



MEDIVIS

MEDIVIS, INC. V. NOVARAD CORP.

IPR2023-00042

U.S. PAT. NO. 11,004,271

Kia Freeman
Representing Petitioner

THE IPR2023-00042 TRIAL RECORD

- “A motion to exclude evidence must be filed to preserve any objection.” (37 CFR § 42.64(c)).
- Novarad waived all of its objections to Medivis’s exhibits (*i.e.*, Exhibits 1001-1028) by **not** moving to exclude any Medivis evidence.
- Medivis’s motion to exclude Novarad’s Exhibits 2002 and 2004 (*i.e.*, Mulumudi and Rosenberg declarations) is pending.

SCOPE OF CHALLENGES

Claims	Grounds
1, 5, 6	Anticipation by <i>Doo</i> (Ex. 1008)
1*-6, 11*-20	Obviousness over <i>Doo</i> in view of <i>Amira</i> (Exs. 1008 & 1005)
1-6, 11-20	Obviousness over <i>Chen</i> , <i>3D Slicer-Visualization</i> , and <i>3D Slicer-GUI</i> (Exs. 1009, 1007, & 1010)

Obviousness

Obviousness must be assessed on the basis of factual inquiries:

- (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); POR, 35.

POSA in this IPR (1 of 5)

A person of ordinary skill in the art (POSA) would have had three qualifications: (Pet., 10 (citing Ex. 1012, ¶ 25)).

- [1] a bachelor's degree in computer science, electrical engineering, or a related field with
- [2] several years of experience in the design, development, and study of augmented reality [AR] devices and
- [3] either (a) familiar[ity] with conventional medical imaging data and visualization of data for medical procedures or (b) working with a team including someone with such familiarity.

Novarad waived the right to dispute Medivis's definition of a POSA.

Scheduling Order, 8 (Board cautioning Novarad about waiver); Reply, 1-2; MTE.

POSA in this IPR (2 of 5)



Peter Kazanzides, Ph.D.

- Kazanzides has necessary credentials to opine on the understanding of a POSA (Ex. 1012, ¶¶ 2-13; Ex. 1013, CV; Pet., 9-10).
- Novarad did not dispute that Kazanzides qualifies as a POSA
- Research Professor in Department of Computer Science at Johns Hopkins University.
- Researches augmented reality systems for surgical applications
- Co-inventor of USPN 11,244,508, entitled “Augmented Reality Display for Surgical Procedures”

POSA in this IPR (3 of 5)



Peter Kazanzides, Ph.D.

Example co-authored paper: *Augmented Reality Goggles with an Integrated Tracking Systems for Navigation in Neurosurgery* (March 2012) (Ex. 1011, Azimi et al.; Pet., 24).



Figure 1. User wearing the optical see-through goggles and head mounted tracker. Figure shows the registration procedure, where the surgeon touches markers using a tracked probe.

POSA in this IPR (4 of 5)

Novarad did not qualify Mulumudi as a POSA: (Reply, 1-2; MTE, 10-12; MReply, 3-5)

- Mulumudi lacks both the academic qualification and AR device experience required by undisputed POSA definition
- Although Petition asserted “[a] POSA would have been familiar with the 3D Slicer application and its ability to load and display data for a user.” (Pet., 17), Mulumudi was not familiar with 3D Slicer (Ex. 1022, 130:6-9, 131:3-6, 131:7-10).
- Mulumudi did not recognize *3D Slicer-Visualization* (i.e., Ex. 1007). (Ex. 1022, 150:10-21).

POSA in this IPR (5 of 5)

Novarad did not qualify Rosenberg as a POSA: (Reply, 1-2; MTE, 12-15; MReply, 5)

- Rosenberg admitted he is “not an expert in the specifics of medical imaging.” (Ex. 2004, ¶ 79).
- Rosenberg did not claim the required qualification as to conventional medical imaging data and visualization of data for medical procedures
- Rosenberg did not claim the required experience with AR devices

Obviousness

Obviousness must be assessed on the basis of factual inquiries:

- (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); POR, 35.

Admitted Prior Art

- “[C]onventional medical imaging systems may create three-dimensional (3D) data for a patient” (Pet., 4-5; Ex. 1001, 2:49-51)
- “[C]onventional AR systems” (Pet., 5; Ex. 1001, 17:11-16)
- “[T]he AR headset may be any computer system in the form of an AR headset that is capable of augmenting real-time views of the patient with 3D data” (Pet., 5; Ex. 1001, 4:39-42)
- “[T]he AR head set may be a modified version of the Microsoft HoloLens” (Pet., 5; Ex. 1001, 4:60-61)

Amira (Ex. 1005)

Amira is a user guide that was publically available before 2017.

- *Amira* is copyrighted “1999-2009”
 - *IBM Corp. v. Intellectual Ventures II LLC*, IPR2014-00681, Paper 11, 18-19 (October 30, 2014) (copyright date can support a threshold showing that a document was an available printed publication)
 - (Ex. 1005, 4; Reply, 19).
- *Amira* was available on the internet by 2012.
 - *Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1374-75 (Fed. Cir. 2021) (Wayback Machine® *prima facie* evidence of public availability).
 - (Ex. 1024, ¶¶ 5-6, 4-406; Reply, 19).

Chen (Ex. 1009)

Chen is an article that was publically available before 2017.

- *Chen* was copyrighted and printed in 2015

(Ex. 1009, 1; Ex. 1028, ¶¶ 6-14, 16 ; Reply, 27).

- *Chen* had been cited by seven publication by January 2017.

(Ex. 1028, ¶ 15 ; Reply, 27).

3D Slicer-Visualization (Ex. 1007)

3D Slicer-Visualization (aka *3D Visualization*) is a training PPT that was publically available before 2017.

- *3D Slicer-Visualization* is copyrighted “2012-2104,” and was available on the internet by September 2014.

(Ex. 1007, 2-2; Ex. 1019; Ex. 1024, ¶¶ 25-29; Reply, 28).

- *3D Slicer-Visualization* was written to help people use 3D Slicer.

(Ex. 1007, 1-2, 7-8, 14-15, 20-46-47, 98-103; Ex. 1021, ¶¶ 11-23; Reply, 27-28).

3D Slicer-GUI (Ex. 1010)

3D Slicer-GUI (aka *3D Slicer*) is GUI documentation for 3D Slicer that was publically available before 2017.

- *3D Slicer-GUI* was “last edited on 7 November 2016, at 08:06.”
(Ex. 1010, 7; Reply, 28).
- Kazanzides opined that *3D Slicer-GUI* is documentation that became available on November 8, 2016.

(Ex. 1021, ¶¶ 34-40 ; Reply, 28).

Obviousness

Obviousness must be assessed on the basis of factual inquiries:

- (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); POR, 35.

CLAIM 1

1. [1pre] A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:

[1a] identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient; and

[1b] 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,

[1c] the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape.

CLAIM 11

11. [1pre] A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:

[1a] 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;

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

[1b] 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.

CLAIM CONSTRUCTION

- Novarad originally took the position that no claim construction is necessary:

“Novarad asserts that all of the claim terms in the asserted patents should be given their plain and ordinary meaning as understood by one having ordinary skill in the art. Therefore, no court claim construction is necessary.”

(Ex. 1014, Novarad email to Medivis relating to stayed litigation; Pet., 11).

- After institution, Novarad proposed unordinary meanings that contradict the ‘271 Patent claims and the specification.

