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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDIVIS, INC.,

Petitioner,

v.

NOVARAD CORP.,

Patent Owner.

Patent 11,004,271 B2

Case IPR 2023-00042

PATENT OWNER RESPONSE

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EXHIBIT LIST

Exhibit No.	Exhibit Description
Ex. 2002	Declaration of Mahesh S. Mulumudi, M.D. (“Mulumudi”)
Ex. 2003	Dr. Mulumudi’s C.V.
Ex. 2004	Declaration of Craig Rosenberg, Ph.D. (“Rosenberg”)
Ex. 2005	Dr. Rosenberg’s C.V.
Ex. 2006	Dr. Kazanzides Deposition (“Kazanzides Depo”)

I. INTRODUCTION

The '271 Patent uses augmented reality (AR) technology in an operating room. The Patent allows a physician to not only view, but also to navigate in real-time, a three-dimensional (3D) volume-rendered image of a patient's anatomy while it is overlaid onto the actual patient in the operating room during pre-operative planning or surgery.

More specifically, claims 1-6 provide a novel virtual tool (*i.e.*, a “virtual 3D shape”) for navigating the 3D volumetric patient anatomy while it is projected onto the actual patient in real-time. The Petition (Paper 3) attacks on the patentability of claims 1-6 lack merit foremost because Petitioner fails to appreciate what is claimed—a virtual tool (*i.e.*, “a virtual 3D shape”) for real-time navigation of the projected 3D volumetric rendering. For example, Petitioner mistakenly equates the “virtual 3D shape” of claim 1 with a simple box that merely surrounds 3D models displayed on conventional computer monitors.

Claims 11-20 provide a novel method for altering the color gradient of the 3D volumetric patient anatomy to: (1) be better visible when projected onto an actual patient in an operating room; and (2) represent various tissue properties, including: hardness, relaxivity, echogenicity, enhancement amount, enhancement speed, density, radioactivity, and water content. The Petition attacks the patentability of claims 11-20 but does so without identifying a single reference that

alters the color gradient of the 3D volumetric medical imaging to be better visible when projected onto an actual patient in an operating room. The Petition also fails to identify a single reference that alters the color gradient of 3D volumetric medical imaging when projected onto an actual patient in an operating room to specifically identify any of the tissue properties identified in claims 12-19.

Petitioner's misconstruction of the claims and prior art¹ aside, the Petition makes many of its allegations in a conclusory fashion. Even in a tribunal with a lowered burden of proof, conclusory allegations are not evidence.

II. BACKGROUND

A. Technology Background

Generally speaking, one source of two-dimensional (2D) medical imaging data is a computed tomography (CT) scan, which uses X-rays to create images of the inside of the body. Ex. 2002, Mulumudi, ¶ 48. X-ray sources and detectors are moved around the body, recording patient anatomy from different angles. *Id.*

“Conventionally, a computer uses this 3D data to reconstruct a set of 2D images or slices.” *Id.* “This set of 2D slices are reconstructed along one of three planes: coronal (front to back), sagittal (left to right), or axial (top to bottom).” *Id.* “Each

¹ Discussed in greater detail below, much of the Petitioner's asserted prior art has not been demonstrated to be actual prior art. Meaning, there is no evidence that the alleged publication was available and disseminated to the POSITA before the applicable priority date.

of these 2D images represents distribution of X-ray attenuation in the patient's body." *Id.* "Each 2D CT scan image consists of a grid of 2D pixels." *Id.*, ¶ 49. "The value of the pixel corresponds to the radiodensity of the tissue within the pixel." *Id.* "While each pixel represents a small volume element, or voxel, of the body, a 2D CT scan image provides no information about the patient anatomy between the slices." *Id.*

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

"There are various methods for visualizing CT and MRI scan data, including 'slice-by-slice viewing,' 'surface rendering,' and 'direct volume rendering (DVR).'" *Id.*, ¶¶ 51-58. "One of the earliest, and still most common, methods for

visualizing medical imaging data is ‘slice-by-slice viewing.’” *Id.*, ¶ 51. “This is where individual 2D slices are viewed sequentially, one at a time, in the direction in which they were compiled.” *Id.* “Traditionally, CT and MRI slices are acquired and viewed along only one axis, typically the axial or transverse plane (horizontal slices as if looking from the feet towards the head).” *Id.* “This ‘slice-by-slice viewing’ method does not provide a complete 3D view of anatomical structures within the volume of a patient.” *Id.*

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

Surface rendering “relies on identifying and rendering the surfaces of specific structures.” *Id.* 53. “As a result, minor errors or noise in the data can

cause significant errors in the final surface rendering.” *Id.* “In surface rendering, it is common to apply thresholding to distinguish between different types of tissues or materials in the data.” *Id.* “However, if thresholds are not set correctly, this can lead to errors or omissions in the final surface rendering.” *Id.* “Also, surface rendering is unable to represent semi-transparent or overlapping structures accurately which can be a disadvantage with medical imaging where these types of structures are common.” *Id.*

Discussed below with respect to claim construction, the concept of “direct volume rendering (DVR) is very different from the other visualization methods described above.” *Id.*, ¶ 54. “DVR is a method for visualizing medical imaging data, including CT and MRI scan or ultrasound data, in three-dimensions.” *Id.* DVR “can offer perspectives that are not limited to the traditional planes (e.g., axial, sagittal, and coronal) used to navigate data, enabling a view of the anatomical structures within the volume of a patient from any direction.” *Id.*

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

“Also, unlike surface rendering, DVR does not require the creation of an intermediate surface representation and does not require segmentation of the data into different structures or tissues.” *Id.*, ¶ 56. “Instead, DVR operates directly on the original dataset (i.e., grid of voxels that make up the raw volume data).”

Id. “Each voxel within the dataset is assigned a color and opacity based on transfer functions.” *Id.* “All the voxels are then composited, or blended together, to create a 3D image of the entire volume of the patient anatomy.” *Id.*

Navigation of that direct volume rendered data in an AR environment, is one subject of the ‘271 Patent. A “common problem faced by AR systems is proper placement of virtual controls for managing virtual elements.” Ex. 1001, 1:29-30. “Virtual 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.

Generally speaking, 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.

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, shown below.

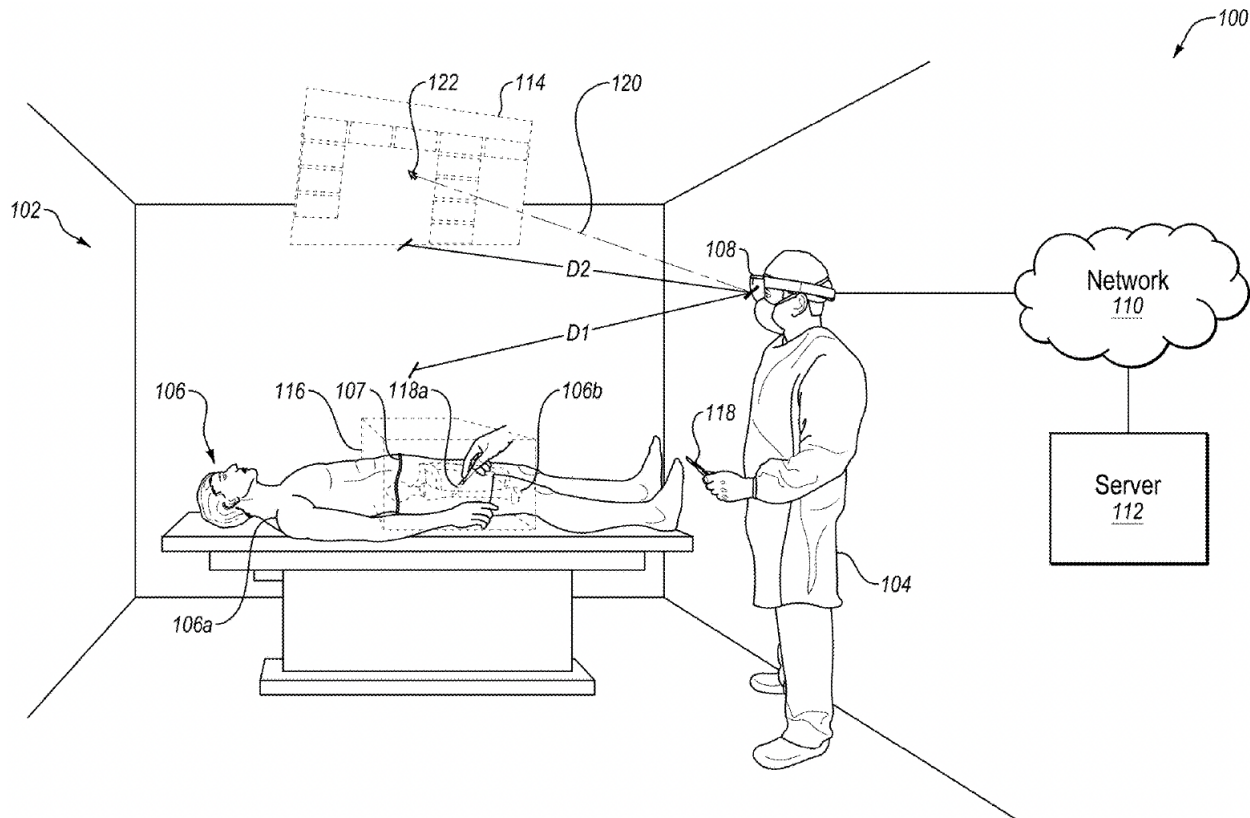


FIG. 1

The AR environment "may also include a virtual user interface 114" and "a virtual spatial difference box 116." Ex. 1001, 4:1-3. 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 three-dimensional (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. 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.

B. The Challenged Claims of the '271 Patent

1.

[Pre]	A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:
[A]	identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient; and
[B]	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,

[C]	the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.
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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.

11.

[Pre]	A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:
[A]	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;
[B]	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
[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, the projected inner layer of the patient from the 3D data being having the altered color gradient.
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12. The method as recited in claim 11, wherein the altered color gradient represents a tissue hardness tissue property of the multiple inner layers of the patient.

13. The method as recited in claim 11, wherein the altered color gradient represents a tissue relaxivity tissue property of the multiple inner layers of the patient.

14. The method as recited in claim 11, wherein the altered color gradient represents a tissue enhancement amount tissue property of the multiple inner layers of the patient.

15. The method as recited in claim 11, wherein the altered color gradient represents a tissue enhancement amount tissue property of the multiple inner layers of the patient.

16. The method as recited in claim 11, wherein the altered color gradient represents a tissue enhancement speed tissue property of the multiple inner layers of the patient.

17. The method as recited in claim 11, wherein the altered color gradient represents a tissue density tissue property of the multiple inner layers of the patient.

18. The method as recited in claim 11, wherein the altered color gradient represents a tissue radioactivity tissue property of the multiple inner layers of the patient.

19. The method as recited in claim 11, wherein the altered color gradient represents a tissue water content tissue 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.

