 Patent also discloses that “the AR headset 108 [may] analyz[e] the 3D data in order to determine the size and shape of the outer layer of the patient [and] may ... generat[e] a point cloud of the outer layer that represents the size and shape of the outer layer. For example, where the outer layer is represented by triangles or other polygonal shapes, the point cloud may include some or all of the vertices of the polygonal shapes.” *Id.*, 12:39-48. Accordingly, the ‘271 Patent discloses virtual 3D shapes as simple as a box and as complex as the outer layer of the patient, all of which would confine a projected inner layer of

the patient. Ex. 1012, ¶ 33.

3. **“being having”**

The term “being having” appears only in Claim 11 within the larger phrase “the projected inner layer of the patient from the 3D data *being having* the altered color gradient.” To a person of ordinary skill in the art, the term “being having” appears to be an error. “Being having” is not a term of art. “Being having” is not plain English. For purposes of his IPR only, however, Professor Kazanzides interprets the term “being having” as “being or having.” Ex. 1012, ¶ 34.

4. **Summary Table of Claim Interpretation**

Claim Term	Proposed Construction
“three-dimensional (3D) data” / “3D data”	“one or more of MRI images, Computerized Tomography (CT) scan images, X-ray images, Positron Emission Tomography (PET) images, ultrasound images, fluorescence images, Infrared Thermography (IRT) images, and Single-Photon Emission Computer Tomography (SPECT) scan image”
“virtual 3D shape”	encompasses virtual 3D shapes as simple as a box and as complex as the outer layer of a patient
“being having”	“being or having”

IV. STANDARDS AND CONTEXT FOR EVALUATION OF PATENTABILITY CHALLENGES

A. The Legal Standards for Anticipation and Obviousness

Medivis challenges Claims 1-6 and 11-20 as anticipated under 35 U.S.C. § 102, obvious under U.S.C. § 103, or both. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). A claim is obvious when the differences between the claim and the prior art are such that the claim as a whole would have been obvious at the relevant time to a person having ordinary skill in the art to which claim pertains. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

In *KSR*, the Supreme Court confirmed the framework for analyzing obviousness originally stated in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). Specifically, “[u]nder §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be determined; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined.” *KSR*, 550 U.S. at 406, quoting *Graham*, 383 U.S. at 17-18.

B. The Scope and Content of the Prior Art

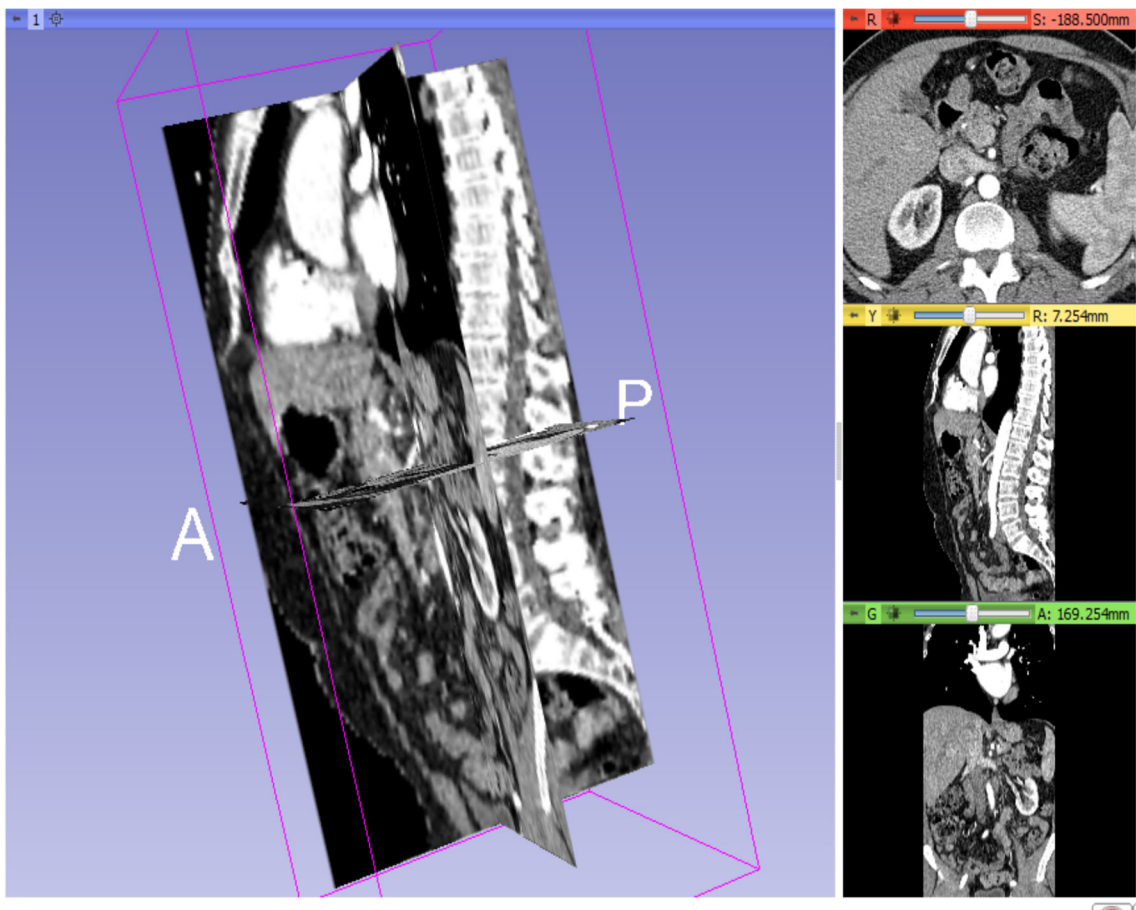
Neither the general concepts disclosed, nor the specific limitations claimed, in the '271 Patent are new. Ex. 1012, ¶ 39.

The '271 Patent itself states that “[c]onventional medical imagining systems may create three-dimensional (3D) data for a patient and then display that 3D data as an image or images on a computer display.” Ex. 1001, 2:49-51 (emphasis added). By characterizing such medical imaging systems as “[c]onventional,” the '271 Patent itself concedes that creation of 3D data for a patient and displaying images based on that data was known at the relevant time. According to Professor Kazanzides, as of March 30, 2017 (the assumed priority date), the creation of 3D data and display of medical images based on that data were known in the art. Ex. 1012, ¶ 40.

By the relevant date, much was known in the art about loading 3D data and visualizing images from such data. For example, by 2014, the 3D Slicer open-source software platform for segmentation, registration, and 3D visualization of medical imaging data was on its fourth major revision. Ex. 1007, S. Pujol, Ph.D. et al., 3D Visualization of DICOM Images for Radiological Applications (Surgical Planning Laboratory, Brigham and Women’s Hospital, Boston, Mass. 2014) (“3D Visualization”), Slide 6-7. The 3D Slicer platform was designed to be easy to use for clinical researchers and easy to extend for programmers. Ex. 1007, Slide 8.

Ex. 1012, ¶ 41. A POSA would have been familiar with the 3D Slicer application and its ability to load and display data for a user. *Id.*

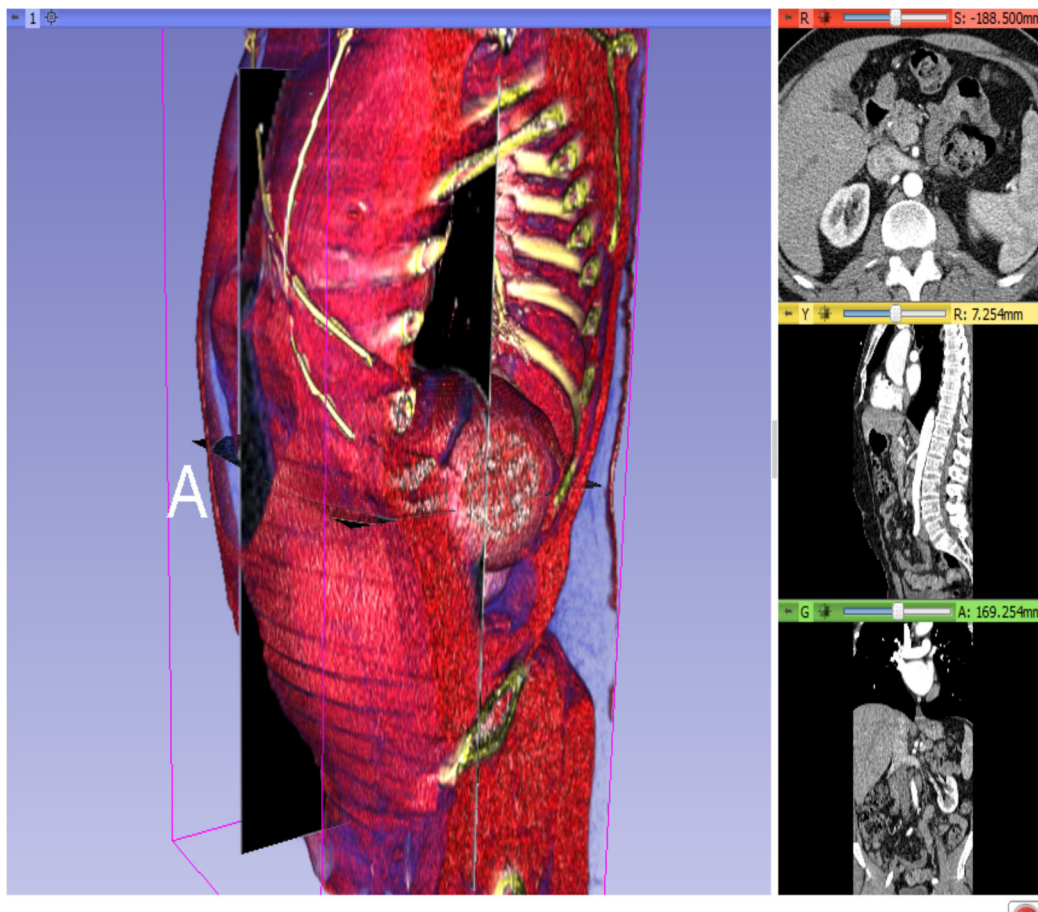
By the relevant date, a POSA would have known how to display 3D data as individual 2D slices of inner layers of a patient's anatomy. For example, in 2014, the Surgical Planning Laboratory ("SPL") published examples of 3D data displayed as individual 2D slices of inner layers of a patient's anatomy:



Ex. 1007, Slide 39. As illustrated by SPL's exemplary image above, it was also known in the art how to display individual 2D slices of inner layers of a patient's anatomy from 3D data where the inner layers are confined within the boundaries of

a rectangular parallelepiped (hereinafter “rectangular box”). The virtual rectangular box is displayed with magenta lines. Ex. 1012, ¶ 42.