CLAIM CONSTRUCTION ISSUES (1 of 2)

- Must “3D data” both (a) exclude X-ray imaging and (b) be limited to data that has been “direct volume rendered” (DVR)? Is so, what does DVR mean?
- Must “inner layer of the patient” be limited to (a) 3D and (b) DVR? Is so, what does 3D and DVR mean?
- Does Claim 1’s “confined within a volume of a virtual 3D shape”:
 - (a) require a tool for navigation along any axis? and
 - (b) require a shape created by DVR?
- Does “3D” have the same meaning in Claim 1’s “3D data” and “virtual 3D shape”? What does “3D” mean?

CLAIM CONSTRUCTION ISSUES (2 of 2)

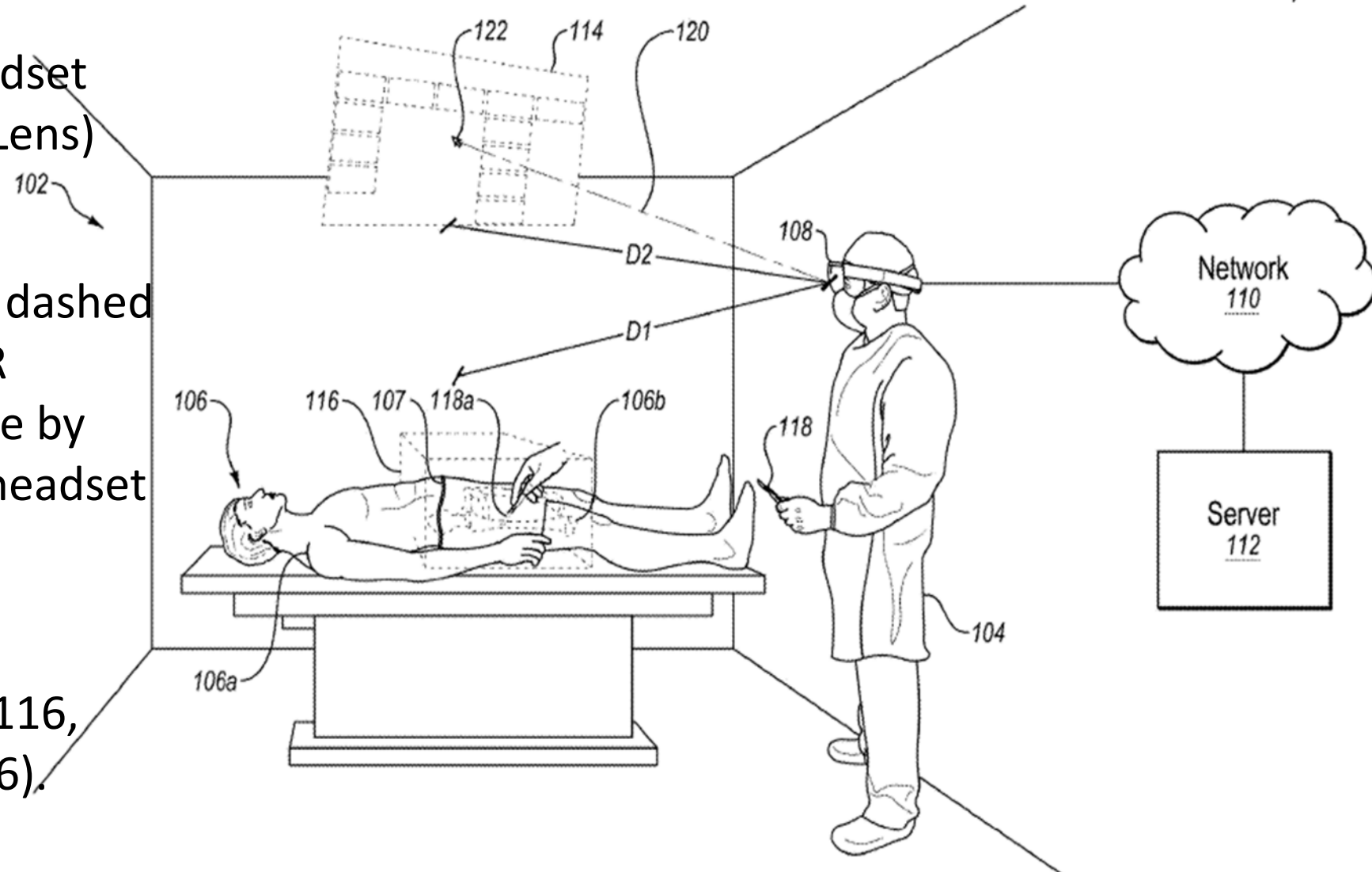
- Is the word “being” meaningless in Claim 11, but not in Claim 1
- Can Novarad have the word “being” construed as meaningless, in Claim 11 only, without moving to amend or seeking a correction of its own error?