III. CLAIM CONSTRUCTION

Patent claims are construed by evaluating claim language, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314–18 (Fed. Cir. 2005). There is a heavy presumption that a term carries its ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

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

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

Claims 1 and 11 of the ’271 Patent recite “real-time” augmentation of “non-image actual views of a patient with three-dimensional (3D) Data.” In its barest

form, a “POSITA would understand, and [Petitioner’s expert] Kazanzides² admitted, that ‘something is three-dimensional if it has the dimension of depth as well as width and height.’” Ex. 2002, Mulumudi, ¶ 68 (citing Ex. 2006, Kazanzides Depo, 58:11-15). In other words, “a 3D volume has x-, y-, and z-data in a Cartesian coordinate system.” *Id.*

Within the context of the ‘271 Patent, “3D data of the patient ... may include, but is not limited to, MRI images, Computerized Tomography (CT) scan images, X-ray images, Positron Emission Tomography (PET) images, ultrasound images, fluorescence images, Infrared Thermography (IRT) images, and Single-Photon Emission Computer Tomography (SPECT) scan image, or some combination thereof.” Ex. 1001, 11:45-51. With those fundamentals as a starting

² Professor Kazanzides’ relationship with Petitioner and Johns Hopkins University, a competitor of Patent Owner, call into question his objectivity and the reliability of his testimony. Kazanzides is a professor at Johns Hopkins University. Ex. 2006, Kazanzides Depo, 18:3-5. Johns Hopkins competes with Patent Owner. Kazanzides does research for Johns Hopkins related to the use of head mounted displays in augmented reality (AR) surgical applications. *Id.*, 20:7-24:16. Kazanzides works with physicians at Johns Hopkins to conduct his research. *Id.*, 24:17-25:9. Kazanzides has co-authored papers with Johns Hopkins physicians about the use of AR in surgery. *Id.* 24:21-25:9. Kazanzides is also a named inventor on several related patents, owned by Johns Hopkins, including U.S. Patent No. 11,244,508, entitled, “Augmented Reality Display for Surgical Procedures.” Ex. 1012, ¶ 12. Finally, at least one of Kazanzides’ former students currently works for Petitioner and that relationship resulted in Kazanzides’ request for a grant involving augmented reality, which was later declined. Ex. 2006, Kazanzides Depo, 12:2-14.

point, “conventional medical imaging systems generally generate 2D images or a series of 2D images taken along a particular axis of the patient anatomy (*e.g.*, axial, sagittal, or coronal).” Ex. 2002, Mulumudi, ¶ 68. Petitioner’s expert, Professor Kazanzides, explained, “It’s like a stack of pancakes through the patient, a stack of 2D slices.” Ex. 2006, Kazanzides Depo, 62:7-8. However, unlike an actual pancake, which has height, width, and depth, Kazanzides admitted that each of these 2D images has no “z information” other than that “common to the slice.” Ex. 2006, Kazanzides Depo, 64:1-7.

With specific reference to the ‘271 Patent, claim 1 requires “real-time” augmentation of “non-image actual views of a patient with three-dimensional (3D) data.” Ex. 1001, Claim 1. A POSITA “would understand that this 3D data must have height, width, and depth.” Ex. 2002, Mulumudi, ¶ 69. Claim 1 also requires that the “3D data include[e] an outer layer of the patient and multiple inner layers of the patient.” And according to the specification, the inner layers of the patient also “have depth as well as height and width.” Ex. 1001, 6:17-21 (“3D slices may include curved slices, such curved slices that follow the natural curve of an anatomical feature, or slices that have a depth as well as a height and width.”). Claim 1 further requires that the projected 3D data be “confined within a volume of virtual 3D shape.” Ex. 1001, Claim 1.

Based on the forgoing, a POSITA would understand that direct volume rendering “is the only visualization method that is: three dimensional (3D), includes an outer layer of the patient and multiple inner layers of the patient (where the layers also have depth as well as height and width), and is capable of being confined³ within a virtual 3D shape.” Ex. 2002, Mulumudi, ¶ 69; *see also id.* at ¶ 60 (“only DVR provides the comprehensiveness, detail, and flexibility to visualize and navigate the internal layers of a projected 3D volume of a patient in real-time: “all the way through the patient,” at a “certain partial depth into the patient,” and along multiple axes, as described and claimed in the ’271 Patent.).

As such, the term “3D data ... including an outer layer ... and multiple inner layers of the patient” means “direct-volume-rendered three-dimensional (3D) imaging of the anatomy of a patient, including an outer layer of the patient and multiple inner layers of the patient.” Ex. 2002, Mulumudi, ¶ 70.

B. “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.”

³ Patent Owner’s construction of “confined within a virtual 3D shape” is explained below. *See infra* at 15.

Claims 1 and 11 of the '271 Patent require “real-time” augmentation of “non-image actual views of a patient with three-dimensional (3D) Data.” Based on the plain and ordinary meaning of the term “three-dimensional,” a POSITA would understand that the projection onto the real, non-image, actual views of the patient must have height, width, and depth. Ex. 2002, Mulumudi, ¶ 69. This is true whether the entire volume of the patient, or some lesser volume (i.e., “one of the inner layers of the patient”), is projected onto the patient. *See id.*, ¶¶ 67-72.

The '271 Patent explains that the “multiple inner layers may be layers that go all the way through the patient 106, or may be layers that only go to a certain partial depth into the patient.” Ex. 1001, 12:13-16. Meaning, the inner layers will **always** have depth (i.e., a z-component) associated with their three-dimensional geometry. Together, with the definition of 3D data above, an “inner layer of the patient” means “a 3D volume rendering of some anatomy of the patient at a certain depth below the outer layer, or skin, of the patient.” Ex. 2002, Mulumudi, ¶¶ 71-72.

C. “confined within a virtual 3D shape”

Claim Term	Petitioner’s Construction	Patent Owner’s Construction
“confined within a virtual 3D shape”		“The virtual 3D shape controls what portion of the projected inner layer(s) are visible to the user. The virtual 3D shape confines

		the projected inner layer(s), it does not merely surround them.”
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Claim 1 of the '271 Patent requires that the “the projected inner layer [is] confined within a volume of a virtual 3D shape.” The language from claim 3 is helpful to understand this claim term. Claim 3 recites that the “virtual 3D shape is configured to be controlled” by the user. More specifically, claim 3 requires that the “virtual 3D shape” can “be controlled to reposition ... 3D slices of the projected inner layer of the patient from the 3D data.”

The specification explains that a “virtual spatial difference box 116 may be generated by the AR headset 108 *to confine within a volume* of the virtual spatial difference box 116 the projected inner layer of the patient 106 from the 3D data.” Ex. 1001, 6:5-8 (emphasis added). The “virtual spatial difference box 116 *may ... assist the user when navigating the projected 3D data....*” Ex. 1001, 6:11-13 (emphasis added). For example, the virtual spatial difference box “may assist the user when moving axial slices, coronal slices, sagittal slices, or oblique slices of the 3D data within the virtual spatial difference box 116.” Ex. 1001, 6:14-17. The “3D slices may include curved slices, such as curved slices that follow the natural curve of an anatomical feature, or slices that have depth as well as height and width.” Ex. 1001, 6:18-21. The '271 Patent further discloses that the “user 104 may move these slices using hand gestures that requires the user 104 to generally

move this hand in the directions of the lines of the virtual spatial difference box 116.” Ex. 1001, 6:21-25.

The “virtual spatial difference box,” described in the ’271 Patent, is an example of the “virtual 3D shape” of claim 1. Ex. 2004, Rosenberg, ¶ 83. The “virtual 3D shape,” like the “virtual spatial difference box” is a virtual user interface or virtual control “for altering the [3D data] projected onto the real-time view of the patient.” *Id.* (citing Ex. 1001, 3:50-54). The “virtual 3D shape” “assist[s] the user when navigating the projected 3D data.” Ex. 1001, 6:14-17. 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.” Ex. 2004, Rosenberg, ¶ 83.

Based on the foregoing, “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.” Ex. 2004, Rosenberg, ¶ 90. “A user may use the 3D virtual shape to move between 3D slices or segments and along any axis.” Ex. 2002, Mulumudi, ¶ 64. A “user may also use the “virtual 3D shape” to view the anatomical structure, i.e., “inner layers”, of the patient as one continuous structural slice as it moves in and out of a defined plane without being confined to any axial plane.” *Id.*, ¶ 73.

Thus, “confinement” of the 3D data within the virtual 3D shape requires a navigational or orientation function that allows the user to manipulate and view 3D slices of the patient’s anatomy along multiple axes. *Id.* In other words, a user can use hand gestures to adjust the boundaries of the virtual 3D shape to reveal 3D slices along any axis within the virtual 3D shape, including slices that “follow the natural curve of an anatomical feature.” Ex. 2004, Rosenberg, ¶ 85. The “virtual 3D shape” is not simply an outer boundary.

D. “being having”

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

To a person of ordinary skill in the art, the term “being having” appears to be a clerical error. *See* Ex. 2002, ¶ 83; Ex. 2004, ¶ 91. For the purpose of this IPR, Patent Owner interprets the term “being having” as “having.”

IV. *AMIRA, CHEN, 3D Visualization, and 3D Slicer* ARE NOT PRIOR ART

Petitioner provides no evidence regarding the availability of *Amira, Chen, 3D Visualization, or 3D Slicer* as prior art. “Petitioner has the burden to make a threshold showing that a reference is a ‘printed publication’ prior art under 35 U.S.C. §§ 102 and 311(b).” *Teva Pharms. USA, Inc. v. Indivio UK Ltd.*, IPR2016-00280, Paper 23 at 10 (PTAB Jun. 10, 2016). Public accessibility is the

“touchstone in determining whether a reference constitutes a printed publication.”

Blue Calypso, LLC v. Groupon, Inc., 815 F.3d 1331, 1348 (Fed. Cir 2016). “A reference will be considered publicly accessible if it was ‘disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence can locate it.’”

Medtronic, Inc. v. Barry, 891 F.3d 1368, 1380 (Fed. Cir. 2018) (alteration mark omitted, quoting *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1350 (Fed. Cir. 2008)).

Here, Petitioner offers no proof in its papers that any of the asserted publications were publicly available. “A party seeking to introduce a reference ‘should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents.’” *Argentum Pharms. LLC v. Res. Corp. Techs., Inc.*, IPR2016-00204, Paper 19 at 9 (PTAB May 23, 2016) (quoting *In re Wyer*, 655 F.2d 221, 227 (CCPA 1981)).

Petitioner also offers no proof that any of the asserted documents were in fact publicly available before the priority date of the ‘271 Patent. Petitioner’s apparent reliance on a copyright notice on several of the asserted documents is not enough. *See, e.g., HewlettPackard Co. v. U.S. Philips Corp.*, IPR2015-01505, Paper 16 at 8 (PTAB Jan. 19, 2016) (“The fact that a date is printed on the face of a reference,

without more, is not enough to establish that the reference was publicly accessible on that date.”).

V. THE CHALLENGED CLAIMS ARE PATENTABLE

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). That burden never shifts to the Patent Owner. *See Dynamic Drinkware v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). “Failure to prove the matter as required by the applicable standard means that the party with the burden of persuasion loses on that point—thus, **if the fact trier of the issue is left uncertain, the party with the burden loses.**” *Id.* at 1379 (emphasis added). Here, the Petitioner has not carried its burden that all of the challenged claims are unpatentable in view of the prior art.