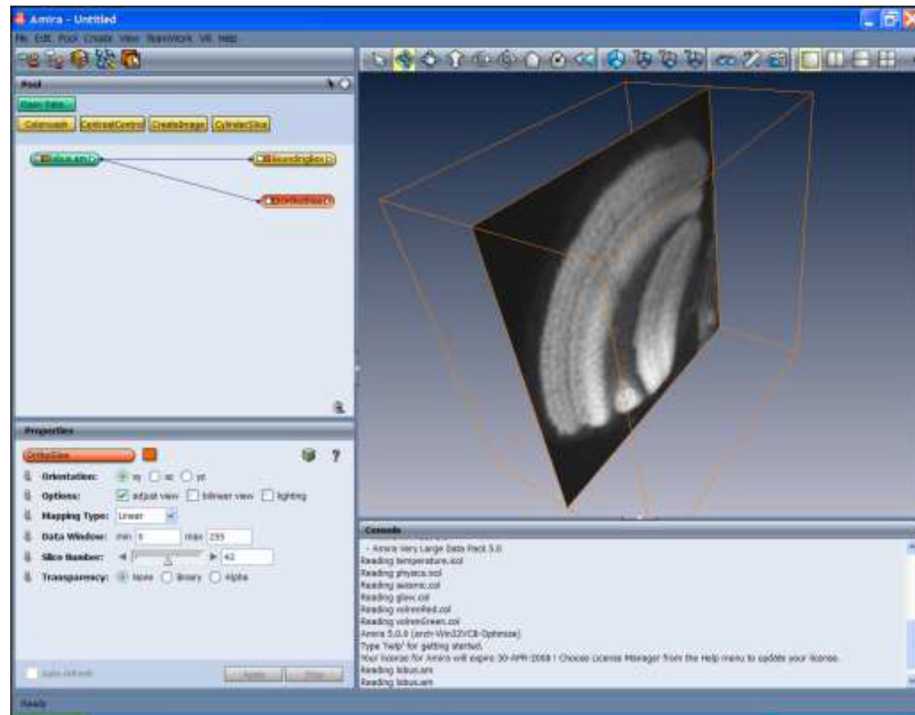
By the relevant date, a POSA would also have known how to display 3D data as a 3D model of inner layers of a patient’s anatomy. For example, in 2014, the SPL published examples of 3D data displayed as a 3D model of inner layers of a patient’s anatomy:



Ex. 1007, Slide 42. The virtual rectangular box is represented by magenta lines in the above image. As such, a POSA would have known how to display a 3D model

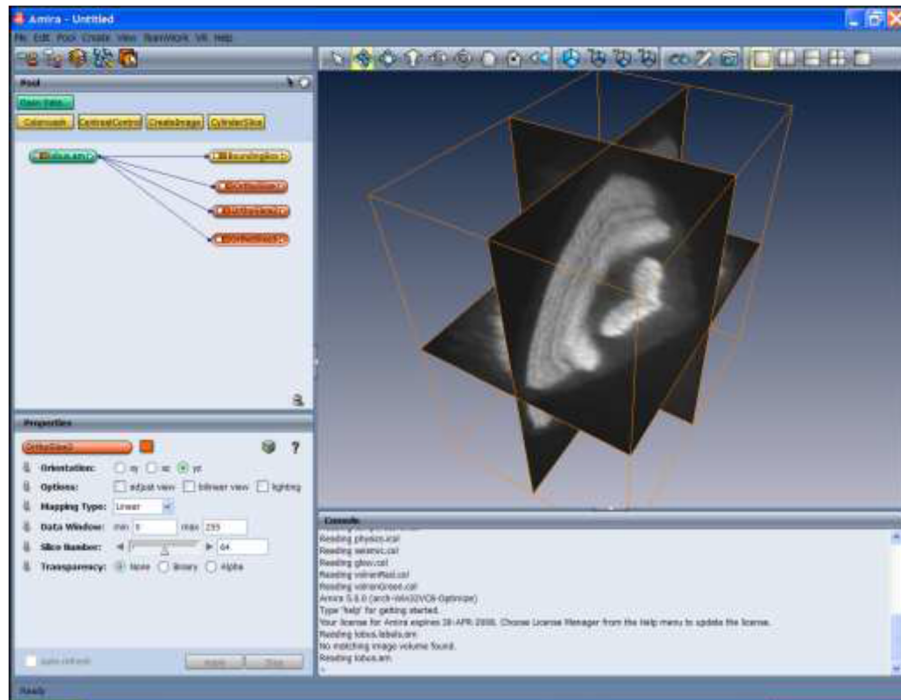
of inner layers of a patient's anatomy from 3D data where the inner layers are confined within the boundaries of a rectangular box. Ex. 1012, ¶ 43.

The 3D Slicer software platform described in *3D Visualization* was not the only platform that had been developed to load 3D data and visualize images in two and three dimensions from such medical imaging data. Ex. 1012, ¶ 44. For example, the 2009 Amira 5 User's Guide ("*Amira*") illustrates further examples of the display of a visual object from 3D data confined within a virtual box. *Amira* discloses that, in the relevant software platform, "the bounding box of an object is the smallest rectangular, axis-aligned volume of 3D space that encompasses the object." Ex. 1005, *Amira*, 28. *Amira* discloses that, by "[c]hoosing the entry called BoudingBox[,] a new BoudingBox module is created and is automatically connected to the data object." Ex. 1005, *Amira*, 22. *Amira* discloses that its "OrthoSlice module is able to extract arbitrary orthogonal slices from a regular 3D scalar field of image volume." Ex. 1005, *Amira*, 25. *Amira* also illustrates this capability:



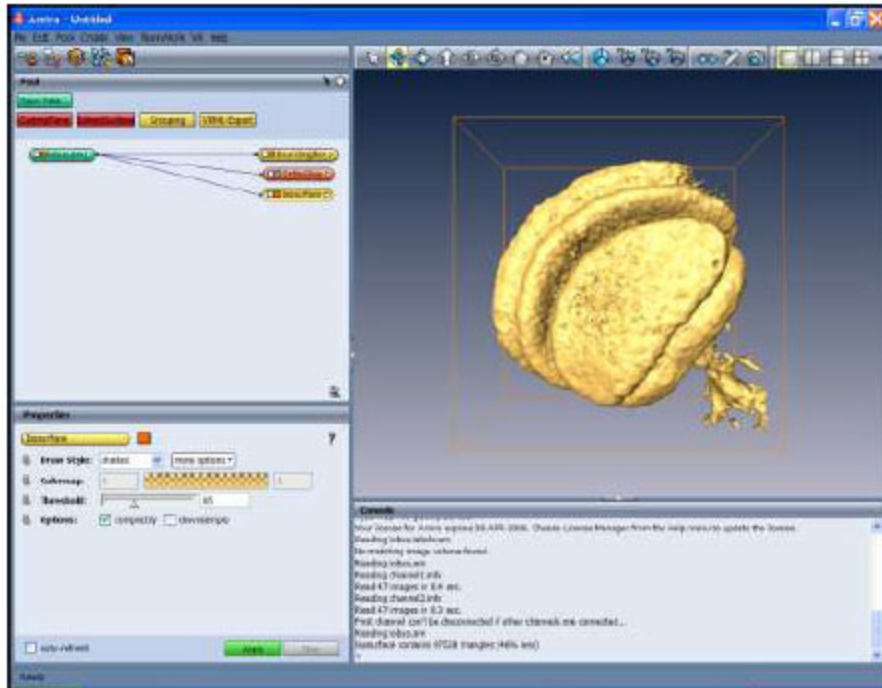
Ex. 1005, *Amira*, 25 (Figure 2.6). The virtual bounding box is illustrated above as yellow lines that confine a slice of image data. The foregoing figure illustrates a two dimensional slice of image data of a fruit fly's brain. Ex. 1005, *Amira*, 20, 25; see also Ex. 1012, ¶ 45.

Amira also discloses that it enables visualization of 3D images bound within a virtual shape. Ex. 1005, 32. *Amira* also illustrates this capability, as seen in the figure below.



Ex. 1005, *Amira*, 34 (Figure 2.12). As seen above, the figure illustrates the simultaneous display of multiple slices of image data within a bounding box.

Further, as seen below, *Amira* illustrates the display of a 3D model, generated from a 3D data set, in a bounding box/virtual 3D shape.



Ex. 1005, *Amira*, 36 (Figure 2.14). In the figures above, each of the virtual bounding boxes are displayed as yellow lines. Ex. 1012, ¶ 46.

The prior art also disclosed that a box bounding an image could be either displayed or hidden. For example, *Amira* discloses that “[e]ach display module has a viewer toggle by which you can switch off the display.” Ex. 1005, *Amira*, 25. *Amira* discloses that a user may “[d]eactivate and activate the display of the ... BoundingBox module using the viewer toggle.” Ex. 1005, *Amira*, 25. Thus, a POSA would have known how to display or hide lines of virtual 3D shape. Ex. 1012, ¶ 47.

By the relevant date, a POSA would have known how to reposition the display of an image confined within a virtual bounding box. For example, *Amira*

discloses: “The 3D viewer lets you look at the model from different positions. If you click on the Trackball button in the viewer toolbar, moving the mouse inside the viewer window with the left mouse button pressed lets you rotate the object.” Ex. 1005, *Amira*, 23-24. *See also* Ex. 1012, ¶ 48. Therefore, a POSA would have known that virtual 3D shapes may be configured to be controlled to reposition 2D and 3D images of a projected inner layer of a patient.

As evident from the foregoing exemplary pictures, the concept of adjusting the color of original 3D data to display images with better visibility was known in the art at the relevant time. Ex. 1012, ¶ 49.

Moreover, the concept of adjusting the color of a virtual overlay image to improve visibility was known in the art at the relevant time. For example, *Amira* discloses that “[t]he process of image fusion consists of combining relevant information from two or more images into a single image using different color mappings.” Ex. 1005, *Amira*, 102. According to *Amira*, image fusion is “very relevant especially in medical science” *Id.*, 102. To achieve the best visibility of an overlay image, *Amira* recommended that users “experiment with changing the color maps.” *Id.*, 103. *Amira* directed users to “[c]hange the minimum and maximum values of the Overlay color map.” *Id.*, 102-103. “To do so, select the 3D viewer to activate it, slide the colormap bar to the left and the right or change the upper and lower limits.” *Id.*, 103. *Amira* explained “[y]ou can do the same for

the 2D viewers.” *Id.*, 103. While *Amira*’s 2009 disclosure applied to a fusion of two virtual images, according to Professor Kazanzides, a POSA would have appreciated that color adjustment technology applied to improving visibility of a virtual image overlaid in other contexts. Ex. 1012, ¶ 49.

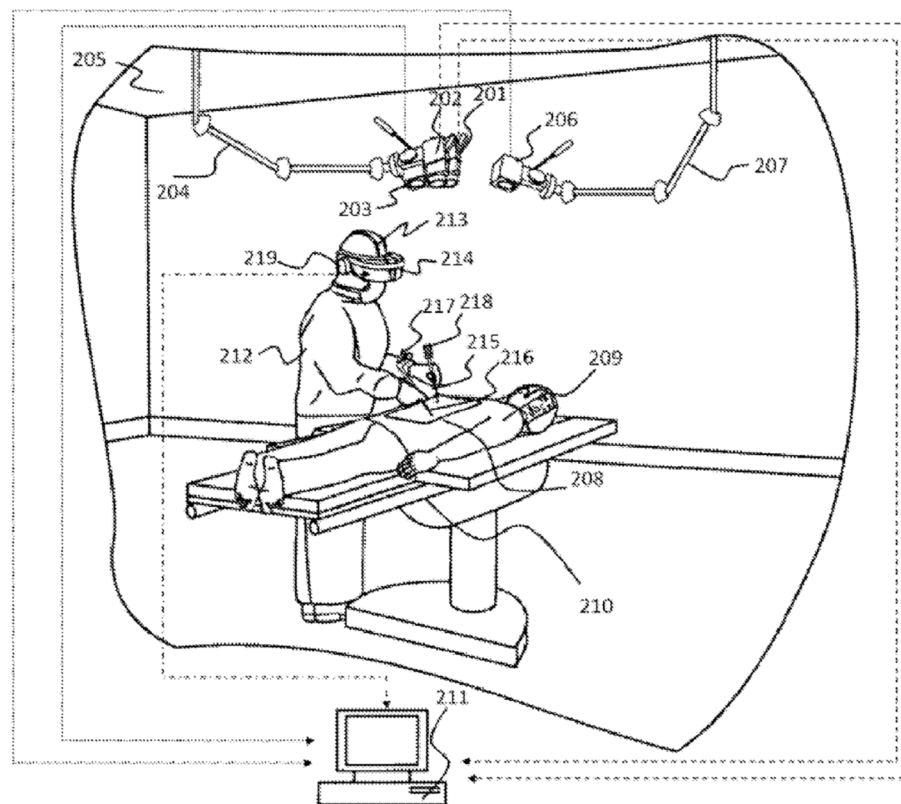
In addition to sophisticated tools for loading 3D data and visualizing and adjusting virtual medical images from such data, by the relevant date, a POSA would have known about augmented reality systems.. According to the “Background” of the ‘271 Patent, “[a]ugmented reality (AR) systems generally take a user’s live view with computer-generated virtual elements such as video, sound, or graphics.” Ex. 1001, ‘271 Patent, 1:17-20. “As a result, AR systems functions to enhance a user’s current perception of reality.” *Id.*, 1:20-21. *See also* Ex. 1012, ¶ 50. A POSA thus would have appreciated that AR systems are designed to combine virtual data with a view of the real world.