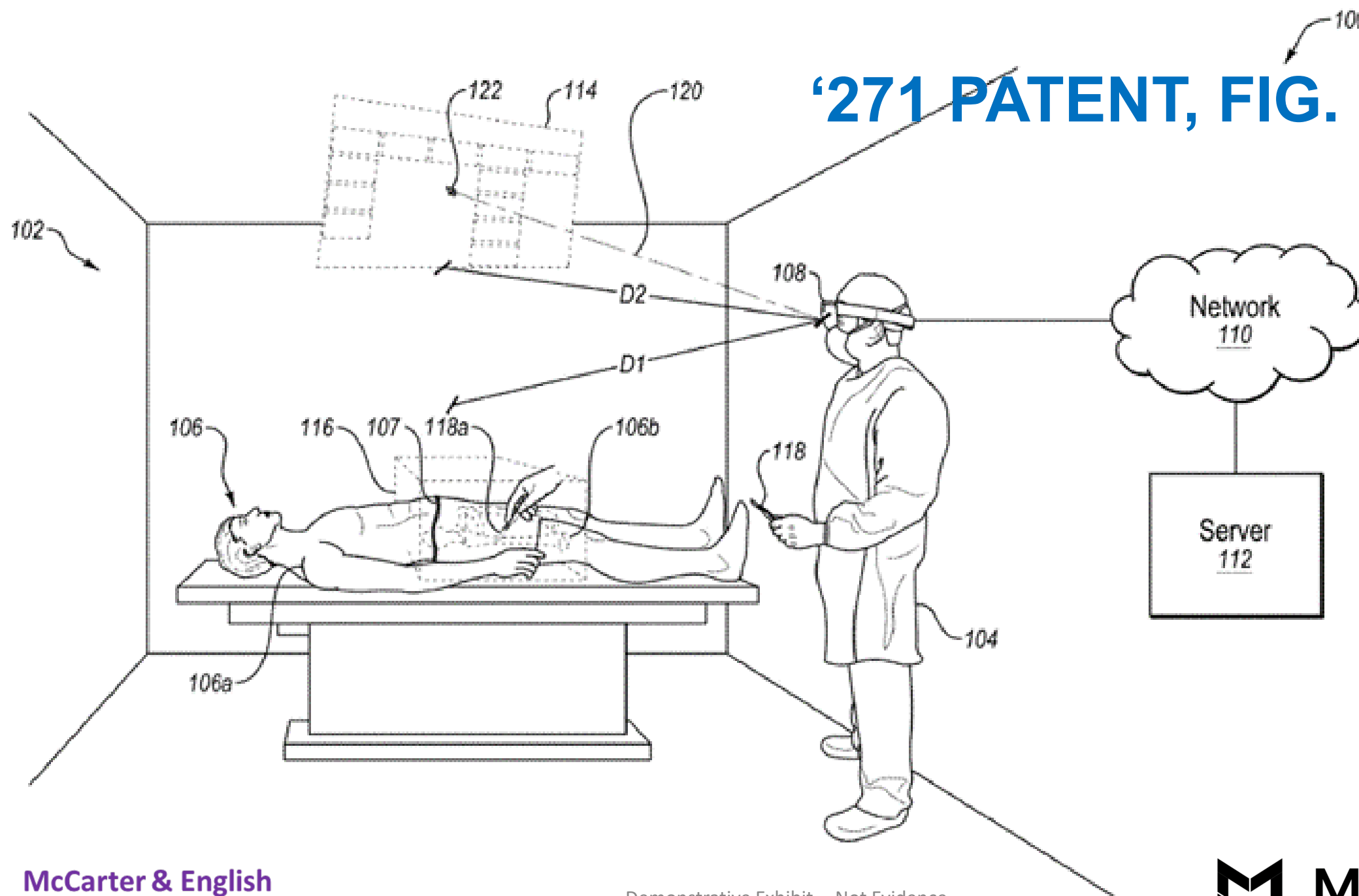
'271 PATENT, FIGURE 1

Patient 106, User 104, AR headset 108 (may be Microsoft HolonLens) (Ex. 1001, 3:63-67, 4:60-61).

“[V]irtual elements [shown in dashed lines] are generated by the AR headset 108 and only viewable by the user 104 through the AR headset 108.” (*Id.*, 4:5-7).

Virtual user interface 114, Virtual spatial difference box 116, Bones 106b (*Id.*, 4:1-8; 4:42-46).



'271 PATENT, FIG. 1

‘271 PATENT, VIRTUAL USER INTERFACE 114

“[V]irtual user interface 114 may ... cause the AR headset 108 to:

...

- (3) adjust the characteristics of the 3D data that is projected onto the patient 106, such as the brightness and color of the projected 3D data,
- (4) adjust the alignment of the 3D data with the patient 106,
- (5) display the virtual spatial difference box 116,
- (6) display a slice of the 3D data instead of a volume of the 3D data,
- (7) drag the 3D data in a direction of the user 104, such as in the repositioning of a slice of the 3D data,
- (8) display different slices of the 3D data including, but not limited to, axial slices, coronal slices, sagittal slices, and oblique slices, ...”

(Ex. 1001, 5:22-40; Reply, 11-12).

‘271 PATENT, EXEMPLARY METHOD

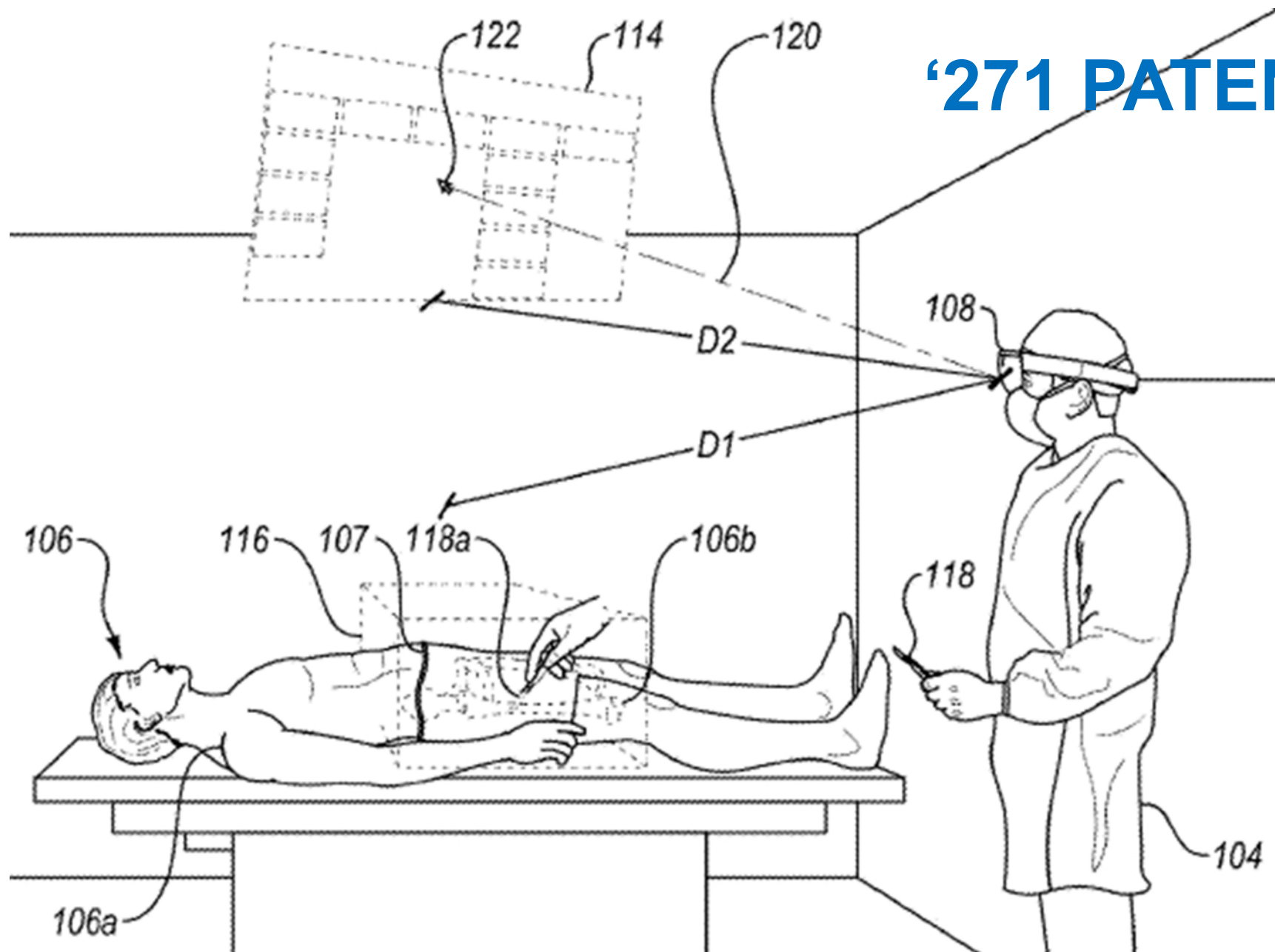
“FIGS. 6A-6E are a flowchart of an example method of augmenting real-time views of a patient with 3D data.” (Ex. 1001, 2:38-39).

Step 612: “Display one of the inner layers of the patient from the 3D data projected onto real-time views of outer layer of the patient.”

Examples of Step 612 (*Id.*, 13:11-34):

- “AR headset 108 of FIG. 1 may display ... the bones 106b of the patient 106 ... projected onto real-time views of the skin 106a”
- “CT scan image of the brain of the patient is projected onto the top of the head of the patient in FIGS. 2B and 2C, or onto the side of the head of the patient in FIG. 2E.”