The challenged claims are patentable over *Doo*, *Amira*, *Chen*, *3D Visualization*, and *3D Slicer*, each of which is summarized below. As discussed below, none of the claims are anticipated by *Doo*, none of the claims are obvious over *Doo* in view of *Amira*, and none of the claims are obvious over *Chen* in view of *3D Visualization* and *3D Slicer*.

A. Summary of Alleged Prior Art

1. *Doo* (Ex. 1008)

Doo discloses an “intra-operative medical image viewing system [that] can allow a surgeon to maintain a view perspective on the patient while calling-up visual images on-the-fly.” Ex. 1008, *Abstract*. *Doo*’s medical image viewing system is meant to allow a “surgeon to maintain a proper viewing perspective on the patient while concurrently obtaining relevant information about the patient.” Ex. 1008, ¶ [0011]. *Doo* also discloses a modality 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 yielding the “appearance” of a three-dimensional image. *See, e.g.*, Ex. 1008, ¶ [0075].

2. *Amira* (Ex. 1005)

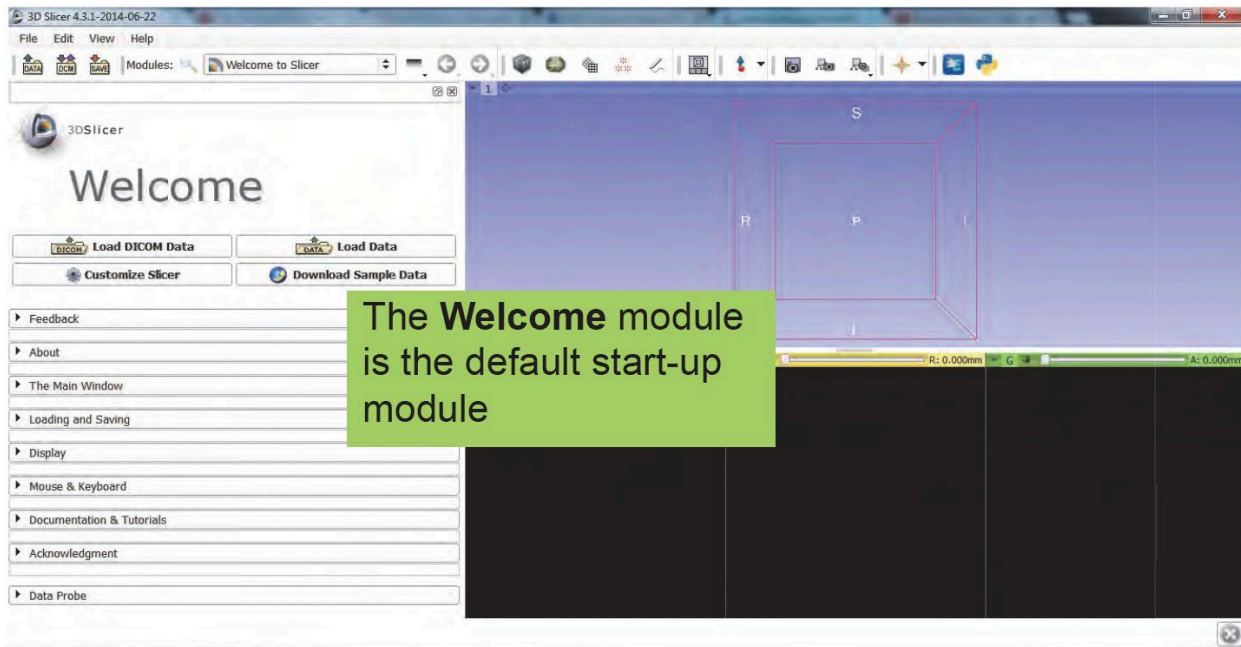
Amira purports to be the first two chapters of a user guide for *Amira* 5. Ex. 1005 at 1. *Amira* is a “3D data visualization, analysis and modeling system,” which “allows you to visualize scientific data sets from various applications areas....” *Amira*, like *3D Slicer*, is a computer software package for medical image visualization and analysis. Ex. 1005 states that *Amira* is “intended for research only” and “is not a medical device.” Ex. 1005 at 4. Like *3D Slicer*, *Amira*’s images are also not visualized in AR. Nor are they projected onto non-image actual views of a patient.

3. *Chen* (Ex. 1009)

Chen discloses “an AR-based surgical navigation system (AR-SNS) ... using an optical see-through HMD (head-mounted display), aiming at improving the safety and reliability of surgery.” Ex. 1009, Abstract. *Chen* acknowledges the “developing a surgical navigation system based on AR is a significant challenge for the next generation.” Ex. 1009 at 1. *Chen* uses surface modeling to reconstruct models of “a 3D bladder and some blood vessels and nerves.” Ex. 1009 at 6.

4. *3D Visualization* (Ex. 1007)

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

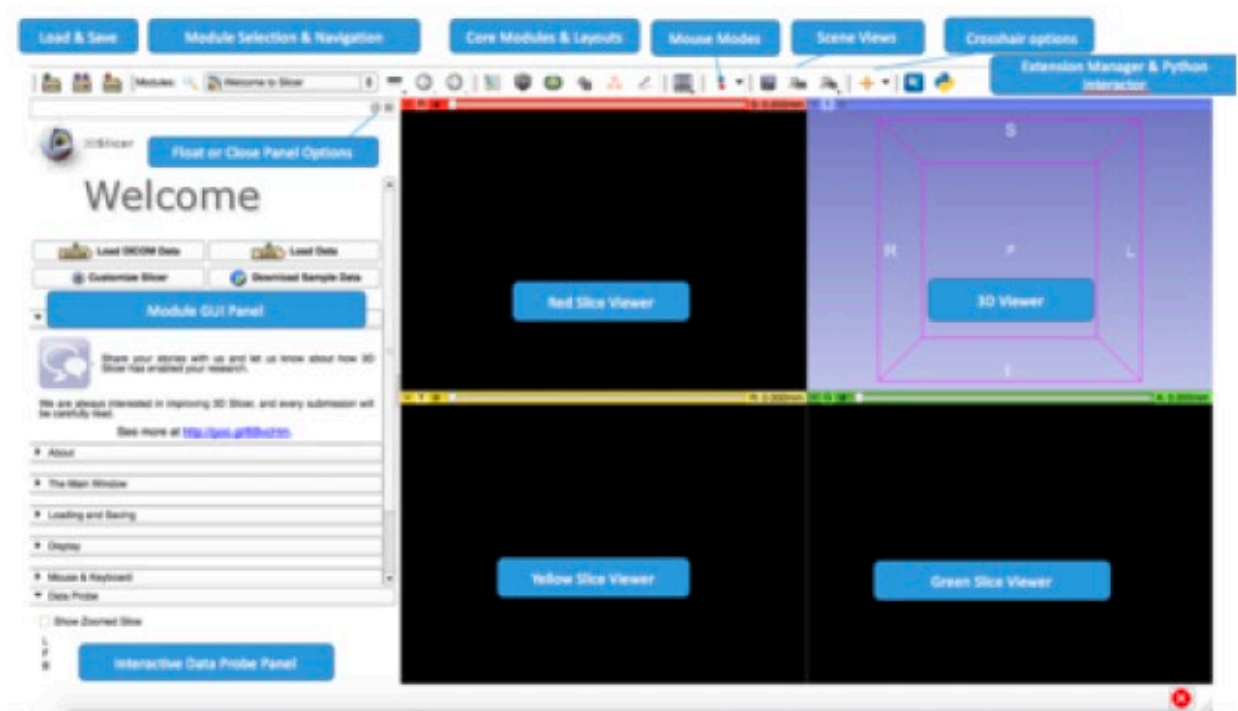


Ex. 1007, Slide 17. Based on *3D Visualization*'s disclosure, presumably "3D Slicer version 4.0" can only be used to view images on a conventional computer monitor. *Id.*

5. *3D Slicer* (Ex. 1010)

Ex. 1010 ("*3D Slicer*") is a seven-page document that purports to be online documentation from "Slicer Wiki" for "Slicer4." Ex. 1010 at 1-2. *3D Slicer* purports to explain "Slicer4's main desktop interface," (Ex. 1010 at 2) but "provides very little information, if any, about what 'Slicer4' actually is or what its capabilities are." Ex. 2002, Mulumudi, ¶ 93. "*3D Slicer* does not disclose that it can be used in an augmented reality (AR) environment." *Id.* *3D Slicer* does not disclose that it can be used to project 3D medical imaging data onto non-image actual views of a patient. *Id.* "*3D Slicer* does not explicitly disclose what imaging

can be loaded into Slicer 4.” *Id.* In its “User FAQ: User Interface” section, it says, “How to load data from a sequence of jpg, tif, or png files?” Ex. 1010 at 7. *3D Slicer* also does not explicitly state how a user can use “Slicer4” to view medical imaging. On page one, *3D Slicer* appears to show a screenshot of a two-dimensional (2D) display, copied below.



Ex. 1010 at 1. Based on *3D Slicer*’s disclosure, presumably Slicer4 can only be used to view “jpg, tif, or png files” on a conventional “desktop” computer monitor. Ex. 2002, Mulumudi, ¶ 93 (citing Ex. 1010 at 2).

B. Ground 1: Claims 1, 5, and 6 Are Not Anticipated by *Doo*.

To establish anticipation, each and every element in a claim, **arranged as recited in the claim**, must be found in a single prior art reference. *See Net*

MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1369 (Fed. Cir. 2008). *Doo* does not disclose all of the elements of claims 1, 5, or 6, much less all of the elements arranged as they are recited in the claims.

1. *Doo* Does not Disclose 1[Pre].

Petitioner relies on Kazanzides' conclusion that a POSITA would understand that *Doo* discloses a “method for augmenting real-time, non-image actual views of a patient with three-dimensional data (3D) data.” Petition at 31 (citing Ex. 1012, ¶ 63-64). Kazanzides cites to *Doo*'s selectively transparent “display worn by the surgeon” that “exhibits to the surgeon an image derived from the image file.” Ex. 1012, ¶ 63 (citing Ex. 1008, *Abstract*). Kazanzides references FIG. 2 of *Doo*, which shows a surgeon viewing a 2D image hovering above a patient.

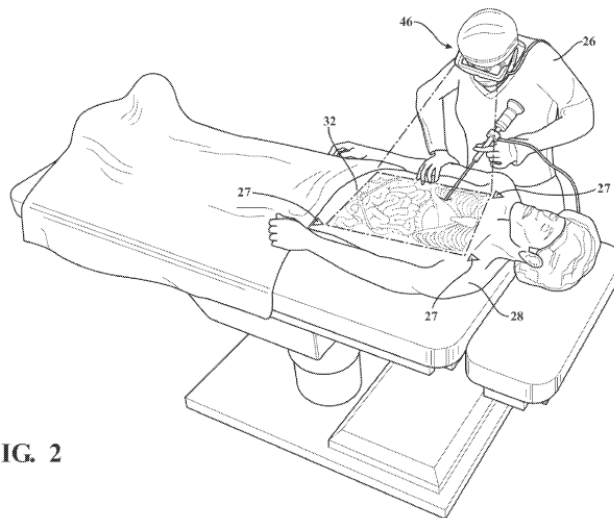


FIG. 2

Petitioner's cited references in *Doo*, do not support Petitioner's allegation. The image projected in FIG. 2 is two-dimensional, not three-dimensional. In addition, *Doo* explains, "In Figure 2, the exemplary image 32 is suggested as an x-ray of the chest of the patient 28.... Figure 2 illustrates how the image 32 can be perceived by the surgeon 26 as hovering directly over the body of the patient." Ex. 1008, [0039]. Meaning, the images are not projected onto the body of the patient.