By the relevant date, POSAs had been developing applications of augmented reality headsets to medical procedures for years. As of 2012, “[t]he majority of related research ha[d] focused on augmented reality visualization with HMDs (i.e., head mounted displays), usually adopting video see-through designs. Ex. 1011, E. Azimi et al., “Augmented Reality Goggles with an Integrated Tracking System for Navigations in Neurosurgery,” IEEE VIRTUAL REALITY 123-124, 123 (IEEE 2012) (“AR Goggle for Neurosurgery”). Accelerating this development was the

commercial release of the Google GLASS HMD in 2013 and then the Microsoft HOLOLENS HMD in 2016. Ex. 1012, ¶ 51.

For example, a 2016 publication, US Patent Application Publication No. US 2016/0191887 A1 to Casas (“*Casas*”) discloses “a real-time surgery method and apparatus for displaying a stereoscopic augmented view of a patient from a ... viewpoint of the surgeon” Ex. 1006, Abstract. *Casas* discloses “the surgeon ... sees a graphical representation of the preoperative or intraoperative images blended ... through a see through display.” *Id.*, Abstract (emphasis added).

Figure 2 of *Casas* illustrates the method and apparatus in an operating room:



Ex. 1006, *Casas*, FIG. 2. *Casas* explains that, “[t]o the surgeon 212, the internal structures of the patient 209 appear directly superimposed on the target portion of the patient 208” *Id.*, [0038].

Professor Kazanzides has reviewed *Casas* and agrees that *Casas* discloses an AR headset superimposing depictions of a patient’s internal structures from image data over actual views of the patient. Ex. 1012, ¶ 52.

Casas also demonstrates that, by the relevant time, color adjustment technology had been applied to AR headsets that project an overlay image onto a surgeon’s actual view of a patient. *Casas* explains that, “[t]o the surgeon 212, the internal structures of the patient 209 appear directly superimposed on the target portion of the patient 208 with the selected transparency.” Ex. 1006, *Casas*, [0038] (emphasis added). *Casas* discloses the use of “any of the available methods for refining the volume rendering.” *Id.*, [0075]. For example, *Casas* discloses that “[t]he surgeon 128 or other users can selectively enhance structures, color or annotate them” *Id.*, [0076]. *Casas* discloses that image rendering algorithms are applied to the 3D data to detect structures, which “are then displayed ... through image processing 124 as determined by the surgeon 128 or other users through available user interface means before 130 or during surgery 132, e.g. in enhanced or different colors (e.g. bright red for arteries), to alert the surgeon 128 of their existence and position.” Ex. 1006, *Casas*, [00153].

According to Professor Kazanzides, based at least on *Casas*, a POSA would have known that color adjustment technology had been applied to AR headsets that project an overlay image onto a surgeon's actual view of a patient. Ex. 1012, ¶ 57.

The prosecution history of the '271 Patent also provides evidence of the state of the art. With respect to Claims 1-6, the office action dated 8/06/2020 states that "Maier-Hein (US 2013/0245461) discloses see-through augmented reality using registration of a surgical image with an actual view of the patient." Ex. 1002, 36. It states: "Hannaford (US Patent 9,538,962) discloses projection of 4D[sic] [3D] images onto a patient through a headset." Ex. 1002, 36. It further states: "Saget (US Patent 10,052,170) discloses projection onto real actual views of the patient using a grid." Ex. 1002, 37. As the office action recognizes, and as discussed above, "see-through augmented reality using registration of a surgical image with an actual view of the patient;" "projection of 4D [sic][3D] images onto a patient through a headset;" and "projection onto real actual views of the patient using a grid" were all known at the relevant time. Ex. 1012, ¶ 53.

With respect to Claims 11-20, the office action dated 8/06/2020 states that "Saget discloses projection onto real actual views of the patient" Ex. 1002, 37. It states: "Guo (US 2018/0020992) discloses a 3D shape and altered color gradients" Ex. 1002, 37. As the office action recognizes, and as discussed

above, “projection onto real actual views of the patient;” and “a 3D shape and altered color gradients” were both known at the relevant time. Ex. 1012, ¶ 55.

The above prior art shows the state of the art as of March 30, 2017, the date assumed to be the relevant date. This state of the art shows that there was nothing particularly innovative or noteworthy about the methods of augmenting actual views of a patient with 3D data claimed in the ‘271 Patent. All of the features of the claimed systems had been known, often in the same configurations and with the same elements as claimed in the patent. Professor Kazanzides relied on this state of the art to inform his understanding and analysis of the ‘271 Patent and the prior art references discussed below. Professor Kazanzides concludes that a POSA—who would, by definition, be familiar with this state of the art—would understand that the challenged claims of the ‘271 Patent were anticipated by the prior art or, at least, were obvious in view of the prior art. Ex. 1012, ¶ 59.

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Summary of Grounds for Challenging Claims

Medivis challenges Claims 1-6 and 11-20 of the ‘271 Patent. Those claims are challenged based on five references. None of five references are cited on the face of the ‘271 Patent so the Patent Office did not consider those references before it issued the ‘271 Patent.

International Publication No. WO 2015/164402 A1 to Doo (hereinafter “*Doo*”) was published on October 29, 2015. Ex. 1008, *Doo*, title page. *Doo* is prior art because its publication date predates the earliest priority date recited in the ‘271 Patent, March 30, 2017.

In 2009, Visual Imaging published the Amira 5 User’s Guide. Ex. 1005, Excerpt of Amira 5 User’s Guide title through Chapter 2 (Visual Imaging 2009) (“*Amira*”). *Amira* is prior art because its publication date predates the earliest priority date recited in the ‘271 Patent.

In 2015, an article by X. Chen and others entitled “Development of a Surgical Navigation System Based On Augmented Reality Using an Optical See-Through Head-Mounted Display,” was published in volume 55 of the JOURNAL OF BIOMEDICAL INFORMATICS. Ex. 1009, X. Chen et al., “Development of a Surgical Navigation System Based On Augmented Reality Using an Optical See-Through

Head-Mounted Display,” 55 JOURNAL OF BIOMEDICAL INFORMATICS 124-131 (2015) (“*Chen*”). *Chen* is prior art because its publication date predates the earliest priority date recited in the ‘271 Patent.

In 2014, S. Pujol and others published a tutorial on 3D Slicer software capabilities based on exemplary data sets. See Ex. 1007, S. Pujol, Ph.D. et al., 3D Visualization of DICOM Images for Radiological Applications (Surgical Planning Laboratory, Brigham and Women’s Hospital, Boston, Massachusetts 2014) (hereinafter “*3D Visualization*”). *3D Visualization* is prior art because its publication date predates the earliest priority date recited in the ‘271 Patent.

In 2016, the 3D Slicer software included published documentation of the Main Application Graphical User Interface (GUI). See Ex. 1010, Main Application GUI for 3D Slicer <<https://www.slicer.org/wiki/Documentation/4.6/Slicer/Application/MainApplicationGUI>> (last edited 7 November 2016) (“*3D Slicer*”). *3D Slicer* is prior art because its publication date predates the earliest priority date recited in the ‘271 Patent.

For reasons explained in detail below, Claims 1, 5, and 6 are anticipated by *Doo*. Further, Claims 1-6 and 11-20 are obvious over *Doo* in view of *Amira*. Finally, Claims 1-6 and 11-20 are also obvious over *Chen* in view of *3D Visualization* and *3D Slicer*.

Grounds	Claims
1. Anticipated by <i>Doo</i> under §102	Claims 1, 5 and 6
2- Obvious over <i>Doo</i> in view of <i>Amira</i> under §103	Claims 1-6 and 11-20
3- Obvious over <i>Chen</i> in view of <i>3D Visualization</i> and <i>3D Slicer</i> under §103	Claims 1-6 and 11-20

B. Ground 1: Anticipation of Claims 1, 5, and 6 by *Doo*

For reasons discussed in detail below, Professor Kazanzides concludes that a POSA would have understood that Claims 1, 5, and 6 are anticipated by *Doo*. Ex. 1012, ¶¶ 62-79.

1. *Doo*'s Disclosure with respect to Independent Claim 1

- (a) “A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data”
(Preamble of Claims 1, 7, and 11)

Based on his review, Professor Kazanzides concludes that a POSA would understand that *Doo* discloses a “method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data.” Ex. 1012, ¶ 63-64.

For example, Professor Kazanzides relied on the following disclosures in *Doo*. *Doo* discloses “[a]n intra-operative medical image viewing system [that] can allow a surgeon to maintain a viewing perspective on the patient while calling up

visual images on the fly.” Ex. 1008, Abstract. *Doo* discloses that “[a] display is worn by the surgeon ... during surgery.” Ex. 1008, *Doo*, Abstract. *Doo* discloses that “[t]he display is selectively transparent, and exhibits to the surgeon an image derived from the image file.” Ex. 1008, Abstract. Figure 2 illustrates *Doo*’s method and system in a surgical environment:

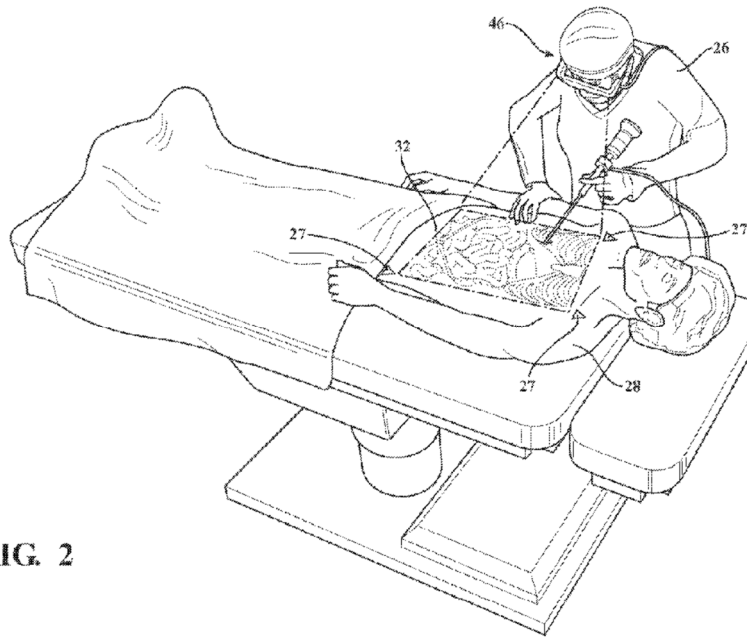


FIG. 2

Ex. 1008, FIG. 2. And *Doo* discloses that “The image can include portions indicating a three-dimensional nature of the anatomical feature of the patient 28. The image control unit 38 can be configured to modify an image in response to the image control signal in any one of a plurality of different two-dimensional, 2-1/2-dimensional, or three-dimensional modalities.” Ex. 1008, *Doo*, [0073].

- (b) “identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient” (“identifying” step of Claims 1, 7, and 11)

Based on his review, Professor Kazanzides concludes that, to a POSA, *Doo* discloses the step of “identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient.” Ex. 1012, ¶¶ 65-68.

For example, Professor Kazanzides relied on the following disclosures in *Doo*. *Doo* discloses “the system 34 can utilize images generated by radiography, computer-aided tomography, positron emission tomography, single-phase emission tomography, magnetic resonance imaging (MRI), ultrasound, elastography, photo-acoustic imaging, thermography, echocardiography, functional near-infrared, and spectroscopy.” Ex. 1008, *Doo*, [0040]. A person of ordinary skill in the art would understand that *Doo*’s disclosed “images generated by radiography, computer-aided tomography, positron emission tomography, single-phase emission tomography, magnetic resonance imaging (MRI), ultrasound, elastography, photo-acoustic imaging, thermography, echocardiography, functional near-infrared, and spectroscopy” would include an outer layer of the patient and multiple inner layers of the patient.

“[E]ach image source 44 can be a collection (or archive or database) of previously-created digital images” *Id.*, [0040]. *Doo* discloses “[a] digital

image source has a least one image file representative of an anatomical or pathological feature of a patient.” Ex. 1008, Abstract.