'271 PATENT, FIG. 1



271 PATENT, FIGURE 2C

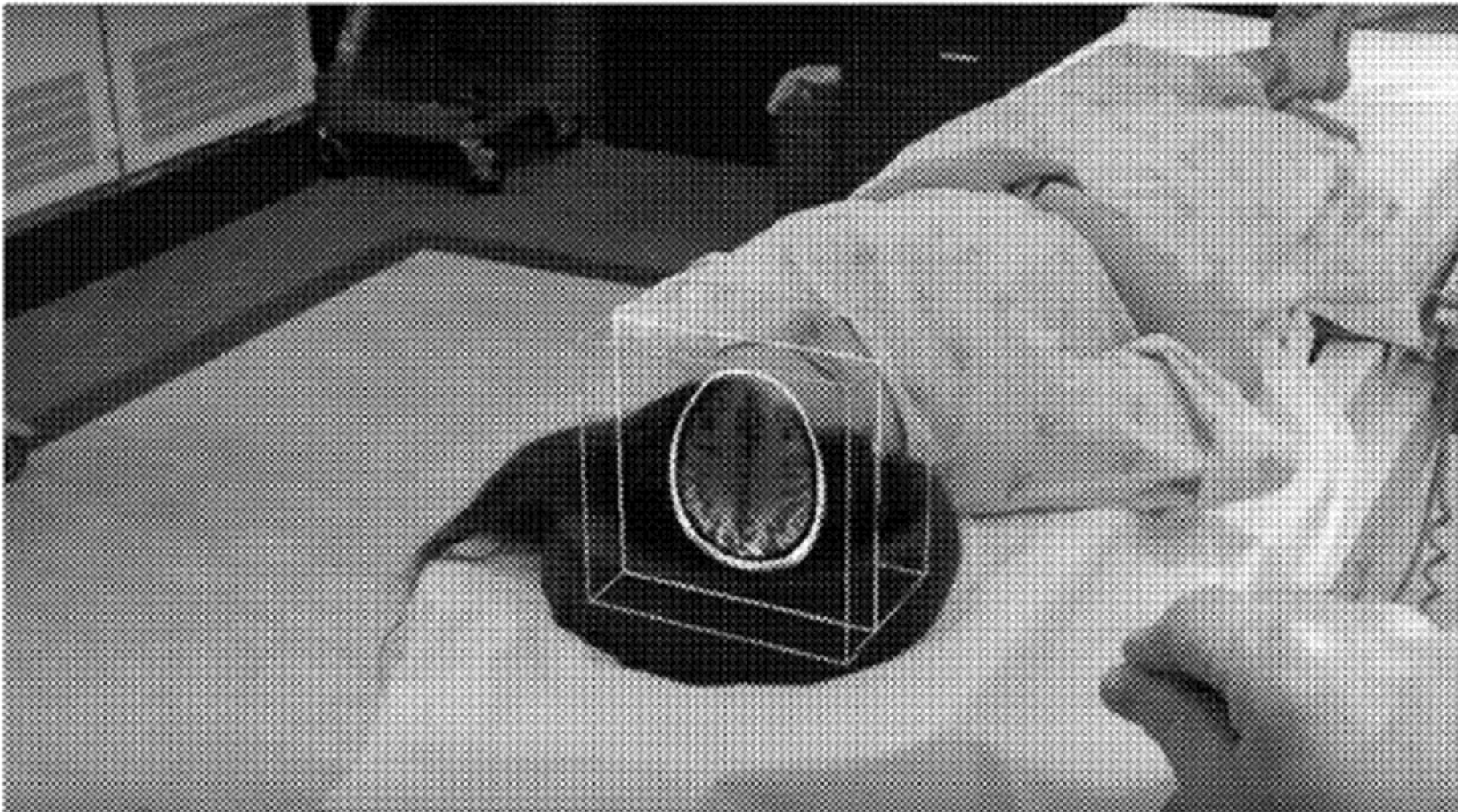


FIG. 2C

Demonstrative Exhibit -- Not Evidence

271 PATENT, FIGURE 2E

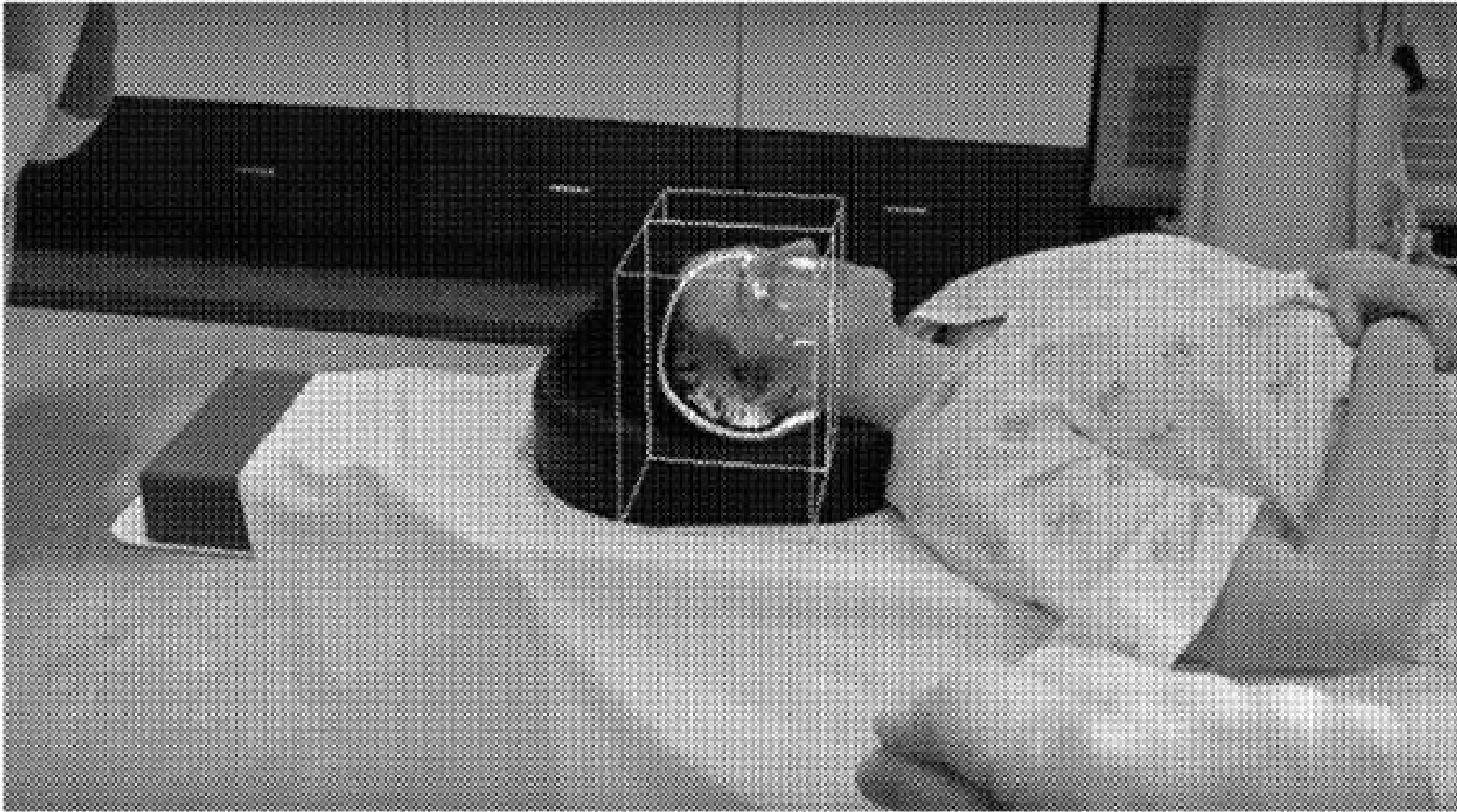


FIG. 2E

Demonstrative Exhibit -- Not Evidence

CLAIM 1

1. [1pre] A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:

[1a] identifying **3D data** for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient; and

[1b] 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,

[1c] the projected inner layer of the patient from the 3D data being **confined within a volume of a virtual 3D shape**.