As such, "a POSITA would not interpret *Doo* as teaching a method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data." Ex. 2002, Mulumudi, ¶ 99.

2. *Doo* Does not Disclose 1[A].

Petitioner asserts that *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." Petition at 31 (citing Ex. 1012, ¶¶ 65-68). Petitioner and Kazanzides effectively assert that any type of medical imaging satisfies this requirement. *See, e.g.*, Petition at 33; Ex. 1012, ¶ 65.

Importantly, however, "the imaging modalities mentioned in *Doo* conventionally produce two-dimensional (2D) images or a series of 2D images." Ex. 2002, Mulumudi, ¶ 101. "While *Doo* identifies potential sources of 3D data for the patient, including "computer-aided tomography" (CT) and "magnetic resonance imaging (MRI)" (Ex. 1008, [0040]), *Doo* does not identify direct

volume rendered data including an outer layer and multiple inner layers of the patient.” *Id.* More specifically, “*Doo* does not disclose 3D ‘inner layers’ that can be confined (i.e., navigated) and viewed along any axis.” *Id.*

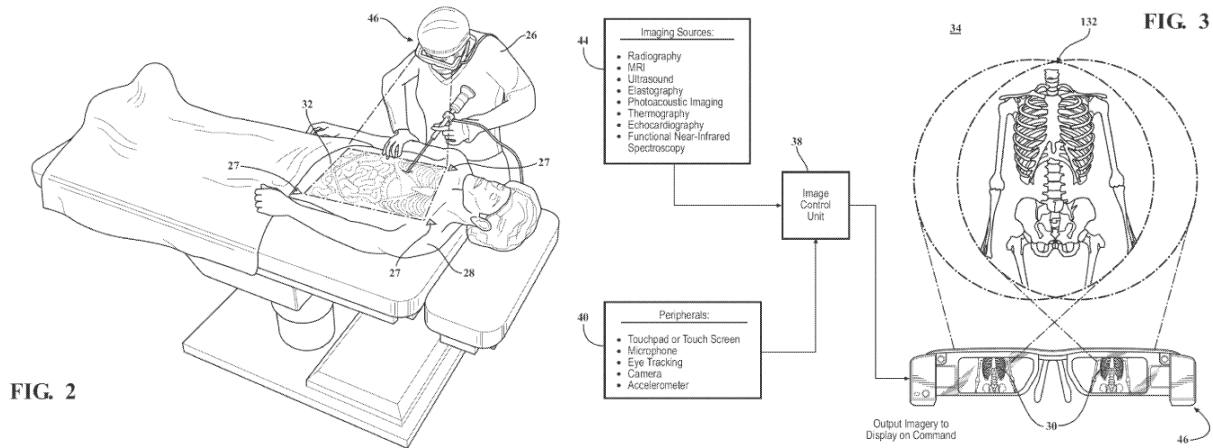
3. *Doo* Does not Disclose 1[B].

Petitioner relies on Kazanzides’ conclusion that *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.” Petition at 34 (citing Ex. 1012, ¶¶ 69-73). Petitioner’s asserted evidence falls short.

Kazanzides contends that, “[a]s illustrated by Figures 2 and 3, *Doo* discloses that the projected display may be inner layers of the patient from the 3D data.” Ex. 1012, Kazanzides, ¶ 103. However, Figures 2 and 3 of *Doo* fail to disclose “displaying ... one of the inner layers of the patient from the 3D data projected onto real-time non-image actual views of the out layer of the patient,” as recited in claim 1. Rather, “Figure 2 shows only a two-dimensional ‘x-ray of the chest of the patient 28.... hovering directly over the body of the patient,’ without any three-dimensional significance.” Ex. 2002, Mulumudi, ¶ 103 (citing Ex. 1008, [0039]). Figure 3 of *Doo* shows only a bone model “overlaid on the patient 28 by at least one of panning, zooming and rotating the image 132, as well as tilting, key-

stoning, half-toning, texturing, wrapping or other image manipulation techniques.”

Ex. 1008, [0041].



Neither Figure 2 nor Figure 3 discloses “displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient.” Ex. 2002, Mulumudi, ¶ 104. Specifically, “neither Figure 2 nor Figure 3 discloses a volume of the anatomy of the patient at a certain depth below the outer layer, or skin, of the patient.” *Id.* Moreover, “*Doo* does not disclose 3D ‘inner layers’ that can be confined (i.e., navigated) and viewed along any axis.” *Id.*

4. *Doo* Does not Disclose 1[C].

Petitioner argues that “[a]t the relevant time, medical imaging displayed images of patients inner layers confined within a virtual 3D shape, which may or may not be displayed.” Petition at 38; Ex. 1012, ¶ 76. However, neither Petitioner

nor Kazanzides identify any reference disclosing “3D [medical imaging] data being confined within a volume of a virtual 3D shape,” as recited in claim 1.

Petitioner relies on Kazanzides’ conjecture that *Doo* discloses “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.” Petition at 36 (citing Ex. 1012, ¶¶74-77). Kazanzides’ unsupported conclusion is incorrect for at least three reasons.

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

Petitioner and Kazanzides contend that Figures 7 and 9 from *Doo* satisfy element 1[C]. Petition at 36-37; Ex. 1012, ¶ 75. Figures 7, 8, and 9 are copied below for the Board’s convenience:

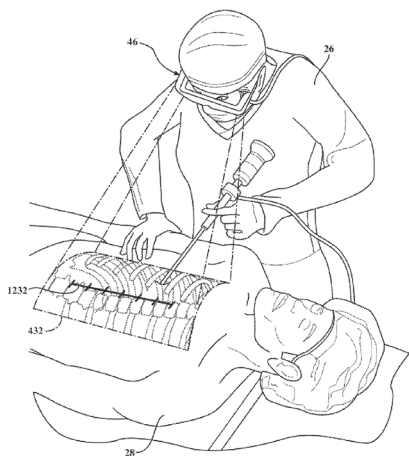


FIG. 7

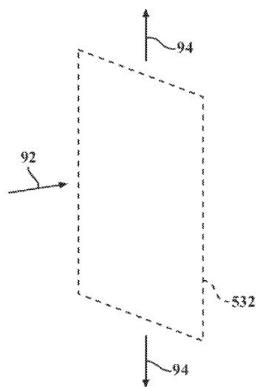


FIG. 8

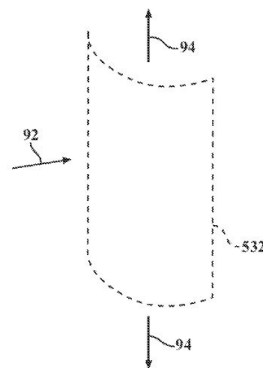


FIG. 9

Doo explains, “Figure 7 illustrates the application of a third three-dimensional modality, sometimes referred to as “false 3D” or “2.5D” in which a

two-dimensional image can be wrapped around a three-dimensional structure, namely the body surface of the patient.” Ex. 1008, ¶ [0075]. *Doo* further explains,

Figures 8 and 9 further illustrate the concept of image wrapping in the preceding Figure 7. Figure 8 is a perspective view of *a two-dimensional image* 532 in a planar configuration. 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.

Ex. 1008, *Doo*, ¶ [0076] (emphasis added).

On its face, *Doo*’s curved 2D plane, illustrated in Figures 7 and 9, is not 3D data. Ex. 2004, Rosenberg, ¶ 123. Rosenberg explained, “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.’” *Id.* (citing Ex. 1001, 6:14-17). “*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. 2004, ¶ 124 (citing Ex. 1001, 6:14-17).

b. *Doo*’s Figure 11 Does Not and Cannot Confine a 3D Volume.

Petitioner and Kazanzides also contend 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.” Petition at 38; Ex. 1012, ¶ 76. Figure 11 is copied below.

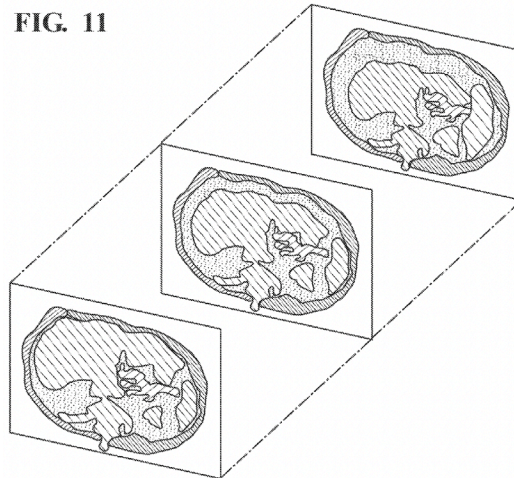


Figure 11 “is a series of three-dimensional tomographic slices of an anatomical feature of a patient.” (Ex. 1008, ¶ [0026]). “FIG. 11 shows only a graphical representation of a series of three tomographic slices of an anatomical feature of a patient.” Ex. 2002, Mulumudi, ¶ 110. The “rectangles surrounding and the dashed lines connecting each slice are only meant to illustrate an alignment of the representative slices.” *Id.* Indeed, they are not representative of any virtual 3D shape, as recited in claim 1. *See Id.* Put plainly, any images from *Doo* would be incapable of being effectively navigated in any direction. Mulumudi explains that stitching slices together creates inaccuracies versus taking an entire volume or block, with 3D volume rendering having the ability to freeze an entire organ and then obtain 3D slices in any direction needed to obtain the necessary anatomic detail. *See* Ex. 2002, ¶¶ 86-90.

c. *Doo*'s Figure 6 Does Not and Cannot Confine a 3D Volume.

Petitioner asserts, “*Doo*'s Figure 6 illustrates the projection of a virtual heart into a patient,” but make no further argument on this point. Petition at 38.

Figure 6 from *Doo* is copied below.

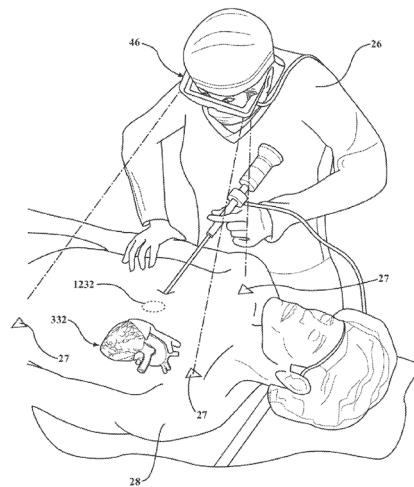


FIG. 6

Figure 6 clearly does not disclose “the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.” On the contrary, *Doo* merely discloses a surface rendering (i.e., a shell) of a heart “that does not appear to include either internal or surrounding anatomical structure.” Mulumudi ¶ 85.