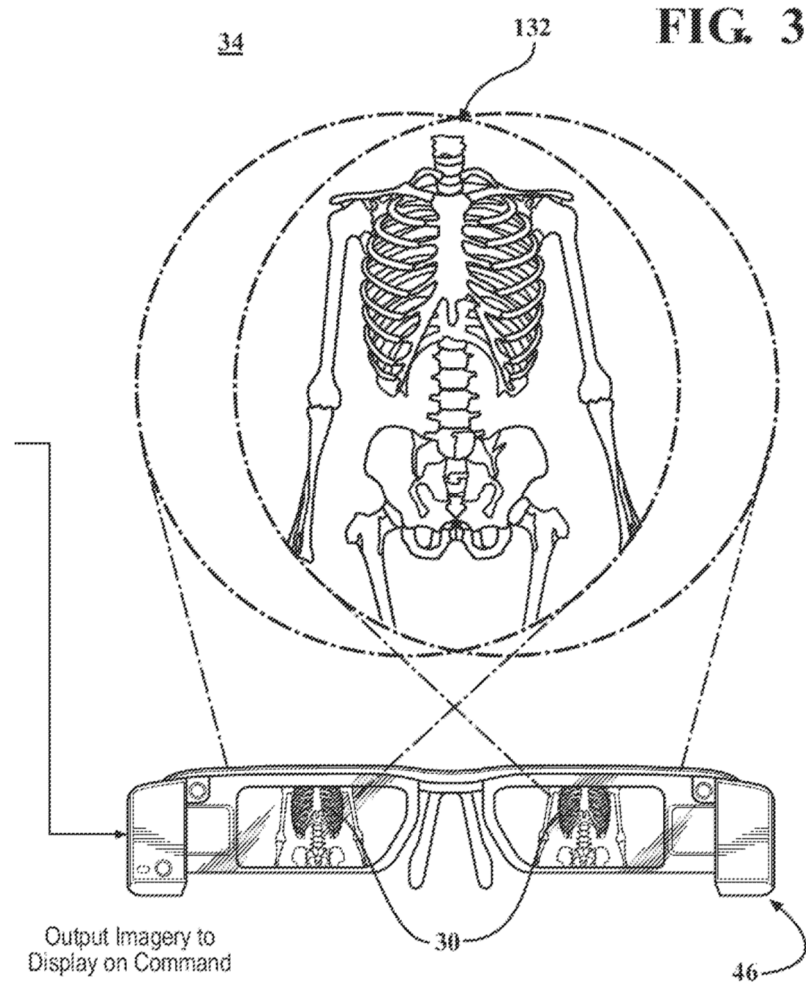
Doo discloses “[a]n image control unit retrieves the image file from the image source and controls the display so that at least a portion of the image depiction can be exhibited” *Id.*, Abstract. *Doo* discloses “[a] plurality of peripheral devices are each configured to receive an image control input from the surgeon and, in response, generate an image control signal.” *Id.*, Abstract.

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

Based on his review, Professor Kazanzides concludes that, to a POSA, *Doo* discloses “displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient.” Ex. 1012, ¶¶ 69-73.

For example, Professor Kazanzides relied on the following disclosures in *Doo*. *Doo* discloses that “[a] display is worn by the surgeon ... during surgery.” Ex. 1008, *Doo*, Abstract. *Doo* discloses that “[t]he display 30 can be can be a goggle-type system worn by the surgeon 26.” Ex. 1008, [0038]. *Doo* discloses that, “[a]s but one example, an Epson® Moverio® BT-200 can be utilized as the display 30.” *Id.*, [0038]. *Doo* discloses “[t]he display 30 can be a component of a

head mountable unit 46” *Id.*, [0044]. *Doo*’s Figure 3 illustrates an exemplary head mountable unit 46:



Id., Excerpt of FIG. 3.

Doo discloses that “[t]he display 30 can be selectively and/or variably transparent and configured to exhibit at least one medical image 32 to the surgeon 26 that is overlaid on the patient” *Id.*, [0038]. *Doo* discloses that “[t]he image 32 can be ... perceived by the surgeon 26, overlaid on the patient 28.” *Id.*, [0039].

Doo discloses that “the image 32 may appear (to the surgeon 26) to be ... projected inside the patient’s body.” *Id.*, [0039].

Doo discloses that the “intra-operative medical image viewing system 34 [can] maintain[] the registration of an image to an actual anatomical feature of the patient 28 despite head movement by the surgeon 26.” *Id.*, [0037]. According to *Doo*, “the image can be overlaid on the patient’s actual anatomical feature and ... sized to match the actual anatomical feature, thus creating the visual impression of a ‘true registration’ and a form of augmented reality.” *Id.*, [0037].

As illustrated by Figures 2 and 3, *Doo* discloses that the projected display may be inner layers of the patient from the 3D data. Ex. 1008, *Doo*, FIGS. 2 and 3. As illustrated by Figures 2, 6, *Doo* discloses the projected display of internal organs, such as bones and a heart, of a patient from the 3D data. *Id.*, FIGS. 2, 6.

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

Based on his review, Professor Kazanzides further concluded that, to a POSA, *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, ¶¶ 74-77.

For example, Professor Kazanzides relied on the following disclosures in *Doo*. *Doo*’s Figure 11 illustrates “a series of three-dimensional tomographic slices of an anatomical feature of a patient.” Ex. 1008, [0026]. *Doo* discloses that “a

fusion of several tomographic slices can be stitched together to create a 3D image.” *Id.*, [0078].

Doo’s Figure 7 illustrate the “application of a ... modality, sometimes referred to as ‘false 3D’ or ‘2.5D’ in which a two-dimensional image can be wrapped around a three dimensional structure, namely the body surface of the patient 28.” Ex. 1008, *Doo*, [0075], FIG. 7. “The image 432 displayed to the surgeon 26 can be rendered by the system as having been wrapped over the chest of the patient 28 yielding the appearance of a three-dimensional image.” Ex. 1008, *Doo*, [0075]. “Figures 8 and 9 further illustrate the concept of image wrapping as introduced in ... Figure 7.” *Id.*, [0075]. “Figure 8 is a perspective view of a two-dimensional image 532 in a planar configuration.” *Id.*, [0075]. “The arrow referenced at 92 indicates the surgeon’s viewing perspective.” Figure 9 is a perspective view of the two-dimensional image 532 shown in Figure 8 but rendered in a warped configuration to mimic the surface curvature of the patient’s body.” *Id.*, [0075]. “In Figure 9, the image 532 has been wrapped around the axis 94.” As illustrated in *Doo*’s Figure 7, the resulting image of the projected inner layer of the patient from the 3D data is confined within the volume of the virtual 3D shape illustrated in Figure 9. *Doo*’s Figure 7, for example, illustrates the projection of bones of the patient from the 3D data being confined within the volume of the virtual 3D shape illustrated in Figure 9. Ex. 1012, ¶ 75.

Additionally, *Doo*'s Figure 6 illustrates the projection of a virtual heart into a patient. Ex. 1008, *Doo*, FIG. 6. At the relevant time, medical imaging displayed images of a patient's inner layers confined within a virtual 3D shape, which may or may not be displayed. For example, *Doo*'s Figure 11 "is a series of three-dimensional tomographic slices of an anatomical feature of a patient." Ex. 1008, *Doo*, [0026], FIG. 11. "A fusion of several tomographic slices can be stitched together to create a 3D image." Ex. 1008, [0078]. A POSA would understand that *Doo*'s Figure 11 illustrates a collection of medical images forming a virtual 3D shape. Ex. 1012, ¶ 76.

The virtual 3D shape illustrated in *Doo*'s Figure 11 is a virtual box including a top side, a bottom side, a left side, a right side, a front side, and a back side. The virtual 3D shape is illustrated, in part, by dashed lines. Each of the inner layers illustrated in *Doo*'s Figure 11 is confined within the virtual 3D shape. Accordingly, Professor Kazantzides concluded that a person of ordinary skill in the art at the relevant time would understand that any projected inner layer of a patient would be confined within a volume of a virtual 3D shape, whether the virtual 3D shape were displayed or not. Ex. 1012, ¶¶ 76-77.

2. **Doo's Disclosure with respect to Dependent Claims 5 and 6**

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

Based on his review, Professor Kazanzides concluded that a POSA 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, ¶ 78. The discussion above of *Doo*'s disclosure as it relates to Claim 1's "confined" limitation is incorporated by reference. As explained above, the dashed lines of *Doo*'s Figure 9 define a virtual 3D shape. Ex. 1008, FIG. 9. *Doo*'s Figure 7 illustrates the projection of inner layers of a patient confined within the volume of a virtual 3D shape, which shape is similar to that illustrated by *Doo*'s Figure 9. *Id.*, FIG. 7. *Doo*'s Figure 7 illustrates the display via an AR headset as a projection over a surgeon's actual view of a patient. The dashed lines in *Doo*'s Figure 7, for example, are hidden because they do not seem to be visible to the surgeon. Accordingly, the POSA would conclude that the lines of the virtual 3D shape illustrated in *Doo*'s Figure 9 and 7, for example, are hidden.

Moreover, as Professor Kazanzides explains above, the technique of hiding or showing the lines of a virtual 3D shape was well known. Ex. 1012, ¶¶ 42-47. Accordingly, reading *Doo*'s disclosure in view of what was known in the art, the POSA would understand that, to the extent that *Doo* does not directly disclose

hiding the lines (although it does, as discussed above), *Doo* at least inherently discloses that the lines of the virtual 3D shape illustrated in Figures 9 and 7 could be hidden. Ex. 1008, [0026], [0075].

- (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.”

Based on his review, Professor Kazanzides concluded that a POSA would understand that *Doo* discloses 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 recited in Claim 1. Ex. 1012, ¶ 79. For example, Professor Kazanzides relied on the following disclosures in *Doo*. *Doo* discloses that “[s]ystem programming can be stored in and accessed from memory 72.” Ex. 1008, [0063]. “Any combination of one or more computer-usable or computer-readable media may be utilized in various embodiments of the invention. For example, a computer-readable medium may include one or more of a portable computer diskette, a hard disk, a random access memory (RAM) device, a read-only memory (ROM) device, an erasable programmable read-only memory (EPROM or Flash memory) device, a portable compact disc read-only memory (CDROM), an optical storage device, and a magnetic storage device. Computer program code for carrying out operations of this invention may be written in any combination of one or more programming languages.” *Id.*, [0063].

C. Ground 2: Obviousness of Claims 1-6 and 11-20 Over *Doo* in view of *Amira*

The discussion above of *Doo*'s disclosure as it relates to the challenged claims is incorporated by reference.

1. Motive to Combine *Doo* and *Amira*

For reasons discussed in further detail below, Professor Kazanzides concludes that Claims 1-6 and 11-20 would have been obvious over *Doo* in view of *Amira* at the relevant time to a POSA. Ex. 1012, ¶¶ 80-103.