CLAIM CONSTRUCTION: “3D DATA” (1 of 2)

Medivis's Construction	Novarad's Construction (POR, 5-6)
“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” (Pet., 11-13). No “direct-volume-rendering” limitation (Reply, 3-5).	“direct-volume-rendered CT, MRI, PET, and SPECT imaging (and also ultrasound and fluorescence imaging, depending on the methods used)” Novarad argues “direct-volume-rendering” means a “non-feature-specific, unsegmented image of the entire volume of the patient anatomy”

CLAIM CONSTRUCTION: “3D DATA” (2 of 2)

Medivis’s Construction	Novarad’s Construction (Sur-reply)
	Novarad argues “the 3D data of the challenged claims is not surface rendered nor segmented” (Sur-reply, 27; <i>see also id.</i>, 25).

CLAIM CONSTRUCTION: “INNER LAYER OF THE PATIENT”

Medivis’s Construction (Reply, 6-10)	Novarad’s Construction (POR)
Plain and ordinary meaning The features of a “3D direct volume rendering” identified by Novarad are inconsistent with preferred embodiments of the projected inner layer	“A 3D direct volume rendering of the anatomy of the patient at a certain depth below the outer layer, or skin, of the patient” Novarad argues “3D” requires the combination of height, width, and depth Novarad argues “direct volume rendering” means a “non-feature-specific, unsegmented image of the entire volume of the patient anatomy”

“3D DATA” (1 of 5)

“Conventional 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; Pet., 4-5).

“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.” (*Id.*, 11:45-51 (emphasis added); Pet., 11).

“3D DATA” (2 of 5)

Contrary to evidence, Novarad argues: “there is no dispute that 3D data has height, width, and depth.” (Sur-reply, 7).

In fact, there is no dispute that 3D data is commonly stored as a series of 2D images. (*Amira*, Ex. 1005, 27/39; Mulumudi, Ex. 1022, 127:12-14; Kazanzides, Ex. 2006, 59:19-61:1).

“Depending on context, [3D] has different meanings.” (Ex. 2006, Kazanzides, 57:20-58:10; Reply, 5).

“One meaning [of 3D] is that it has three coordinates, X, Y, and Z.” (Kazanzides, Ex. 2006, Kazanzides, 57:20-58:10; Reply, 5).

Each slice in a stack of 2D slices may provide information “common to the slice” but “relative to the other slices.” (Kazanzides, Ex. 2006, 62:17-66:1 ; Reply, 5).

“3D DATA” (3 of 5)

“3D data for patient 106 may include a 2D X-ray image that may be projected onto ... the patient 106.” (Ex. 1001, 12:7-9; Reply, 5).

“3D data may include a 2D image, such as an X-ray image, because when the 2D image is projected into a 3D space the 2D image has 3D significance.” (Ex. 1001, 12:4-7 ; Reply, 5).

“3D DATA” (4 of 5)

Novarad argues “the 3D data of the challenged claims is not surface rendered nor segmented.” (Sur-reply, 27).

- Claim 1, 2d step: “displaying ... one of the inner layers of the patient from the 3D data”
- Step 612: “Display one of the inner layers of the patient from the 3D data”
 - First example: “AR headset 108 of FIG. 1 may display, at block 612, the **bones 106b** of the patient 106 from the 3D data projected onto real-time views of the skin 106a” (Ex. 1001, 13:27-31 (emphasis added); Reply, 7-8).

“3D DATA” (5 of 5)

Novarad argues “3D data is a 3D volume” (Sur-reply, 8; *see also id.*, 16).

Novarad argues “any lesser portion of a 3D volume is also 3D”
(Sur-reply, 10).

Novarad argues “while a user may ‘display a slice of 3D data instead of a volume of the 3D data,’ the 3D data [slice] is still three-dimensional”
(Sur-reply, 7).

‘271 Patent discloses “virtual user interface 114 may ... cause the AR headset 108 to: ... (6) display **a slice** of 3D data **instead of a volume** of 3D data.”
(Ex. 1001, 5:22-40 (emphasis added); Reply 11-12).

NO “DIRECT VOLUME RENDERING” REQUIRED

- ‘271 Patent nowhere mentions “direct volume rendering” (DVR)
- Novarad’s proffered expert Mulumudi testified he can only recognize DVR by the phrase “direct volume rendering”
(Ex. 1022, 129:17-130:1; Reply, 3-4; MTE, 11-12).
- Both Novarad and Mulumudi distinguish “3D data” and DVR:
 - “DVR is a method for visualizing medical imaging data”
(POR, 5; Ex. 2002, ¶54).
 - “DVR operates ... on the original dataset”
(POR, 6; Ex. 2002, ¶56).

NO “DIRECT VOLUME RENDERING” REQUIRED

Novarad argues: “The prior art only displays 2D images, stacks of 2D images, and 3D surface models.” (Sur-reply, 1).

Casas discloses displaying volume rendering:

(Ex. 1006, ¶[0075]; Pet. 26).

[0075] The volume rendering 104 techniques include 3D surface rendering, 3D volume rendering, as well as fusion, parametric mapping, and multi-object rendering. More precisely, the volume rendering 104 may be done using one or more of the available methods, such as direct volume rendering (e.g. volume ray casting, splatting, shear warp, texture-based volume rendering, etc.), maximum intensity projection, hardware-accelerated volume rendering, and any of the available optimization techniques (e.g. empty space skipping, early ray termination, volume segmentation, image-based meshing, pre-integrated volume rendering, etc.). Such methods may be further helped by the user by using regions (ROI) or volumes of interest (VOI), lookup tables (LUT), and any of the available methods for refining the volume rendering 104. It will be understood that these examples of volume rendering methods and their outputs are presented for the purpose of example, and are not intended to be limiting in any manner.

CLAIM CONSTRUCTION: “CONFINED WITHIN A VOLUME OF A VIRTUAL 3D SHAPE”

Medivis’s Construction	Novarad’s Construction
“virtual 3D shape” encompasses a “virtual 3D shape (i.e., form) as simple as a box and as complex as the outer layer of a patient” “confined within a volume of” has its plain and ordinary meaning, which does not involve any navigation function, but rather requires the virtual 3D shape to be a boundary	“confined within ... a virtual 3D shape” means “navigated along any axis ... a virtual control;”

CLAIM 3

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.

CLAIM CONSTRUCTION: “CONFINED WITHIN A VOLUME OF A VIRTUAL 3D SHAPE”

Novarad’s proffered expert Mulumudi opined that the following terms are **not technical**:

- “confined” (Ex. 1022, 19:12-20:1; Reply, 10).
- “shape” means form (Ex. 1022, 17:5-18:13; Reply, 11).

Novarad argues the “virtual 3D shape” is a box:

- “a virtual 3D shape, *i.e.*, a virtual spatial difference box 116”
(Sur-reply, 7).

CLAIM CONSTRUCTION: “CONFINED WITHIN A VOLUME OF A VIRTUAL 3D SHAPE”

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Novarad wrongly argues “confined within a volume” means “navigable along any axis”? (Sur-reply, 12; *see also id.*, 1).

The ‘271 patent claims do **not** include word “navigate.”

The ‘271 patent specification only uses the word “navigate” once:

“In some embodiments, **the virtual spatial difference box 116 may also assist the user when navigating the projected 3D data by providing a frame of reference** for the user 104.”

(Ex. 1001, 6:11-13 (emphasis added)).

CLAIM CONSTRUCTION: “CONFINED WITHIN A VOLUME OF A VIRTUAL 3D SHAPE”

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According to Novarad, navigation along any axis excludes rotation:

“Importantly, the **repositioning** function in claim 3 is **not** the same as merely **rotating** an object in space. *See* Ex. 2004, Ros.Dec., ¶174 (“... the projected 3D data is not rotated because it’s registered to the patient.”).”