5. *Doo* Does Not Disclose the Elements of Claim 5.

Petitioner asserts 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” arguing that “the dashed lines of *Doo*'s Figure 9 define a virtual

3D shape.” Petition at 39 (citing Ex. 1012, ¶¶ 78). Petitioner also argues that “*Doo*’s Figure 7 illustrates the projection of inner layers of a patient confined within a volume of a virtual 3D shape, which is shape is similar to that illustrated by *Doo*’s Figure 9.” Petition at 39. For the reasons provided above, *Doo*’s curved 2D plane, illustrated in Figures 7 and 9, is clearly not 3D data. *Supra* at 29-32. For convenience, Figure 7 is copied below.

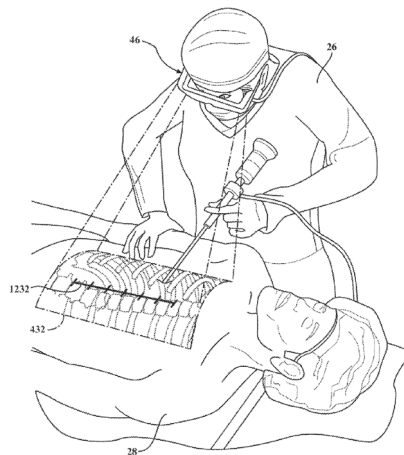


FIG. 7

Petitioner asserts that the “dashed lines in *Doo*’s Figure 7 ... are hidden because they do not **seem** to be visible to the surgeon.” Petition at 39 (emphasis added). Petitioner is speculating. *Doo*’s curved 2D image 432 is nothing more than the virtual equivalent of a folded piece of paper. It is like printing out a 2D picture and bending it over the patient’s chest. Tacitly admitting this fact, Petitioner argues that that the folded paper discloses a “virtual 3D shape” and the edges of the paper disclose “wherein the lines of the virtual 3D shape are hidden”

because “they do not seem to be visible.” But *Doo* plainly does not disclose a virtual 3D shape. And nowhere does *Doo* disclose the hidden lines required by claim 5.

Petitioner argues, without support, that “to the extent that *Doo* does not directly disclose hiding the lines ... *Doo* at least inherently discloses that the lines of the virtual 3D shape illustrated in Figures 9 and 7 could be hidden.” Petition at 40. Petitioner offers no evidence for *Doo*’s purported inherent disclosure. It is true that when a reference is silent about an “inherent” characteristic, the gap may be filled with extrinsic evidence. However, “[s]uch evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). “Inherency, however, **may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**” *Id.* at 1269 (emphasis added). Petitioner’s inherency arguments constitute conjecture based on possibilities, not scientific fact.

As discussed above, *Doo* does not disclose a “virtual 3D shape,” as recited in claim 1. *Supra* at 28-31. 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.

6. *Doo* Does Not Disclose the Elements of Claim 6.

Because *Doo* does not disclose all of the elements of the method as recited in claim 1, as discussed above (*supra* at 24-32), *Doo* also does not disclose all of the elements of claim 6.

C. Ground 2: Claims 1-6 and 11-20 Are Not Obvious Over *Doo* in View of *Amira*⁴.

Claims are not patentable where “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103. Obviousness must be assessed on the basis of factual inquiries regarding (i) the scope and content of the prior art, (ii) differences between the claimed subject matter and the prior art, (iii) the level of skill in the art, and (iv) objective evidence of nonobviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966). In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would

⁴ As noted above, Petitioner has not demonstrated that *Amira* is prior art. *Supra* at 2 n.1. Patent Owner, however, addresses *Amira* herein irrespective of that fact.

have been obvious, but whether the claimed invention **as a whole** would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983) (emphasis added). Petitioner has failed to meet that burden. Rather, it cherry picks portions of alleged references in a general fashion and combines them with nothing but conclusory statements.

In that vein, Petitioner's burden also requires it "to identify a reason that would have prompted a person of ordinary skill . . . to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Petitioner has failed to adequately do so. Obviousness cannot be established unless the combination of references teaches or suggests **all claim elements**. *See, e.g., KSR Int'l v. Teleflex, Inc.*, 550 U.S. 398, 418–419 (2007). A reason to modify and combine the references must be provided. And that reason must be more than conclusory allegations and suppositions. *Id.*

1. Doo and Amira Do Not Disclose All of the Claim Elements Recited in 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."

As noted above (*supra* at 24-34), *Doo* does not disclose all the elements recited in Claims 1-6. *Amira* does not ameliorate those deficiencies.

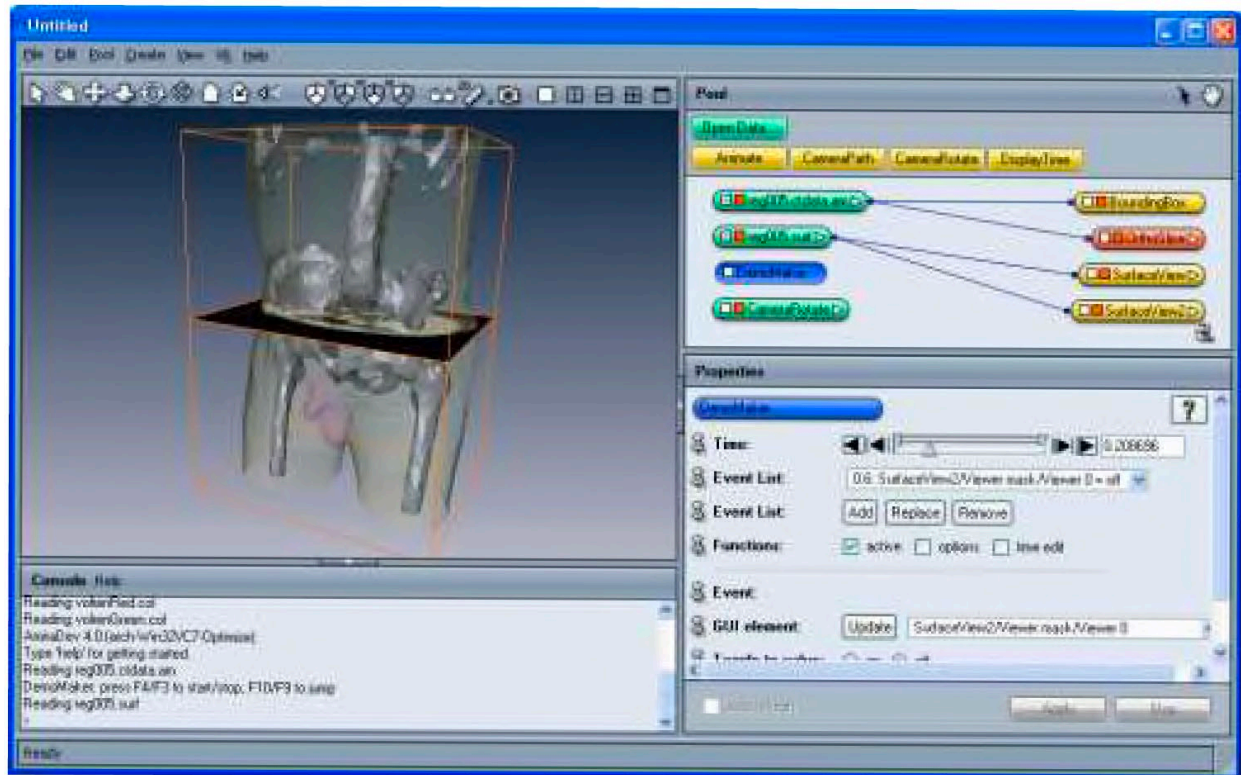
Namely, *Amira* does not disclose the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape. Specifically, *Amira* does not “**project** an inner layer of the patient from the 3D data,” onto the patient at all. Ex. 2004, Rosenberg, ¶ 134. Kazanzides appears to draw his conclusions based on a description of an optional, but unexplained, module (“*Amira* Virtual Reality Option”) from *Amira*’s introduction. Even if *Amira* offered a “virtual reality option”, “in a virtual reality (VR) environment on a computer, objects are not projected onto the real world.” *Id.* “In VR the entire environment is virtual.” *Id.* This is significantly different from an augmented reality environment where virtual objects are projected onto a real-life object. See Ex. 2004, Rosenberg, ¶¶ 117-18. “*Amira*’s 2D and VR solutions are not solutions to the challenges of projecting medical imaging onto a real patient in an AR environment.” *Id.*, ¶ 118.

The Petitioner must specifically identify where the cited prior art references disclose each and every element of the claim. It is not enough to identify a few structural elements of the claim. The specific relationship between the elements, if recited by the claim, must be present in the references. In *Microsoft Corp. v. Global Touch Solutions, LLC*, the PTAB agreed a publication disclosed “detecting user proximity and user contact,” but found the petitioner failed to “distinguish[] between proximity and physical contact events” as the claim required. IPR2015-

01024, Paper 11, slip op. at 7 (September 23, 2015) (emphasis in original).

Petitioner likewise failed to identify specific relationships as recited in the claims.

In addition to the forgoing deficiencies, *Amira* also does not disclose “the 3D data being **confined** within a volume of a **virtual** 3D shape.” Petitioner relies on a screenshot on page 80 of *Amira* (Ex. 1005 at 92), shown below, in an effort to show the contrary.



Specifically, Petitioner contends that *Amira*’s illustration of “a 3D bone model within both a [3]D translucent skin model and a bounding box” satisfies the “virtual 3D shape” requirement. Petition at 42. However, the ‘virtual 3D shape’ of claims 1-5 is a virtual tool for navigating the projected 3D data in an augmented

reality environment. Ex. 2004, Rosenberg, ¶¶ 86-87. *Amira* does not disclose such a virtual 3D shape. *Id.*, ¶¶ 136-139. “*Amira* shows only a bounding box that is not used in an AR environment at all.” *Id.*

Put another way, “*Amira*’s bounding box merely represents the space in which the displayed data set exists.” Ex. 2002, Mulumudi, ¶ 128. “In *Amira* the bounding box of an object is the smallest rectangular, axis-aligned volume in 3D space that encompasses the object.” Ex. 1005 at 40. “*Amira* does not disclose that its bounding box can be used to ‘assist the user when navigating the projected 3D data.’” Ex. 2004, ¶ 139 (citing Ex. 1001, 6:14-17); *see also id.* at ¶ 138 (“*Amira* also does not disclose that its ‘skin model’ can be used to “assist the user when navigating the projected 3D data.”).