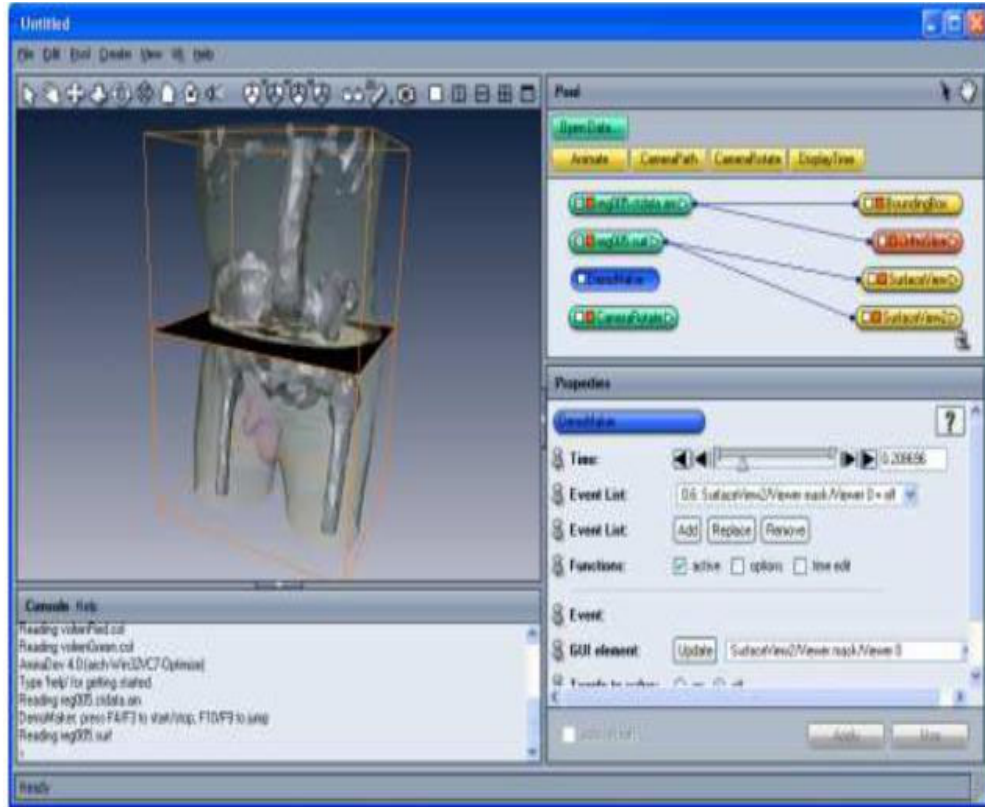
As Professor Kazanzides observes, “*Doo* “relates generally to generating, processing, transmitting or transiently displaying images in a medical environment” Ex. 1008, *Doo*, [0002]. “*Amira* is a 3D data visualization, analysis and modelling system [that] allows you to visualize scientific data sets from various application areas, e.g. medicine” Ex. 1005, *Amira*, 3. According to Professor Kazanzides, a person of ordinary skill in the art at the relevant time 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* (or any similar visualization software). Further, in Professor Kazanzides’s opinion, a POSA would have had a reasonable expectation of success in combining the intra-operative medical image viewing

system and method disclosed in *Doo* with the visualization technology disclosed in *Amira*. Ex. 1012, ¶ 103.

2. 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”

To the extent *Doo* is deemed not to disclose the “confined” limitation of Claim 1, for example, Professor Kazanzides concludes that Claim 1 would have been obvious over *Doo* in view of *Amira*. See Ex. 1012, ¶¶ 81-83. Professor Kazanzides relied, for example, on the following disclosures in *Amira*. Like *Doo*, *Amira* also “Operat[es] on 3D data.” Ex. 1005, *Amira*, 11 (section 1.2.7.2). According to Professor Kazanzides, *Amira* discloses “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.” For example, *Amira* illustrates a 3D bone model within both a D translucent skin model and a bounding box:



Ex. 1005, *Amira*, 79-80 (Section 2.11.6). *Amira*'s bounding box is indicated by yellow lines. *Amira*'s bounding box is a virtual box including a top side, a bottom side, a left side, a right side, a front side, and a back side. *Amira* illustrates the 3D bone model confined within both the virtual 3D translucent skin model and the virtual bounding box. Like *Amira*'s bounding box, *Amira*'s skin model also forms a virtual 3D shape that the bone model is confined within. Ex. 1012, ¶ 83.

- (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."

According to Professor Kazanzides, Claim 2 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*. Ex. 1012, ¶¶ 81, 84. With

respect to Claim 2, and as further discussed above, Professor Kazanzides relies for example on *Amira*'s disclosure that the virtual inner layers of a patient are confined within a bounding box that is a virtual box including a top side, a bottom side, a left side, a right side, a front side, and a back side. *Amira* discloses a virtual 3D shape that is a virtual box; including a top side, a bottom side, a left side, a right side, a front side, and a back side. See, e.g., Ex. 1005, *Amira*, 79-80 (Section 2.11.6). As discussed above, *Amira*'s bounding box confines all of its medical images based on 3D data.

- (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."

According to Professor Kazanzides, Claim 3 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*. Ex. 1012, ¶¶ 81, 85-86. With respect to Claim 3, Professor Kazanzides relies for example on *Amira*'s disclosure that "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." See Ex. 1012, ¶¶ 85-86.

In addition to *Doo*'s disclosure discussed previously, *Amira* discloses that the display of the BoundingBox can be deactivated or activated using the viewer toggle. Ex. 1005, *Amira*, 25. Further, like *Amira*'s bounding box, the user "can switch on the skin model" using a viewer toggle. *Id.*, 79-80 (Section 2.11.6).

Amira also 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. 1005, *Amira*, 24, 100. "The 3D viewer lets you look at the model from different positions. If you click on the Trackball button in the viewer toolbar, moving the mouse inside the viewer window with the left mouse button pressed lets you rotate the object." *Id.*, 24. Similarly, "the 3D Rotate icon [can be used to] rotate the object in the 3D viewer." *Id.*, 100. Accordingly, based on these disclosures, a POSA would understand that *Amira* discloses toggling on and off the lines of the 3D shape and that the 3D shape is configured to reposition 2D and 3D slices from the 3D data,

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

According to Professor Kazanzides, Claim 4 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*. Ex. 1012, ¶¶ 81, 87. With respect to Claim 4, Professor Kazanzides relies for example on *Amira*'s disclosure of displaying the lines of the virtual 3D shape. As discussed above, *Amira* illustrates the display of yellow lines of a virtual 3D shape in the form of the

bounding box. Ex. 1005, 25, 34, 36, 79-80 As discussed above, *Amira* also illustrates the display of a virtual 3D shape in the form of the skin model.

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

According to Professor Kazanzides, Claim 5 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*. Ex. 1012, ¶¶ 81, 88. With respect to Claim 5, and as discussed above, Professor Kazanzides relies for example on *Amira*’s disclosure that the display of yellow lines of a virtual 3D shape/bounding box can be deactivated using the viewer toggle. When they are deactivated they are not displayed (i.e. they are “hidden”). *Amira* also illustrates the bone model without the overlay skin model (another form of virtual 3D shape) and discloses that the user “can switch on the skin model” using a viewer toggle. Ex. 1005, *Amira*, 77 (figure without overlay skin model), 79-80 (Section 2.11.6). As such, according to Professor Kazanzides, a POSA would conclude that *Amira* discloses toggling the lines off such that they are hidden. Ex. 1012, ¶ 88.

- (f) 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”

According to Professor Kazanzides, Claim 6 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*. Ex. 1012, ¶¶ 81, 89. With respect to Claim 6, Professor Kazanzides relies for example on, *Doo*’s disclosure

that 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. Ex. 1012, ¶ 89; *see also* Ex. 1008, [0063].

3. **Disclosure with Respect to Independent Claim 11**

According to Professor Kazanzides, Claim 11 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*. Ex. 1012, ¶¶ 81, 90. The discussion of the prior art disclosure as it relates to the challenged claims above is incorporated by reference. The preamble and the “identifying” step, and the “displaying ... inner layer[s]” step of Claim 1 are the same as the preamble, “identifying” step, and the “displaying ... inner layer[s]” step of Claim 11. Accordingly, the discussion of the disclosure of *Doo* and *Amira* as it relates to the preamble, the “identifying” step, and the “displaying ... inner layer[s]” step of Claim 1 above applies equally to the preamble and steps of Claim 11.

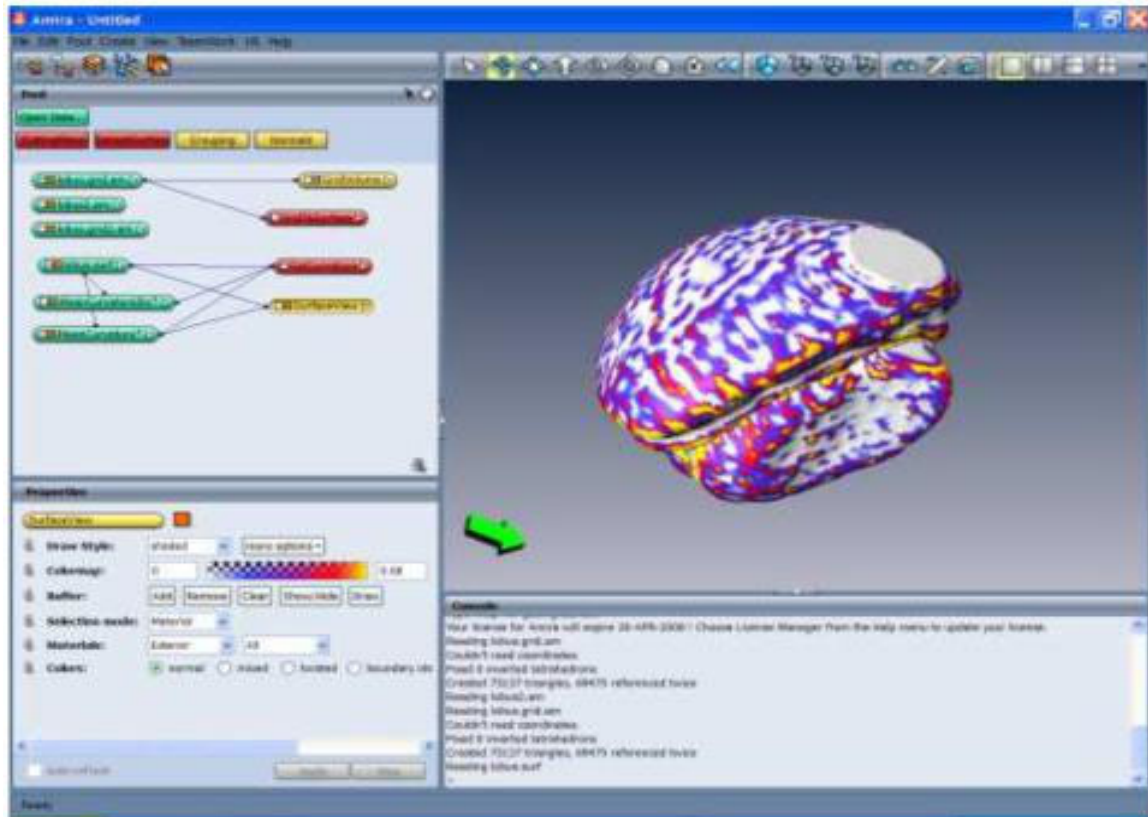
- (a) “altering the original color gradient of the multiple inner layers to be lighter than the original color gradient in order to be better visible when projected onto real-time, non-image actual views of the outer layer of the patient” (“altering” step of Claim 11)

With respect to the “altering” step of Claim 11, and in addition to *Doo*’s disclosure with respect to the other limitations of Claim 11, Professor Kazanzides relies for example on *Doo*’s disclosure of altering and enhancing the visibility of an image. Ex. 1012, ¶¶ 91-96. For example, *Doo* discloses “adjusting the

transparency of the overlaid image.” Ex. 1008, 28 (Claim 5). *Doo* further discloses that “The system 34 can present a selectively or variably transparent image of an anatomical feature of a patient 28 to a surgeon 26 during surgery, as the surgeon 26 maintains a viewing perspective generally centered on the actual anatomical feature of the patient 28 or at least toward the patient 28 on whom some operation is being performed.” *Id.*, [0030].

Moreover, *Doo* discloses that “The image as perceived by the surgeon 26 is selectively and/or variably transparent, in the sense that the surgeon 26 controls the image opacity throughout the range of fully transparent, e.g., when the image is not in use, to fully opaque, e.g. when high-contrast is desired, and through some if not all levels in –between.” *Id.*, [0030]. “Typically, the image will appear to ... be overlaid on the skin of the patient 28 (Figures 7 and 14) or have the appearance of being inside the patient’s body volume (Figure 6).” *Id.*, [0030].