(Sur-reply, 24 (emphasis added)).

According to Rosenberg, navigation along any axis excludes navigation along any rotational axis:

“‘[C]onfigure [sic] to be controlled to reposition ... slices’ means ‘**navigating** the projected 3D data’ by repositioning slices registered to the patient ...—**not rotation**.”

(Ex. 2006, ¶174 (emphasis added)).

CLAIM CONSTRUCTION: “CONFINED WITHIN A VOLUME OF A VIRTUAL 3D SHAPE”

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“[V]irtual user interface 114 may ... cause the AR headset 108 to:

...

(4) adjust the alignment of the 3D data with the patient 106 ...

...

(7) drag the 3D data in a direction of the user 104, such as in the
repositioning of a slice of the 3D data,”

(8) **display different slices** of the 3D data, ...”

(‘271 Patent, 5:22-40 (emphasis added)).

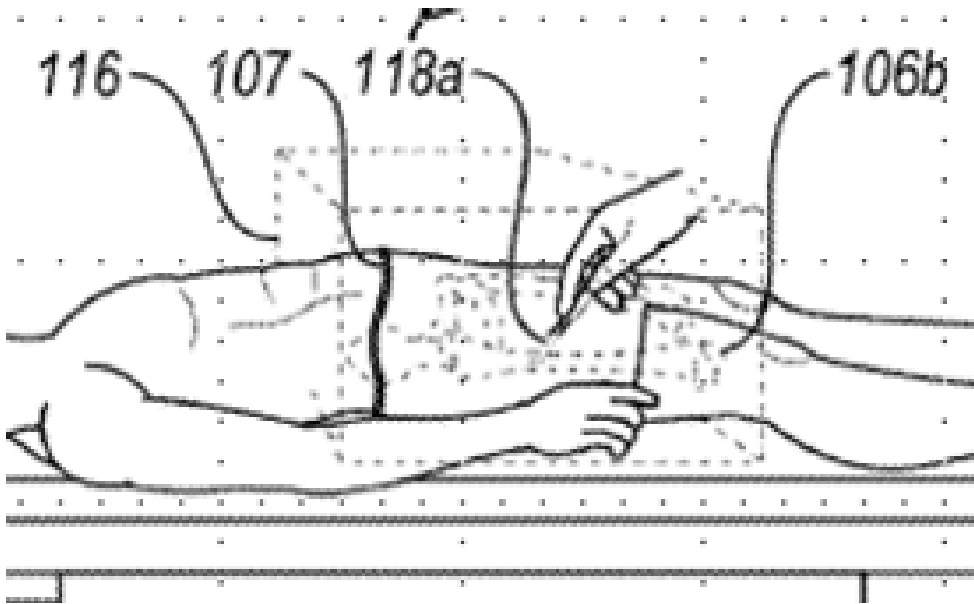
CLAIM CONSTRUCTION: “CONFINED WITHIN A VOLUME OF A VIRTUAL 3D SHAPE”

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According to Novarad, a “virtual 3D shape” is derived from DVRing:

“The ‘virtual 3D shape’ is derived from direct volume rendering the detail of the object” (Opp., 8 (citing Mulumudi ¶178)).

“a virtual 3D shape, *i.e.*, a virtual spatial difference box 116” (Sur-reply, 7).



CLAIM CONSTRUCTION: “CONFINED WITHIN A VOLUME OF A VIRTUAL 3D SHAPE”

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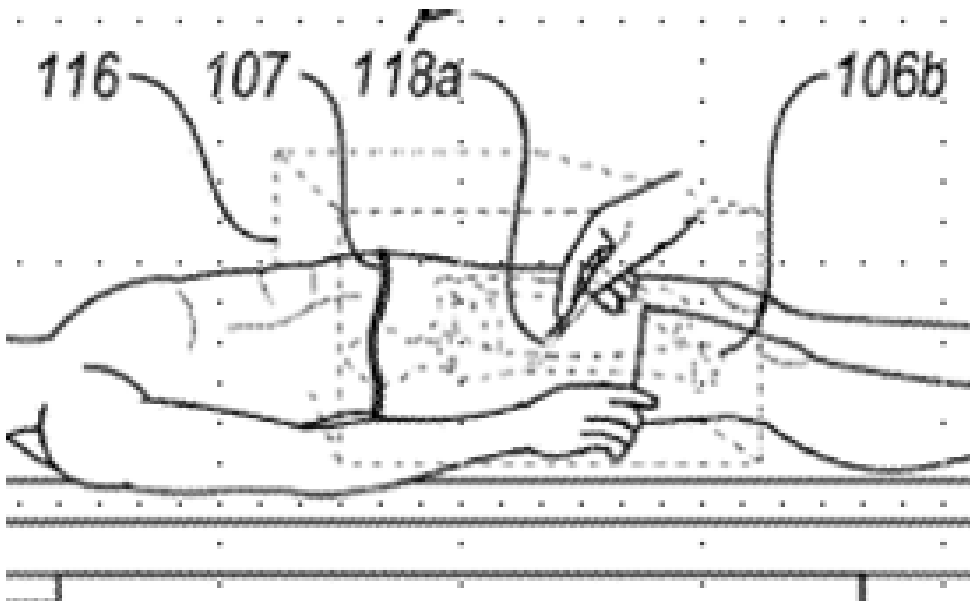
According to Novarad, 3D requires height, width, and depth:

“based on the plain and ordinary meaning of the [sic] ‘three-dimensional (3D),’ a POSITA would understand that ... in an AR environment [it] must at least appear to the user to have height, width, and depth.”

(Opp., 14 (citing Rosenberg ¶179)).

“a virtual **3D** shape, *i.e.*, a virtual spatial difference box 116”

(Sur-reply, 7 (emphasis added)).



CLAIM CONSTRUCTION: “BEING HAVING”

Medivis’s Construction	Novarad’s Construction
“being or having”	“having” (<i>i.e.</i> , “being” is meaningless)

CLAIM 11

11. [1pre] A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:

[1a] 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;

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

[1b] 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.

“BEING HAVING” (1 of 2)

Not a term of art (Ex. 1012, ¶34; Pet., 14).

Kazanzides opined inclusion of “being having” in Claim 11 appears to be an error, but did not opine as to the nature of the error. (Ex. 1012, ¶34; Pet., 14).

Novarad did **not** move to amend

Novarad did **not** solicit any correction

“BEING HAVING” (2 of 2)

Novarad admitted inclusion of “being having” in Claim 11 was its own error. (Sur-reply, 12-13).

“For purposes of this IPR, [Novarad] interprets ‘being having’ as ‘having.’” (POR, 18).

Novarad proposed to construe the word “being” as meaningless in Claim 11 (but not in Claim 1)—without explanation. (POR, 18; Sur-reply, 13).

Motive to Combine *Doo* & *Amira*

Doo provides **motive to combine** its disclosure with *Amira*:

- Novarad admits “*Amira* is [2009] software for displaying medical imaging.” (POR, 43-44).
- “*Doo* disclosed ‘a need for an improved system in which the customary ... medical images ... are better managed so that a surgeon [need not] look away from the patient’ and has a lower cognitive load.” (Reply, 20 (citing Ex. 1008, [0010])).
- “*Doo* suggests an improvement on conventional medical imaging displays, such as disclosed in *Amira*.” (*Id.*).