Mulumudi explained that “the ‘virtual 3D shape’ [] is a tool for navigating, in real time, direct volume rendered 3D data, while it is projected onto non-image actual views of a patient.” Ex. 2002, Mulumudi, ¶ 128. “*Amira* shows only polygonal surface models (bones and skin) surrounded by a box.” *Id.* “*Amira* does not show direct volume rendered 3D data confined within a virtual 3D shape.” *Id.*

More specifically, “*Amira*’s bone model is a ‘polygonal surface model’ (“data/medical/reg005.surf”) generated only after segmentation of the 3D image volume.” Ex. 2002, Mulumudi, ¶ 125 (citing Ex. 1005 at 89). Here, the projected inner layer of claim 1 is a volume rendering of the anatomy of the patient “without

segmentation and without constructing intermediate polygonal models.” Ex. 2002, Mulumudi, ¶ 126. This is not what *Amira* discloses. *Id.*

Even if *Amira* disclosed what Petitioner claims, the Petition has not explained, nor can it, how *Amira* would have been modified to operate in an AR environment. “If the proposed modification of the prior art would change the basic principles of operation of the prior art being modified, the teachings of the references are insufficient to render the claims obvious.” *See, e.g., Ex parte LARS STOPPE*, 2023 Pat. App. LEXIS 1765, *9 (P.T.A.B. May 23, 2023) (citing *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959)).

- 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.”

As discussed above, *Amira* does not disclose the “virtual 3D shape” of claim 1. *Supra* at 36-40. 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.”

As discussed above, *Amira* does not disclose the “virtual 3D shape” of

claim 1. *Supra* at 36-40. *Amira* also does not disclose “wherein ... the virtual 3D shape is configured to be controlled to reposition ... 3D slices of the projected inner layer of the patient from the 3D data,” as recited in claim 3.

Petitioner and Kazanzides contend 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.” Petition at 44; Ex. 1012, Kazanzides, ¶ 86. As support, Kazanzides cites to *Amira*’s trackball button in the viewer tool bar and 3d rotate icon. Ex. 1012, ¶ 86 (citing Ex. 1005 at 24 and 100).

In doing so, Kazanzides tacitly admits that *Amira* discloses using a conventional mouse and a user interface displayed on a conventional computer monitor to rotate an object displayed on the computer monitor. This “is vastly different from a virtual control or virtual user interface in an augmented reality (AR) environment.... virtual controls in an augmented reality (AR) environment are very different from using a mouse and keyboard in front of a computer monitor.” Ex. 2004, Rosenberg, ¶ 143.

“[T]he ‘virtual 3D shape’ of claim 1 is a ‘virtual control’ designed for an AR environment.” *Id.* at 144. “The user uses hand gestures to move 3D slices “confined within a volume of a virtual 3D space.” *Id.* Because it is a virtual control, “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.” *Id.* “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 the combination would fundamentally change how *Amira*’s box works.” *Id.*

For example, *Amira* cannot be used in an AR environment. *Id.* at ¶ 145. *Amira* does not disclose that its bounding box can be used to “assist the user when navigating the projected 3D data.” *Id.* (citing 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. *Id.* *Amira* does not disclose that its bounding box can “reposition ... 3D slices of the projected inner layer of the patient.” *Id.* 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. Ex. 2004, Rosenberg, ¶ 145.

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

As discussed above, *Amira* does not disclose the “virtual 3D shape” of claim 1. *Supra* at 36-40. 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.”

As discussed above, *Amira* does not disclose the “virtual 3D shape” of claim 1. *Supra* at 36-40. 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.”

As discussed above, *Amira* does not disclose the method as recited in claim

1. *Supra* at 36-40. For the same reasons, *Amira* does not disclose the elements of claim 6.

2. *Doo* and *Amira* Do Not Disclose All of the Claim Elements Recited in Claim 11.

- a. ***Doo* and *Amira* Do Not Disclose the Preamble or claim element 11[A].**

As noted above (*supra* at 25-26), *Doo* does not disclose 1[A]. For the same reasons, *Doo* does not disclose 11[A]. *Amira* does not remedy that deficiency.

Amira generally displays images and objects on 2D computer monitors. Ex. 2004, Rosenberg, ¶ 149. *Amira* does not disclose projecting 3D data on to non-image actual views of the patient. *Id.*

- b. ***Doo* and *Amira* Do Not Disclose claim element 11[B].**

Kazanides broadly concludes that “the same color adjustment technology applies to improving visibility of a virtual image overlaid on the actual patient view.” Ex. 1012, Kazanides, ¶ 96. Kazanides appears to begin with *Doo*’s “adjusting the transparency of the overlaid image” to reach that conclusion. Ex.

1012, ¶ 91. But changing transparency or opacity of an image is different from “altering the original color gradient of the multiple inner layers to be lighter than the original color gradient in order to be better visible when projected onto real-time, non-image actual views of the patient.” Ex. 2002, Mulumudi, ¶ 138.

Kazanvides uses *Amira* in an attempt to cure *Doo*’s deficiency. However, *Amira* is software for displaying medical imaging on a computer monitor. Ex. 2004, Rosenberg, ¶ 149. *Amira* does not “augment[] real-time, non-image actual views of a patient.” *Id.* *Amira* also does not project “3D data ... onto real-time, non-image actual views of the outer layer of the patient.” *Id.* Nor does *Amira* “alter the original color gradient [of the 3D data] to be better visible when projected onto real-time, non-image actual views of the outer layer of the patient.” *Id.*, ¶ 155. A POSITA, looking at *Amira*, would not appreciate the challenges associated with “altering the color gradient of direct volume rendered 3D imaging to be better visible when projected on to non-image actual views of a patient in an operating room.” Ex. *Id.*

Rosenberg explained that “[a]ugmented reality (AR) adds extra layers of complexity to the processes of rendering and visualizing 3D medical data, including the adjustment of color gradients.” Ex. 2004, ¶ 151. “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.”

Id. Rosenberg provided numerous examples, including: lighting conditions, display technology limitations, and subjective perception. *Id.*, ¶¶ 152-154.

Rosenberg explained that, “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.” *Id.* at ¶ 155. “*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 in AR.” *Id.*

Kazanvides also appears to rely on *Amira*’s “segmentation of 3D data into different structures, in which different portions of the 3D data have been assigned different colors.” Ex. 1012, ¶ 94. However, unlike *Amira*, the projected 3D data of the ’271 patent does not require an intermediate segmentation step and is not a surface model. Ex. 2002, Mulumudi, ¶¶ 58, 126. Moreover, adjusting the color gradient of a surface model displayed on a conventional computer monitor is vastly different from adjusting color gradients within a direct volume rendered 3D image. *Id.*, ¶¶ 150-155. One is not a substitute for the other. *Id.*, ¶ 155.

Kazanvides also relies on *Amira*’s use of “an editable color map to control visualization of an overlay image” and “image fusion,” which “consists of combining relevant information from two or more images into a single image using different color mappings.” Ex. 1012, Kazanvides, ¶ 96. Again, Kazanvides

mistakenly equates “altering the original color gradient of the multiple inner layers” with *Amira*’s use of “overlay image[s]” and “image fusion” on a computer monitor. Ex. 2002, Mulumudi ¶ 139. This is different from “altering the original color gradient of the multiple inner layers.” See Ex. 2004, Rosenberg, ¶¶ 150-155.

c. *Doo* and *Amira* Do Not Disclose claim element 11[C].

As discussed above, neither *Doo* nor *Amira* disclose projecting an inner layer of the patient from 3D data onto non-image actual views of the outer layer of the patient, where the projected inner layer has an altered color gradient. *Amira* does not project images onto real-world environments in AR at all. Ex. 2004, Rosenberg, ¶ 156. And *Amira* certainly does not project inner layers of a patient with an altered color gradient directly onto the outer surface of a patient. Ex. 2002, Mulumudi, ¶ 140.

3. *Doo* and *Amira* Do Not Disclose All of the Claim Elements Recited in Claims 12-20.

Kazanides opines, with absolutely no support, that a POSITA “would have understood that a color gradient could be applied to represent any parameter that a user could identify or define based on the available 3D data.” Ex. 1012, ¶ 101. Kazanides fails to identify any of the tissue properties recited in claims 12-19. Ex. 2004, ¶ 159.

Petitioner contends that “*Amira* discloses coloring based on a detected property in a 3D data set.” Petition at 48. However, the only properties Petitioner identifies in *Amira* are “a surface colored according to its curvature” (Ex. 1005, 17) and “blood flow.” Petition at 49, 53. *Amira*’s blood flow visualization requires “[l]oad[ing] the surface model of the carotids *bloodFlow.ruf.am* from the tutorial directory *data/tutorials/vector*; Attach[ing] an *SurfaceView* module to this data object; Load[ing] the data set called *bloodFlow.vector.am* from the tutorial directory;” and “Connect[ing] a *Vectors* module to the vector field *bloodFlow.vector.am*.” Ex. 1005 at 81. *Amira*’s labeling of surface models is very different from identifying tissue properties within the direct volume rendered 3D data. Ex. 2002, Mulumudi, ¶ 143. 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]. *Id.*

In surface rendering, colors are typically assigned to the vertices or faces of the polygonal surface model. Ex. 2002, Mulumudi, ¶ 170. The model is then illuminated using computer graphics techniques such as shading, which can simulate the effects of light reflection, refraction, and shadow. *Id.* Changing the color gradient in surface rendering usually involves changing the vertex or face colors and adjusting the lighting parameters. *Id.* In surface rendering, the colors

are typically determined by the segmentation step, where different structures are labeled with different colors. *Id.* at 171. The colors can then be adjusted manually, or they can be mapped to the surface curvature or other geometric properties to highlight certain features. *Id.* While both DVR and surface rendering methods involve assigning colors to create a visual representation of the 3D data, the specifics of how the colors are assigned and how they can be adjusted are very different.” *Id.* at 172.

As discussed above, *Amira* also does not disclose “the projected inner layer of the patient from the 3D data ... having the altered color gradient,” as recited in claim 11. *Supra* at 43-46. Foremost, *Amira* does not project images onto real-world environments in AR or adjust original color gradients of 3D images to be better visible when projected onto a real patient in an operating room. For at least this reason, *Amira* also does not disclose the elements of claims 12-19.

Based on the foregoing, “a POSITA would understand that *Amira* does not disclose the “altering” step of claim 11.” As discussed above, *Amira* and *Doo* do not disclose the method as recited in claim 11. *Supra* at 43-46. For the same reasons, *Amira* does not disclose the elements of claim 20.

4. There is No Motivation to Combine *Doo* with *Amira*.

Petitioner’s proposed combinations are hindsight. “Care must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the

maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.” *In re NTP, Inc.*, 654 F.3d 1279, 1299 (Fed. Cir. 2011).

Here, the POSITA would not think to ameliorate *Doo*’s deficiencies with *Amira*. First, the ‘271 Patent discloses the projection of 3D data onto non-image actual views of a patient in an augmented reality (AR) environment. The 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. That virtual tool can be “configured to be controlled” to “reposition ... 3D slices of the projected inner layer of the patient,” as also recited in claim 3.

Petitioner has failed to “include articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Volkswagen Grp. of Am., Inc. v. Velocity Patent LLC*, IPR2015-00276, Paper 8, slip op. at 11 (PTAB Jun. 1, 2015) (quoting *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007)). To prevail, the analysis must be explicit as to why one skilled in the art would “combine the elements in the way the claimed new invention does.” *Id.* at 11.