In addition to *Doo*’s disclosure, *Amira* discloses coloring based on a detected property in a 3D data set:

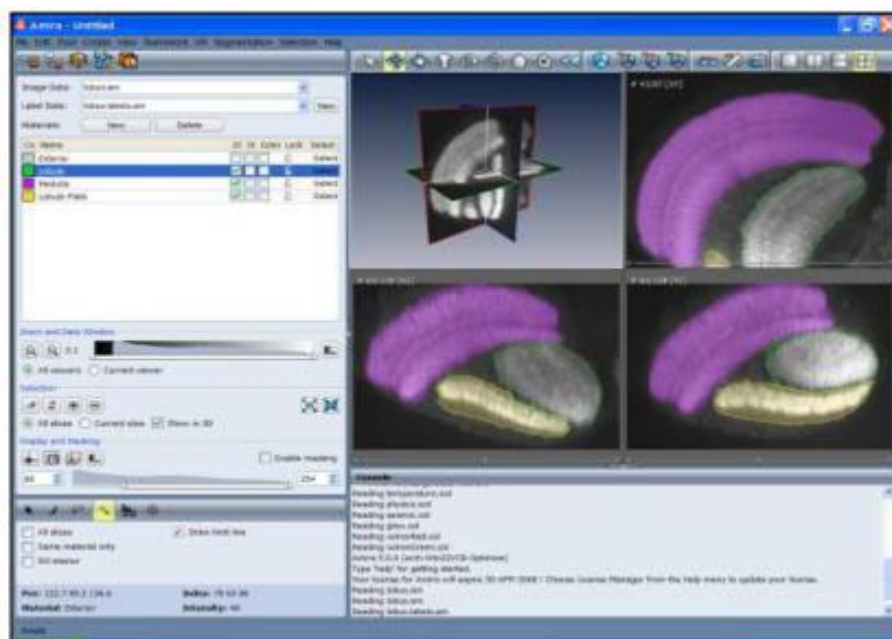


Ex. 1005, *Amira*, 5 (FIG. 1.1). As *Amira* explains: “Figure 1.1: Data objects and modules are represented as little icons in the Pool (top left). In the 3D graphic window a surface colored according to its curvature is shown. Curvature information has been computed by a computational module and is stored as a separate data object” Ex. 1005, *Amira*, 5.

Amira explains that “3D data can be quickly explored, analyzed, compared, and quantified.” Ex. 1005, *Amira*, 3.

Amira includes a tutorial on segmentation of 3D images. Ex. 1005, *Amira*, 40-45. *Amira*’s Figure 2.17 illustrates the results of exemplary segmentation of 3D

data into different structures, in which different portions of the 3D data have been assigned different colors:



Id., 41, FIG. 2.17. *Amira* discloses “you can give the materials more meaningful names or colors using the context menu” *Id.*, 42.

Amira discloses the use of colormaps to alter color gradients. For example, *Amira* discloses that, “[f]or some data objects such as ... colormaps there exist special-purpose interactive editors that allow the user to modify the objects.” *Id.*, 4.

Amira discloses the use of an editable color map to control visualization of an overlay image. For example, *Amira* discloses that “[t]he process of image fusion consists of combining relevant information from two or more images into a single image using different color mappings.” Ex. 1005, *Amira*, 102. According

to *Amira*, image fusion is “very relevant especially in medical science” *Id.*, 102. To achieve the best visibility of an overlay image, *Amira* recommended that users “experiment with changing the color maps.” *Id.*, 103. *Amira* directed users to “[c]hange the minimum and maximum values of the Overlay color map.” *Id.*, 102-103. “To do so, select the 3D viewer to activate it, slide the colormap bar to the left and the right or change the upper and lower limits.” *Id.*, 103. *Amira* discloses a user can “change the contrast ... or change the brightness.” *Id.*, 101. *Amira* explained “[y]ou can do the same for the 2D viewers.” *Id.*, 103.

While some of *Amira*’s 2009 disclosure applied to a fusion of two virtual images, Professor Kazanzides concluded that, based on the above-cited disclosures and the knowledge in the art at the time, the POSA would have appreciated that the same color adjustment technology applies to improving visibility of a virtual image overlaid on an actual patient view. Ex. 1012, ¶¶ 91-96.

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

With respect to the “altered” limitation of Claim 11, and in addition to the disclosure with respect to the other limitations of Claim 11 discussed above, Professor Kazanzides relies for example on *Doo*’s disclosure of displaying the projected inner layer of the patient with selective transparency/opacity enabling the altering and enhancing of the visibility of the image. Ex. 1012, ¶ 97; *see also* Ex.

1008, [0030]. In addition to *Doo*'s disclosure, as discussed above *Amira* discloses projection of an overlay image with an adjusted color map that alters a color gradient. *Amira* further discloses that a user can “visualize one or two data set at the same time using a Multi Planar reconstruction (MPR) and a 3D viewer.” *Id.*, 100. Ex. 1012, ¶ 97.

4. 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/radioactivity/water content] tissue property of the multiple inner layers of the patient.

According to Professor Kazanzides, Claim 12-19 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*. Ex. 1012, ¶¶ 81, 98-101. Professor Kazanzides opined that a POSA 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, ¶¶ 98-101.

In addition to *Doo*'s disclosure discussed above, Professor Kazanzides relied, for example, on *Amira*'s disclosure that “[t]he Quantification+ Option provides an extensive set of intensity and geometrical measurements on image or label data” Ex. 1005, *Amira*, 11 (Section 1.2.7.3). *Amira* discloses “[a] number of ... coloring schemes help to yield meaningful and informative visualizations of polygonal models” *Id.*, 9 (Section 1.2.6.2). *Amira* discloses

“[s]urface ... can be colored ... in order to visualize a second independent data set.” *Id.*, 9 (Section 1.2.6.2).

Amira discloses “combining relevant information from two or more images into a single image using different color mappings. The Image Fusion became very relevant especially in medical science, where different imaging modalities can be obtained from the same patient. Typically, the multi-modal imaging includes magnetic resonance (MR), computer tomography (CT), and positron emission tomography (PET/SPECT).” Ex. 1005, 102 (Section 2.15.2).

Amira discloses a color gradient representing curvature. *Id.*, 5. *Amira* discloses a color gradient representing blood flow inside the carotid artery. *Id.*, 69-70. *Amira* discloses different color gradients representing features of a bone model and features of a skin model. *Id.*, 79-80 (Section 2.11.6).

- (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.”

According to Professor Kazanzides, Claim 20 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*. Ex. 1012, ¶¶ 81, 102, 89. With respect to Claim 20, Professor Kazanzides relies, for example, on *Doo*’s discloses 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 recited in Claim 11. Ex. 1012, ¶ 102; *see also* Ex. 1008, [0063].

D. Ground 3: Obviousness of Claims 1-6 and 11-20 Over *Chen* in view of 3D Visualization and 3D Slicer

1. Motive to Combine *Chen* with 3D Slicer and 3D Visualization

Chen discloses “[c]urrently, there is a well-known free and open-sourced software package named 3D Slicer (<http://www.slicer.org/>) for visualization and medical image computing.” Ex. 1009, *Chen*, p. 131 at 1:29-31. *Chen* discloses that, “during the past several years, many research groups have developed loadable extension modules based on 3D Slicer” *Id.*, 131/1:34-39. *Chen* discloses “we also plan to integrate the AR-SNS into the 3D Slicer in the future so that it can be shared with the global research community.” *Id.*, 131/1:39-41. As such, Professor Kazanzides concluded that *Chen* expressly suggests combination of the systems and methods disclosed therein with the open-sourced package named 3D Slicer (<http://www.slicer.org/>) for visualization and medical image computing. Ex. 1012, ¶ 105.

By the time of *Chen*’s publication, S. Pujol and others has published a tutorial (3D Visualization) on 3D Slicer software capabilities based on exemplary data sets. See Ex. 1007, S. Pujol, Ph.D. et al., 3D Visualization of DICOM Images for Radiological Applications (Surgical Planning Laboratory, Brigham and

Women's Hospital, Boston, Massachusetts 2014) (hereinafter "*3D Visualization*"). By 2016, the 3D Slicer software included published documentation of the Main Application Graphical User Interface (GUI). See Ex. 1010, Main Application GUI for 3D Slicer <<https://www.slicer.org/wiki/Documentation/4.6/Slicer/Application/MainApplicationGUI>> (last edited 7 November 2016) ("*3D Slicer*"). Professor Kazanzides concluded that a POSA would have understood that *Chen* expressly suggests combination of the systems and methods disclosed therein with the features and capabilities described in *3D Slicer* and *3D Visualization*. Professor Kazanzides concluded that, at the relevant time, a POSA would have looked to *3D Slicer* and *3D Visualization* to understand what the suggested combination would encompass and would have had an expectation of success in the combination. Ex. 1012, ¶ 106.

For reasons discussed in further detail below, Professor Kazanzides concluded that Claims 1-6 and 11-20 would have been obvious over *Chen* in view of *3D Visualization* and *3D Slicer* at the relevant time to a person of ordinary skill in the art. Ex. 1012, Kazanzides Decl., ¶¶ 104-133.

2. Disclosure with Respect to Independent Claim 1

(a) preamble of Claim 1

Professor Kazanzides concluded that, to a POSA, *Chen* discloses "[a] method for augmenting real-time, non-image actual views of a patient with three-

dimensional (3D) data,” as recited in the preamble of Claim 1 (and, indeed, in independent Claim 11 as well). Ex. 1012, ¶¶ 109-110.

For example, Professor Kazanzides relied on the following disclosures. *Chen* discloses that “virtual anatomical structures, such as soft tissues, blood vessels, and nerves can be integrated with the real-world scenario in real time.” Ex. 1009, *Chen*, Abstract. *Chen* discloses “an AR-based [Augmented Reality-based] surgical navigation system (AR-SNS) ... developed using an optical see-through HMD (head-mounted display), aim[ed] at improving the safety and reliability of the surgery.” *Id.*, Abstract. *Chen* discloses that, “[w]ith the use of this system, including the calibration of instruments, registration, and the calibration of HMD, the 3D virtual critical anatomical structures in the head-mounted display are aligned with the actual structures of patient in real-world scenario” *Id.*, Abstract.

(b) “identifying” step of Claim 1

Professor Kazanzides concluded that, to a POSA, *Chen* discloses the step of “identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient.” Ex. 1012, ¶¶ 111-112.

For example, Professor Kazanzides relied on the following disclosures. Figure 2 of *Chen* illustrates “Load of preoperative CT data” as the first step in the framework of the AR-SNS. Ex. 1009, Figure 2. “[O]n the basis of the

preoperative CT data of a patient, imaging segmentation is conducted, so that 3D models including hard and soft tissues, especially critical anatomical structures such as blood vessels and nerves can be reconstructed.” *Id.*, 125/2:1-5. “All of the work including the image segmentation and 3D modeling is realized.” *Id.*, 125/2:37-38.

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

Professor Kazanzides concluded that, to a POSA, *Chen* discloses the step of “displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient.” Ex. 1012, ¶¶ 113-117.

For example, Professor Kazanzides relied on the following disclosures. *Chen* discloses “an optical see-through head-mounted display is adopted so that an immersive augmented reality environment can be obtained and the virtual tissue can be integrated with the direct view.” Ex. 1009, *Chen*, 125/2:14-17. *Chen* discloses “the real world is seen ... with the optical see-through HMD.” *Id.*, 130/1:39-44.

Chen discloses that, “[w]ith the original CT data..., a 3D pelvis model was reconstructed ... and fabricated using 3D printing technology.” *Id.*, 129/2:7-10. *Chen* discloses that “a 3D bladder and some blood vessels and nerves were reconstructed.” *Id.*, 29/2:13-14. “Seen through the HMD, the 3D virtual

anatomical structures were aligned with the real plastic model ... (see Fig. 6).” *Id.*, 129/2:15-18; FIG. 6. Figure 6 illustrates the display, as seen from the HMD, of the virtual 3D bladder projected onto the real plastic pelvis model:

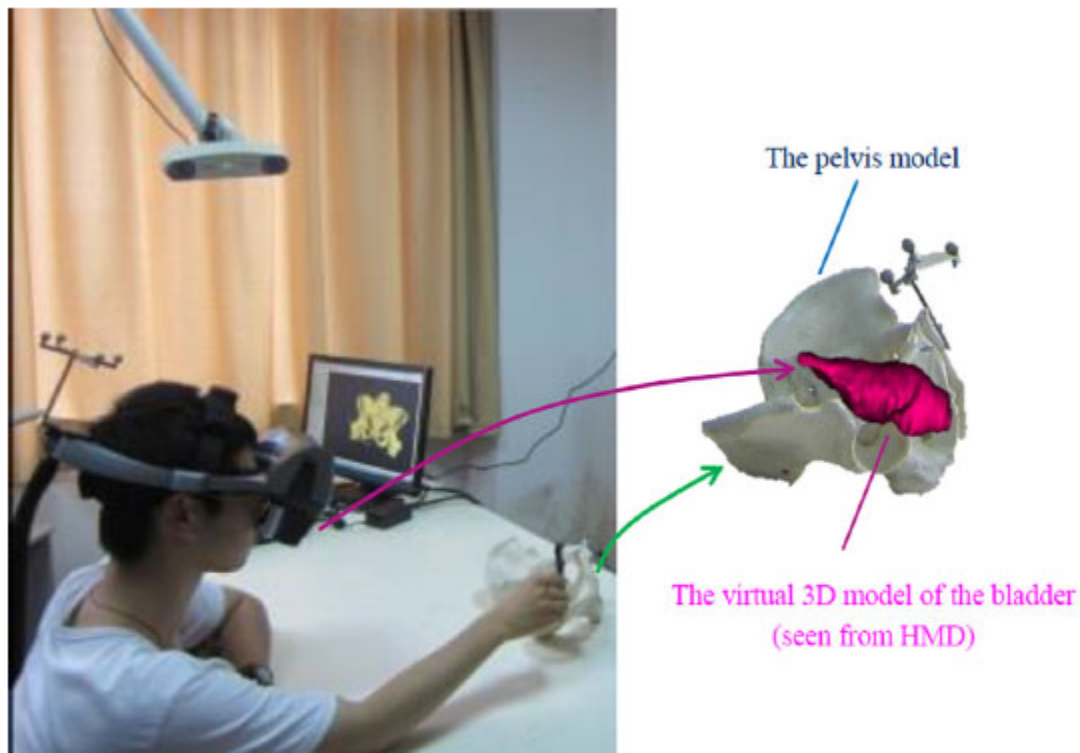


Fig. 6. Wearing HMD to conduct a phantom experiment.