Expectation of Success Combining *Doo* & *Amira*

“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*.”

(Pet., 41-42 (citing Kazanzides, Ex. 1012, ¶103)).

Claim 1 Obvious over *Doo* and *Amira*

Doo (Exhibit 1008)

Intra-operative Medical Image Viewing System And Method (Ex. 1008, Title).

“[T]he image 32 may appear (to the surgeon 26) to be ... projected inside the patient’s body.” (Ex. 1008, [0039]).

Board preliminarily found that *Doo* anticipates Claims 1, 5, and 6 (Decision Granting Institution, 7-12).

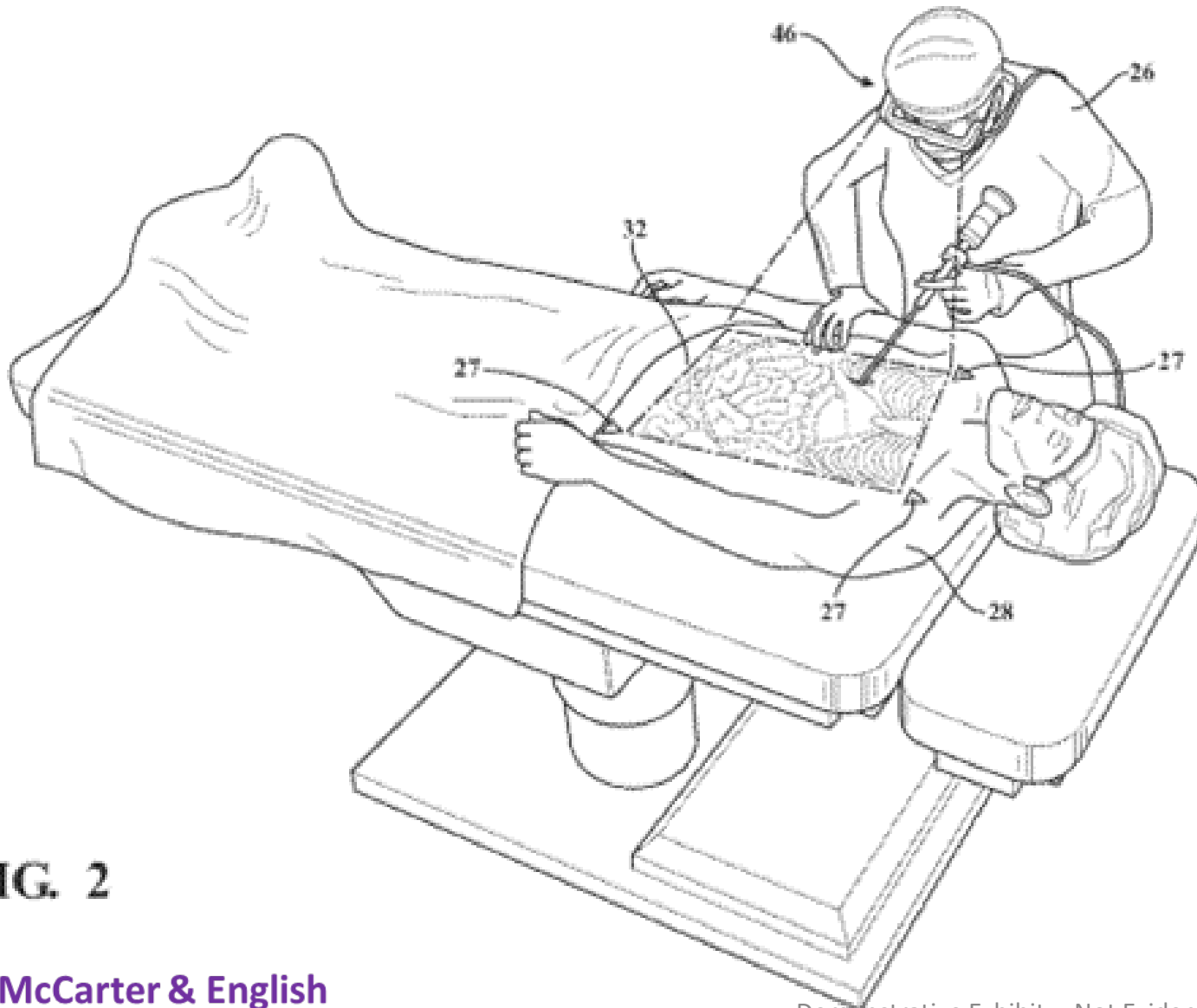
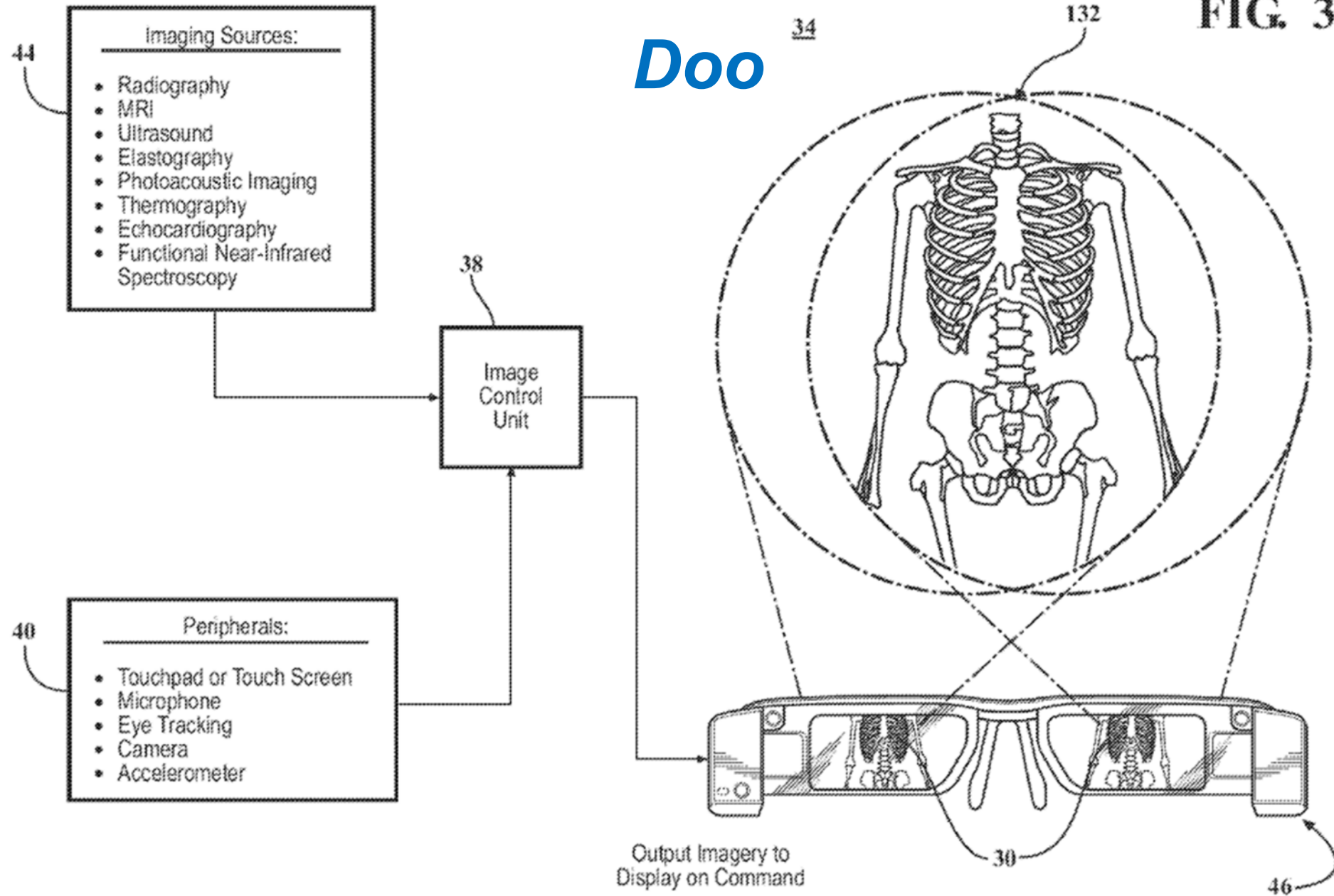