Similarly, in *Shopkick, Inc. v. Novitaz, Inc.*, the petitioner failed to provide a meaningful analysis and relied on the fact that the cited references were analogous art and shared common design incentives with the patent under review. IPR2015-

00279, Paper 7, slip op. at 26–30 (May 29, 2015). In denying institution, the PTAB explained that “conclusory labels do not substitute for a fact-based analysis ... establishing what is being modified and why, based on the differences between the prior art and the claimed invention, it would have been obvious to a person of ordinary skill to make the modification.” *Id.* at 30.

Here, Petitioner has not provided any meaningful analysis of the art nor provided evidence as to 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. According to Rosenberg, “such a conclusion is unsupportable and unreasonable.” Ex. 2004, ¶ 169. Neither *Doo* nor *Amira* discloses 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* discloses 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* discloses 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* adjusts the color gradient of direct volume 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. Although *Amira* adjusts the color of surface models, it does not project 3D medical imaging

in an augmented reality (AR) environment at all. For that reason, a POSITA would understand that *Amira* could not possibly disclose cure the deficiencies of *Doo*.

Petitioner stretches the prior art to the point of breaking, particularly where *Amira* cannot be used in an AR environment at all. *Doo* and *Amira* must disclose all the elements of the claim. They do not. As such, there is no motivation to combine and no expectation of success. *Par Pharm. Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1195–96 (Fed. Cir. 2014) (where the motivation to combine and reasonable expectation of success is only considered “if all the elements of an invention are found in a combination of prior art references.”).

Missing elements cannot be supplied by bare allegations that a POSITA might be able to “predict” them. Rather, Petitioner must prove anticipated success from known, finite options. *Teva Pharms, USA, Inc. v. Sandoz Inc.*, 906 F.3d 1013, 1025 (Fed. Cir. 2018). Petitioner has not done so. It is not enough to have general guidance in a promising field of experimentation. *Id.* “[T]o have a reasonable expectation of success, one must be motivated to do more than merely...try each of numerous possible choices until one possibly arrived at a successful result.” *In re Stepan Co.*, 868 F.3d 1342, 1347 (Fed. Cir. 2017). Petitioner’s proposed combination are no more than an attempt to try each of a number of possible choices until one possibly arrived at combination of elements recited in the claims

of the '271 Patent. This is not enough.

A POSITA would not have been motivated to so combine *Doo* and *Amira*, nor would they have had a reasonable expectation of success if they had. *See* Ex. 2004, Rosenberg, ¶ 163.

D. Ground 3: Claims 1-6 and 11-20 Are Not Obvious Over *Chen* in view of *3D Visualization* and *3D Slicer*.

1. *Chen*, *3D Visualization* and *3D Slicer* Do Not Disclose All of the Elements Recited in Claims 1-6 and 11-20.

a. *Chen* Does Not Disclose the Preamble of Claim 1.

As a starting point, *Chen* does not disclose an AR method using DVR medical imaging. Rather, *Chen* discloses the use of surface modelling to reconstruct 3D models of a pelvis, bladder, and miniscrews, shown below:

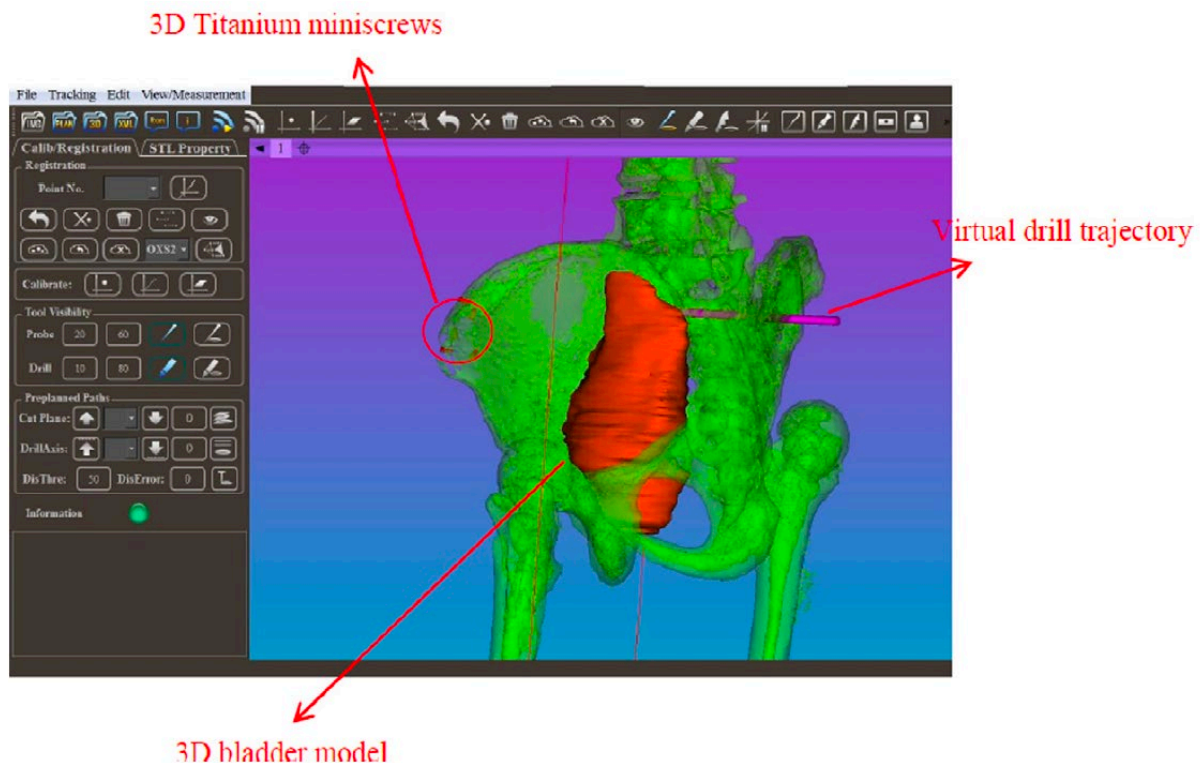


Fig. 3. A 3D pelvis model and a bladder imported into the AR-SNS.

Ex. 1009 at 3. “As with the other surface modelling references relied upon by Dr. Kazanzides, *Chen*’s imaging is different from the claimed invention.” Ex. 2002, ¶ 153. *Chen* explains, “[O]n the basis of the preoperative CT data of a patient, imaging segmentation is conducted, so that 3D models including hard and soft tissues, especially critical anatomical structures such as blood vessels and nerves can be reconstructed.” Ex. 1009 at 2. “*Chen*’s ‘feature specific’ models were created using surface rendering techniques and then “imported into the AR-SNS system.” Ex. 2002, ¶ 144 (citing Ex. 1009 at 2).

As discussed above, in view of the claims 1-6 and the specification, “3D data including an outer layer of the patient and multiple inner layers of the patient” requires direct-volume-rendered imaging. *Supra* at 11-14. “*Chen* discloses only surface models.” Ex. 2002, ¶ 145.

b. *Chen* Does Not Disclose 1[A], 1[B].

Chen identifies potential sources of data for the patient, including “CT data.” Ex. 1009, Figure 2. However, *Chen* converts only a portion of the data into a few ‘feature-specific’ surface models. Petitioner states that in *Chen* “imaging segmentation is conducted, so that 3D models ... especially critical structures ... can be reconstructed.” Petition at 57 (citing Ex. 1009, 125/2:1-5). “This is different from the 3D data used in the claimed invention.” Ex. 2002, Mulumudi, ¶ 147.

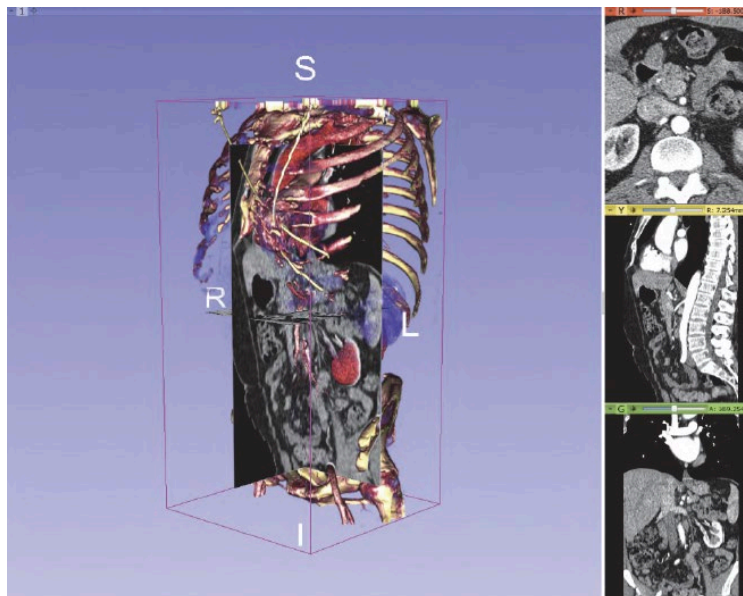
Kazanides concludes that *Chen* discloses the step of ‘displaying, in an augmented reality (AR) headset, one of the inner layers of the patient from the 3D data projected onto real-time, non-image actual views of the outer layer of the patient.’” Ex. 1012, ¶ 117. However, *Chen*’s models, unlike DVR imaging, do not disclose an inner layer of the “3D data”. Ex. 2002, Mulumudi, ¶ 148. *Chen*’s models are only graphical representations of the surfaces of anatomical features of interest. They do not include any internal and or surrounding anatomical structure. *Id.*, ¶ 85. Moreover, *Chen* does not disclose “inner layers” that can be navigated

all the way through the projected 3D data and viewed from any angle like DVR imaging can. Ex. 2002, ¶ 147.

c. *Chen, 3D Visualization and 3D Slicer Do Not Disclose 1[D].*

Neither Petitioner nor Kazanzides argue that *Chen* discloses the “confined” limitation of claim 1. As explained below, *3D Slicer* and *3D Visualization* also do not disclose the “confined within a virtual 3D shape” limitation of claim 1 and, therefore, do not cure the deficiencies of *Chen*.

Petitioner contends that the “virtual 3D shape in the image of *3D Visualization*’s slide 44 is a virtual 3D box illustrated in magenta.” Petition at 60. Slide 44 of Exhibit 1007 is copied below:



Kazanzides contends that *3D Visualization*’s magenta box satisfies the “virtual 3D shape” of claims 1-6. Ex. 1012, ¶ 118. However, “the ‘virtual 3D

shape’ of claims 1-6 is a tool for navigating the projected 3D data.” Ex. 2004, Rosenberg, ¶ 168; *see supra* 15-17. *3D Slicer* and *3D Visualization* do not disclose such a ‘virtual 3D shape,’ as required by claims 1-5. *Id.* *3D Slicer* and *3D Visualization* show only a non-virtual box that cannot be used in an AR environment at all. *Id.* Moreover, “*3D Visualization* does not disclose that its box can be used to ‘assist the user when navigating the projected 3D data.’” *Id.*, ¶ 169 (citing Ex. 1001, 6:14-17).

In addition to the foregoing, *3D Slicer* and *3D Visualization* also do not ‘*project* an inner layer of the patient from the 3D data,’ as required by claim 1.” Ex. 2004, Rosenberg, ¶ 166. *3D Slicer* and *3D Visualization* only display images and objects on 2D computer monitors. *Id.*

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.”. *Id.*

d. *Chen, 3D Slicer* and *3D Visualization* Do Not Disclose Claim 2.