Ex. 1009, *Chen*, FIG. 6.

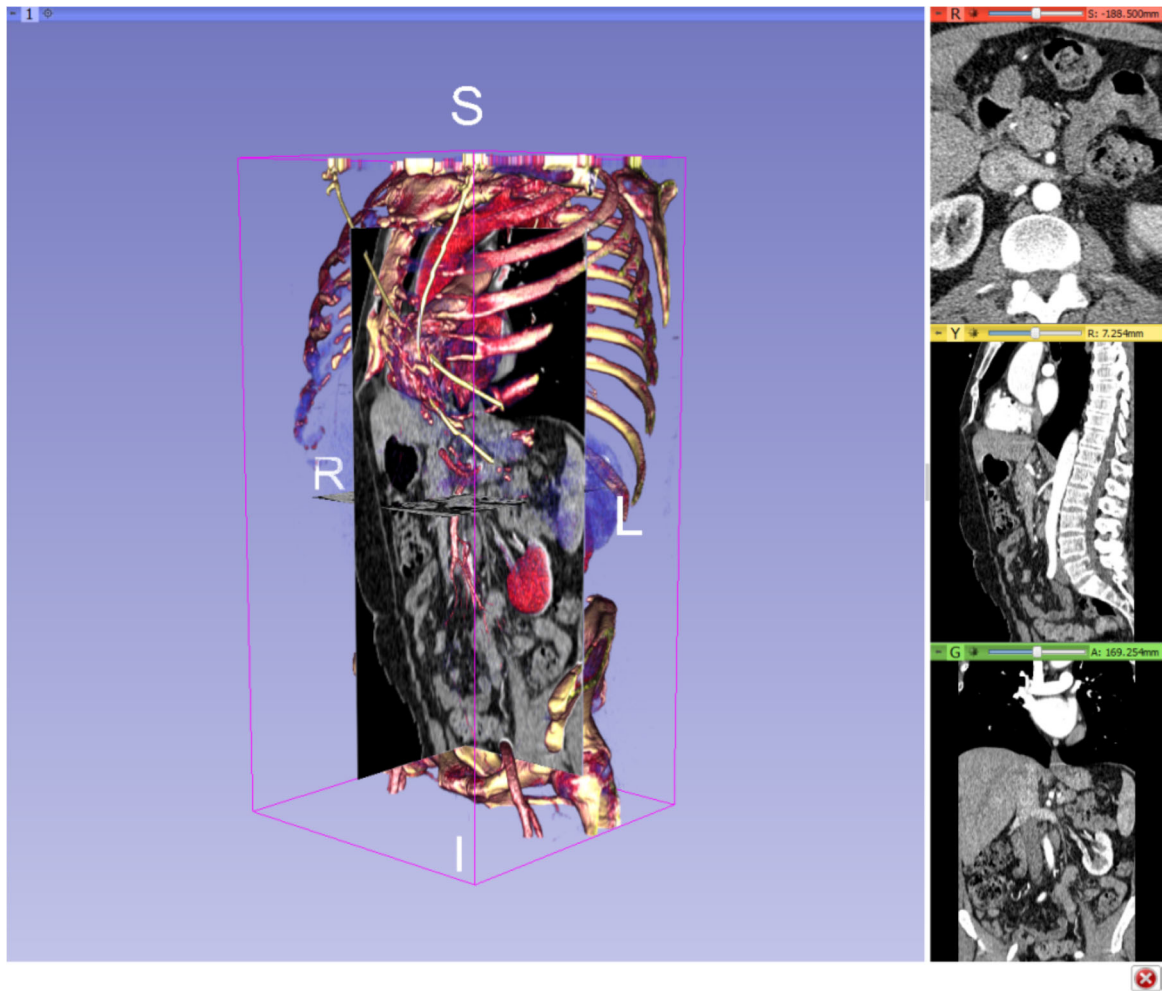
Chen “also conducted a cadaver experiment for percutaneous implantation of sacroiliac joint screw in an operating room.” *Id.*, 129/2:19-21. “[B]ased on the CT data, 3D-reconstruction ... were conducted and the data imported were imported to AR-SNS.” *Id.*, 129/2:22-24. “the 3D virtual bladder was aligned with the real cadaveric pelvis during the intra-operative process, and the 3D instrument model is displaying in HMD in real time, so that the operator can implant the

sacroiliac joint screw into the pelvis along with [sic] the preoperative planned trajectory.” *Id.*, 130/1:3-9.

Chen also discloses that, “[w]ith the use of [the disclosed] system, ... the 3D virtual critical anatomical structures in the optical see-through head-mounted display are aligned with the actual structures of the patient in the real-world scenario.” Ex. 1009, *Chen*, 130/2:1-5. “Therefore, the real- and virtual-world view are fused directly in the optical see-through HMD” *Id.*, 130/1:44-46.

(d) “confined” limitation of Claim 1

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. For example, *3D Visualization* discloses “you will be able to load and visualize DICOM volumes with 3D Slicer, and to interact in 3D with structural images and models of the anatomy.” Ex. 1007, *3D Visualization*, slide 2. As seen below, *3D Visualization* illustrates the 3D volume rendered image of the aorta and rib cage along with other two dimensional CT slices of the thorax and abdomen.



Ex. 1007, slide 44. As Professor Kazanzides explains, *3D Visualization's* slide 44 illustrates the aorta and rib cage confined within a virtual 3D shape. The virtual 3D shape in the image of *3D Visualization's* slide 44 is a virtual 3D box illustrated in magenta. The virtual 3D box includes a top side, a bottom side, a left side, a right side, a front side, and a back side. Ex. 1012, ¶ 118.

3. **Disclosure with respect to Claims 2-6**

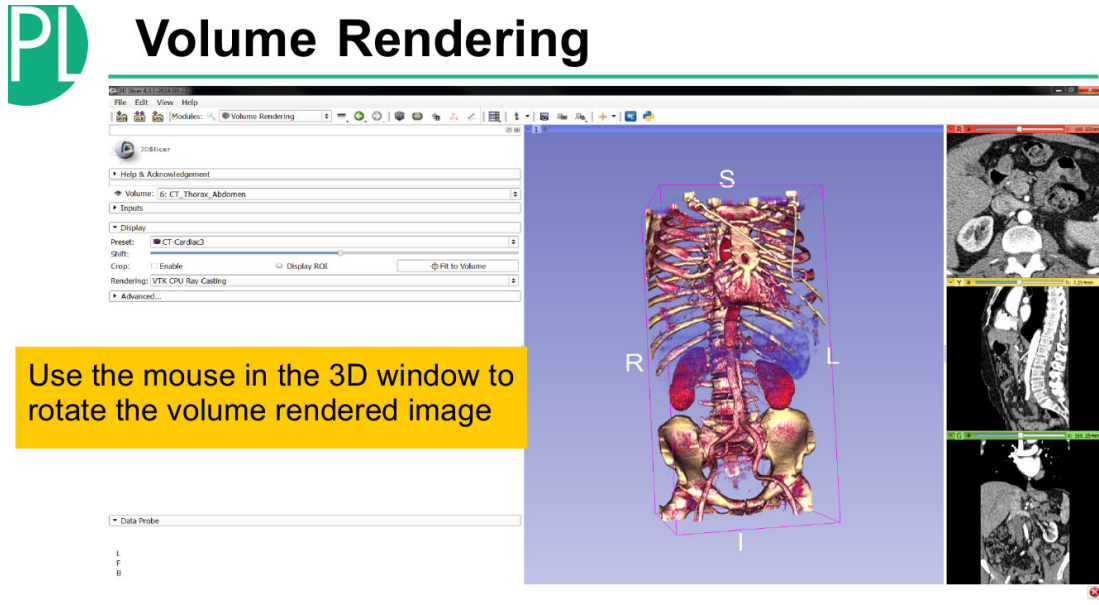
- (a) Claim 2: “The method of claim 1, wherein: the virtual 3D shape is a virtual box; and the virtual box includes a top side, a bottom side, a left side, a right side, a front side, and a back side.”

See discussion above with respect to the “confined” limitation of Claim 1. For example, the virtual 3D box of slide 44 in 3D Visualization includes a top side, a bottom side, a left side, a right side, a front side, and a back side. Ex. 1007, slide 44; Ex. 1012, ¶¶ 118-119.

- (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.”

3D Slicer teaches that the user may toggle the display of the lines of the virtual 3D box on and off. “The eye icon contains controls for visibility of ... the bounding box in the 3D viewer.” Ex. 1010, 5 (“3D Viewer” section).

As seen in the illustration below, and as Professor Kazanzides explains, *3D Visualization* teaches that the virtual 3D box of the 3D Slicer software is configured to be controlled to reposition two-dimensional (2D) slices and/or 3D slices of the projected inner layer of the patient confined within:



Ex. 1007, slide 46. *See also* Ex. 1012, Kazanzides Decl., ¶¶ 120-121.

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

See discussion above with respect to the “confined” limitation of Claim 1.

The virtual 3D shape in the image of *3D Visualization*’s slide 44 is a virtual 3D box illustrated in magenta. Ex. 1007, slide 46; Ex. 1012, ¶¶ 118, 122.

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

See discussion above with respect to Claim 3. *3D Slicer* teaches that the user may toggle the display of the lines of the virtual 3D box on and off. “The eye icon contains controls for visibility of ... the bounding box in the 3D viewer.” Ex. 1010, 5; Ex. 1012, ¶ 123.

- (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”

Based on the following disclosures, Professor Kazanzides concluded that, a POSA would have understood that *Chen* teaches a non-transitory computer-readable media storing one or more programs that are configured to cause one or more processors to perform the method as recited in Claim 1, when executed. Ex. 1012, ¶ 124-125.

Chen discloses that “The AR-SNS is constructed based on a high-performance graphical workstation (HP) The workstation is equipped with a 4 GB memory card, a core i7 CPU and an nVIDIA Quadro FX4800 graphic card, running on the windows 7 operating system.” Ex. 1009, *Chen*, 125/1:16-27. “The AR-SNS is developed under the platform of the Integrated Development Environment (IDE) of VS2008. All of the functions are programmed in Microsoft Visual C++ and some famous toolkits are also involved, such as the Visualization Toolkit (VTK, an open source, freely available software system for 3D computer graphics, image processing, and visualization etc., <http://www.vtk.org/>), CTK, ITK, IGSTK and QT, and then integrated into the AR-SNS.” *Id.* 125/1:30-2:23.