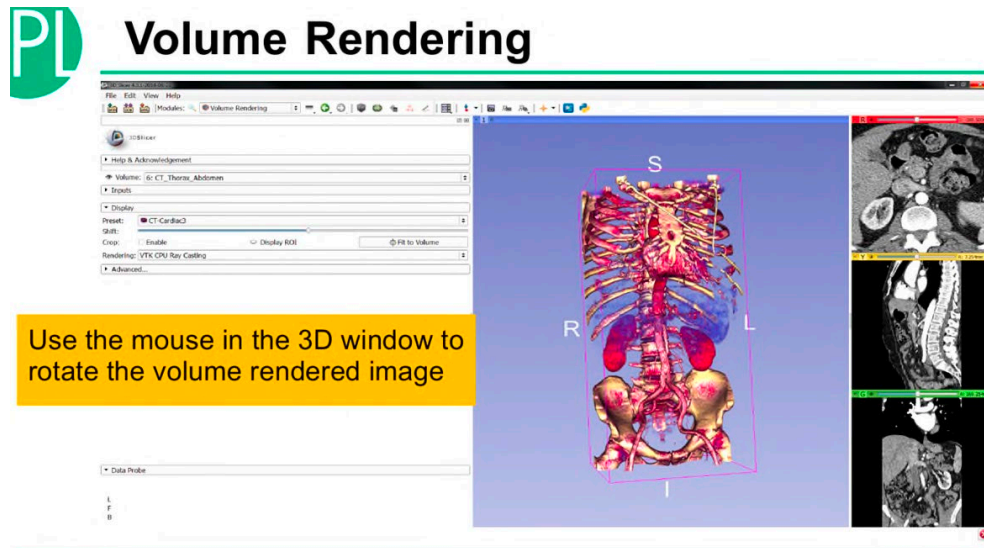
Petitioner tacitly acknowledges that *Chen* does not disclose the limitations of claim 2. As discussed above, *3D Slicer* and *3D Visualization* do not disclose the “confined within a virtual 3D shape” limitation of claim 1 and, therefore, does not cure the deficiencies of *Chen*. *Supra* at 54-55. In other words, whatever shape

may be shown in *3D Slicer* and *3D Visualization*, the shape is nothing more than a static boundary for the images shown on the computer monitors. It is unquestionably not a tool used to navigate projected DVR medical imaging. *See* Ex. 2004, ¶¶ 168-169.

e. *Chen, 3D Slicer and 3D Visualization Do Not Disclose Claim 3.*

Petitioner and Kazanzides tacitly acknowledge 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 *Chen*’s deficiencies. *Supra* at 54-55.

That deficiency aside, Petitioner and Kazanzides contend that *3D Visualization* discloses a box “configured to be controlled to reposition ... 3D slices of the projected inner layer of the patient.” Ex. 1012, ¶ 121. As support, Petitioner and Kazanzides provide only slide 46 from *3D Visualization*, copied below, which states one can, “Use the mouse in the 3D window to rotate the volume rendered image.” Ex. 1007, slide 46.



Petitioner and Kazanzides acknowledge that *3D Visualization* uses a conventional mouse and a user interface on a conventional computer monitor to rotate an object displayed on the computer monitor. Petition at 61-62. As stated previously, “this is vastly different from a virtual control or virtual user interface in an augmented reality (AR) environment.” Ex. 2004, Rosenberg, ¶ 173.

Rosenberg explained that a “POSITA would understand that the ‘virtual 3D shape’ is a ‘virtual control’ designed for an AR environment.” Ex. 2004, ¶ 174. “The user uses hand gestures to move 3D slices ‘confined within a volume of a virtual 3D space.’” *Id.* “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.” *Id.* This is vastly different than simply rotating a 3D image on a static computer screen.

Moreover, *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. Nor does it disclose that its static box can “reposition ... 3D slices of the projected inner layer of the patient,” as recited in claim 3.

f. *Chen, 3D Slicer and 3D Visualization Do Not Disclose Claim 4.*

Petitioner tacitly acknowledges that *Chen* does not disclose the limitations of claim 4. As discussed above, *3D Slicer* and *3D Visualization* do not disclose the “virtual 3D shape” limitation required by claim 1 and, therefore, do not cure the deficiencies of *Chen*. *Supra* at 54-55. In other words, they do not disclose a virtual 3D shape that is a navigation tool. Rather, any static box, with or without lines, is simply a boundary.

g. *Chen, 3D Slicer and 3D Visualization Do Not Disclose Claim 5.*

Kazanides tacitly 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*. *Supra* at 54-55.

h. *Chen, 3D Slicer and 3D Visualization Do Not Disclose Claim 6.*

Kazanides opines, without any support, that *Chen* teaches the limitations of

claim 6, when executed. However, because *Chen*, fails to disclose the method as recited in claim 1 (*see supra* at 52-55), it also fails to disclose the limitations of claim 6.

2. *Chen, 3D Visualization and 3D Slicer Do Not Disclose All of the Elements Recited in Claims 11-20.*

a. *Chen, 3D Visualization and 3D Slicer Do Not Disclose 11[A], [B].*

As discussed above, in view of claims 1-6 and the specification, a POSITA would understand that “3D data including an outer layer of the patient and multiple inner layers of the patient” requires direct-volume-rendered imaging. *Supra* at 11-14. “*Chen*’s surface model was not created to be “sliced” or “repositioned” or navigated.” Ex. 2002, Mulumudi, ¶ 156. *Chen*’s surface model is not 3D direct volume rendered data comprising an outer layer and multiple inner layers of the patient. *See Id.*

In addition, *Chen* does not alter the color gradient of any direct-volume-rendered CT data. *Id.*, ¶ 158. *Chen* alters the color gradient of surface-rendered models. *Id.* This is different from altering the color gradient of direct volume rendering. *Id.* For example, in surface rendering, the colors are typically determined by the segmentation step, where different structures are labeled with different colors. *Id.* Moreover, *Chen*’s method of using a black background in the HMD would not work for projecting a 3D DVR image onto a real patient in an

operating room, because the black background would mask data in the projected 3D image. *Id.* As such, *Chen*'s method for changing the color of its surface models and the background of its HMD is vastly different from the elements of claim 11. *Id.*

3D Visualization that *3D Slicer* do not remedy *Chen*'s deficiency. As discussed above, *3D Slicer* does not disclose altering a color gradient at all. And *3D Visualization* only discloses altering the color gradient of a pixel on a computer monitor not in an AR environment.

b. *Chen, 3D Visualization, and 3D Slicer Do Not Disclose 11[C].*

None of *Chen*, *3D Visualization*, or *3D Slicer* disclose an AR headset display with the recited elements of 11[C]. *Chen* discloses the use of AR in surgical procedures generally, but it fails to disclose inner layers of 3D DVR medical images onto an outer layer of the patient with an altered color gradient. *3D Visualization* discloses the use of different colors, but does not disclose how the original color gradient of a direct volume rendered image could be altered to improve visibility while projected onto a real patient in an operating room.

Petitioner does not provide any evidence of how the POSITA would even think to modify *3D Visualization* or *3D Slicer* to “augment real-time, non-image actual

views of a patient with three-dimensional (3D) data,” much less why the POSITA would do so.

c. *Chen, 3D Visualization, and 3D Slicer Do Not Disclose Claims 12-19*

Petitioner relies on Kazanzides unsupported opinion that “*3D Slicer* enabled a user to apply a color gradient to represent a variety of parameters that a user could identify or define based on the available 3D data.” Ex. 1012. at ¶ 132. As discussed above, neither *Chen, 3D Slicer*, nor *3D Visualization* disclose “the projected inner layer of the patient from the 3D data ... having the altered color gradient.” For the same reasons, neither *Chen, 3D Slicer*, nor *3D Visualization* disclose the limitations of claims 12-19. Moreover, neither *Chen, 3D Slicer*, nor *3D Visualization* disclose altering a color gradient to identify **any** of the characteristics specifically identified in claims 12-19, e.g., tissue [hardness/relaxivity/echogenicity/enhancement amount/enhancement speed/density/ radioactivity/water content].

d. *Chen, 3D Visualization, and 3D Slicer Do Not Disclose Claim 20.*

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

3. There is No Motivation to Combine *Chen* with *3D Visualization* and *3D Slicer*.

Petitioner 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* to understand what the suggested combination would encompass.” Petition at 54 (citing Ex. 1012, ¶ 105). However, neither Petitioner nor Kazanzides provides support for this contention.

Assuming for the sake of argument that all of the elements recited in the claims are disclosed in *Chen*, *3D Visualization*, and *3D Slicer* (they are not) “[a]n invention ‘composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.’” *Volkswagen Grp. of Am., Inc. v. Velocity Patent LLC*, IPR2015-00276, Paper 8, slip op. at 10 (PTAB Jun. 1, 2015) (quoting *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007)). “A party that petitions the Board for a determination of obviousness must show that ‘a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *Apotex Inc. v. Wyeth LLC*, IPR2014-00115, Paper 94, slip op. at 11

(Apr. 20, 2015) (quoting *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009)).

Here, the ‘271 Patent claims the projection of 3D data onto non-image actual views of a patient in AR. That projected 3D data is confined (i.e., navigable) 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.” Ex. 1001, 6:11-26 and Claim 3.

Kazanvides has not explained why a POSITA would have been motivated or expected to have success combining the medical image viewing system of *Chen* with the *3D Slicer* computer software to arrive at the claims of the ‘271 Patent. Neither *Chen*, *3D Slicer*, nor *3D Visualization* disclose navigating 3D data while it is projected onto non-image actual views of a patient. 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.

Moreover, neither *3D Slicer* nor *3D Visualization* adjust 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” or to represent tissue properties as recited in claims 11-20. “[A] POSITA would 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.” Ex. 2004, Rosenberg, ¶ 187.

Among other reasons for a lack of motivation to combine, controls used to manipulate data on a conventional computer monitor are very different from the types of controls needed an AR environment (especially when the user is a surgeon and the environment is an operating room with a real patient) and are not amenable to simple substitution. *See*, e.g., Rosenberg ¶¶ 68-76 (discussing differences in AR virtual controls and conventional computer controls.).

VI. CONCLUSION

Based on the foregoing, Patent Owner asks the Board to confirm the patentability of the Challenged Claims and deny the Petition in its entirety.

Dated: July 18, 2023

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CERTIFICATE OF COMPLIANCE PURSUANT TO 37 C.F.R. §42.24

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing **PATENT OWNER RESPONSE** complies with the typeface requirements of 37 C.F.R. §42.6(a)(ii) and the style requirements of 37 C.F.R. §§42.6(a)(iii) and (iv). This document contains 13,272 words, excluding the parts exempted as provided in 37 C.F.R. § 42.24(b). The undersigned relies on the word count of the computer program used to prepare this brief.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a correct copy of this Patent Owner's Response was served upon the Petitioner on July 18, 2023, by email to the email addresses identified in Petitioner's Updated Mandatory Notices dated February 2, 2023:

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Dated: July 18, 2023

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