4. Disclosure with Respect to Independent Claim 11

The discussion of the prior art disclosure of *Chen*, *3D Slicer*, and *3D Visualization* as it relates to the challenged claims above is incorporated by

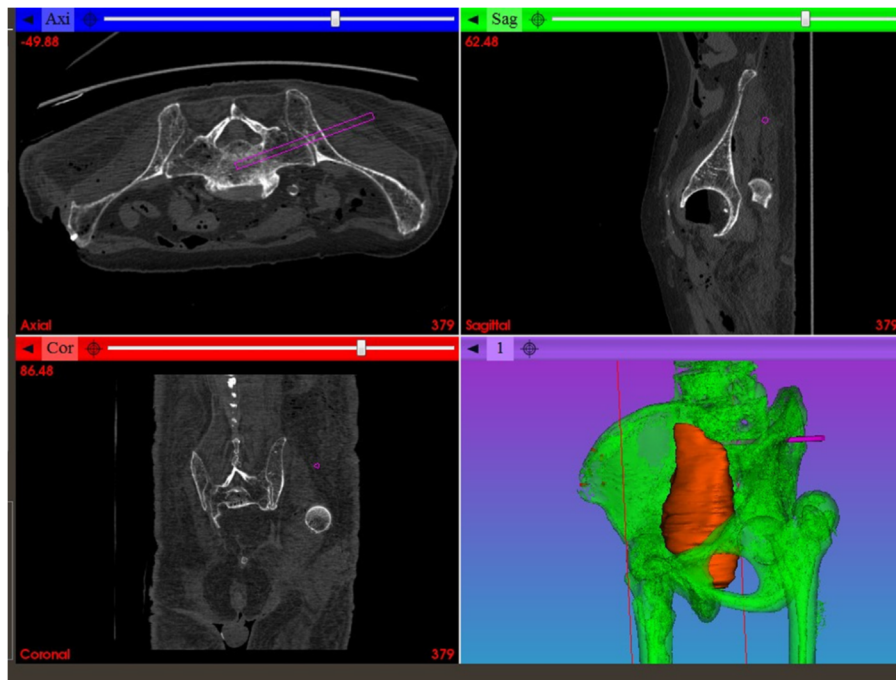
reference. The preamble and the “identifying” step, and the “displaying ... inner layer[s]” step of Claim 1 are the same as the preamble, “identifying” step, and the “displaying ... inner layer[s]” step of Claim 11. Accordingly, the discussion of the disclosure of *Chen*, *3D Slicer*, and *3D Visualization* as it relates to the preamble, the “identifying” step, and the “displaying ... inner layer[s]” step of Claim 1 above applies equally to the same preamble and steps of Claim 11. Ex. 1012, ¶ 126.

(b) “altering” step of Claim 11

Professor Kazanzides concluded that, to a POSA, *Chen* discloses the “altering” step of Claim 11, “altering the original color gradient of the multiple inner layers to be lighter than the original color gradient in order to be better visible when projected onto real-time, non-image actual views of the outer layer of the patient.” Ex. 1012, ¶ 127.

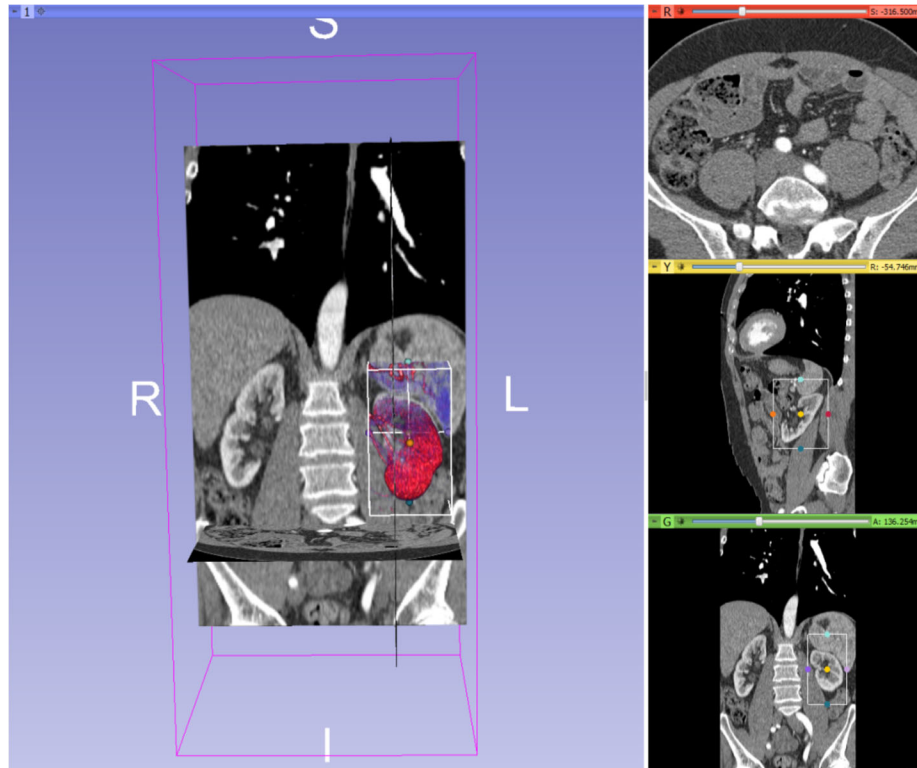
Professor Kazanzides further concluded that a POSA would understand that *Chen* illustrates and discloses the results of experimentation with altering the original color gradient to be better visible. Ex. 1012, Kazanzides Decl., ¶¶ 127-128.

For example, Professor Kazanzides relies on the following disclosures. *Chen* illustrates different color gradients for the same inner layers in Figures 4 and 6. Ex. 1009, *Chen*, FIGS. 4 and 6. *Chen* first illustrates the same bladder separately in shades of gray and of orange. *Id.*, FIG. 4.



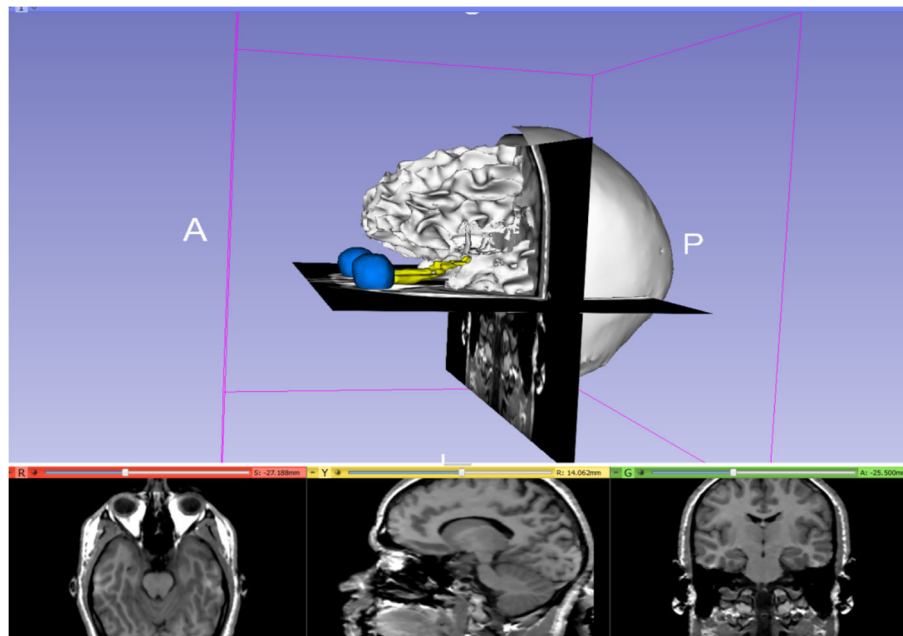
Ex. 1009, Chen, Fig. 4. *Chen* then illustrates the virtual 3D model of the bladder (seen from HMD) in a bright pink. *Id.*, FIG. 6. *Chen* discloses that, “according to feedback from the surgeons and human-machine interaction experts, we found that the bright colors of virtual anatomical models with the black background in the HMD had a more vivid mixed reality effect.” *Id.*, 131/1:11-15.

Similarly, as Professor Kazanzides explains, *3D Visualization* teaches altering color values for different inner layers. For example, *3D Visualization* illustrates a right kidney volume rendered in a bright red to enhance visibility:



Ex. 1007, *3D Visualization*, slide 53; Ex. 1012, ¶ 128.

Likewise, *3D Visualization* illustrates coloring of the brain's white matter and the right and left optic nerves:



Ex. 1007, *3D Visualization*, slide 73. Ex. 1012, ¶ 128.

(c) “altered color” limitation of Claim 11

Professor Kazanzides concludes that a POSA would understand that *Chen* teaches displaying the projected inner layer of the patient in an altered color gradient for a better effect. Professor Kazanzides also concludes that, to a POSA, *Chen* discloses the “altered color” limitation of Claim 11, “the projected inner layer of the patient from the 3D data being having the altered color gradient.

Professor Kazanzides further concludes that a POSA would understand that *3D Visualization* teaches the displaying of the projected inner layer of the patient in an altered color gradient for better visibility. Ex. 1012, ¶¶ 129-130.

For example, Professor Kazanzides relies on the following disclosures. *Chen* first illustrates the same bladder separately in shades of gray and of orange. Ex. 1009, *Chen*, FIG. 4. *Chen* then illustrates the virtual 3D model of the bladder (seen from HMD) in a bright magenta. *Id.*, FIG. 6. *Chen* discloses that, “according to feedback from the surgeons and human-machine interaction experts, we found that the bright colors of virtual anatomical models with the black background in the HMD had a more vivid mixed reality effect.” *Id.* 131/1:11-15; Ex. 1012, ¶ 129.

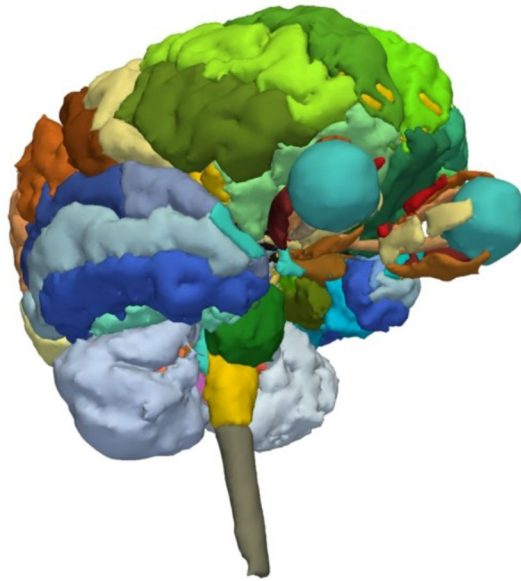
3D Visualization teaches altering color values for different inner layers. For example, *3D Visualization* in slide 53 illustrates a right kidney volume rendered in a bright red to enhance visibility. Ex. 1012, ¶ 128.

5. 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/radioactivity/water content] tissue property of the multiple inner layers of the patient.

Professor Kazanzides concludes that a POSA at the relevant time would have understood that the 3D Slicer application described in *3D Visualization* 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 Decl., ¶¶ 131-132.

For example, Professor Kazanzides relied upon the following disclosures. As illustrated for example in *3D Visualization*’s slides 44 and 46 (above), by the relevant date, the 3D Slicer software enabled structures with different characteristics to be represented by different color gradients. Similarly, *3D Visualization*’s slide 57 illustrates 3D visualization of surface models of subcomponents of the brain in different color gradients:



Ex. 1007, *3D Visualization* , slide 57.

- (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.”

The discussion above related to Claim 6 is incorporated by reference. Ex. 1012, ¶ 133. *See also* Ex. 1009, *Chen*, 125/1:30-2:23.

VI. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests institution of *inter partes* review of Claims 1-6 and 11-20 of the '271 Patent and cancellation of all of those challenged claims.

Respectfully submitted,

Dated: October 12, 2022

By: /s/ Kia Freeman /s/
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sCERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing petition for *inter partes* review—excluding the Table of Contents, the Table of Authorities, the Table of Exhibits, the Mandatory Notices, this Certificate of Word Count, and the Certificate of Service—includes less than 14,000 words based on a word count using that feature of WORD.

By: /s/ Kia Freeman /s/
Kia L. Freeman
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Attorney for Petitioner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition For *Inter Partes* Review (including Exhibits 1001-1014, the Fee Authorization page, the Certificate of Compliance, and the Power of Attorney) was served on October 12, 2022 by transmitting a copy via Priority Mail Express to the patent owner at the correspondence address of record for the subject patent:

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