FIG. 2



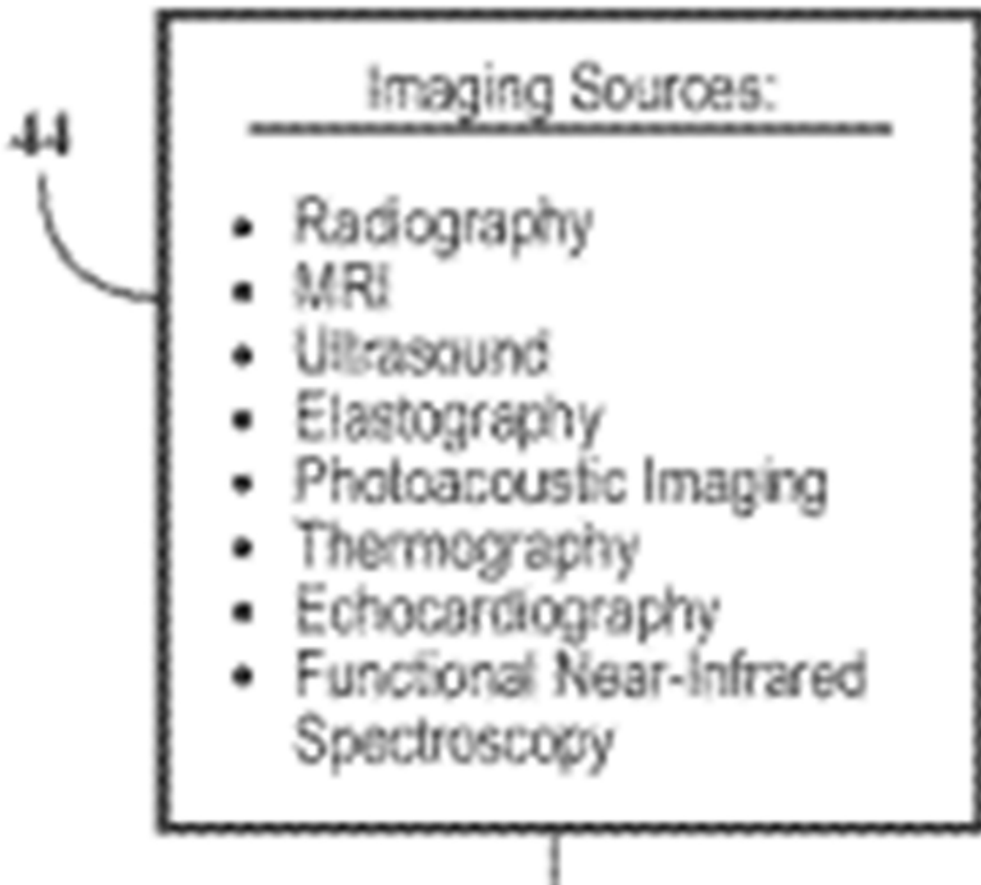
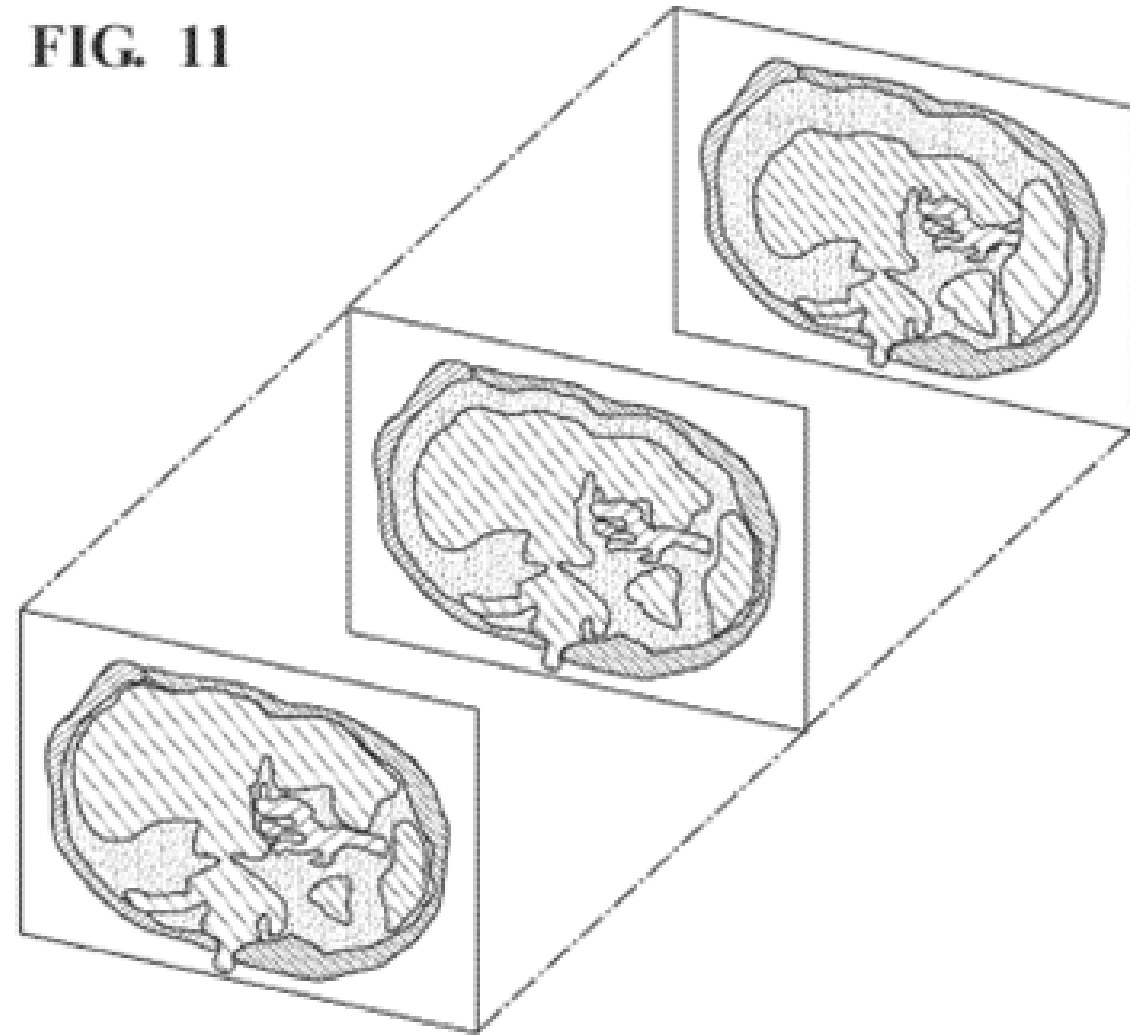
Doo**FIG. 11**

Figure 11 “is a series of three-dimensional tomographic slices of anatomical feature of a patient.” (Ex. 1008, ¶26; Pet., 38).

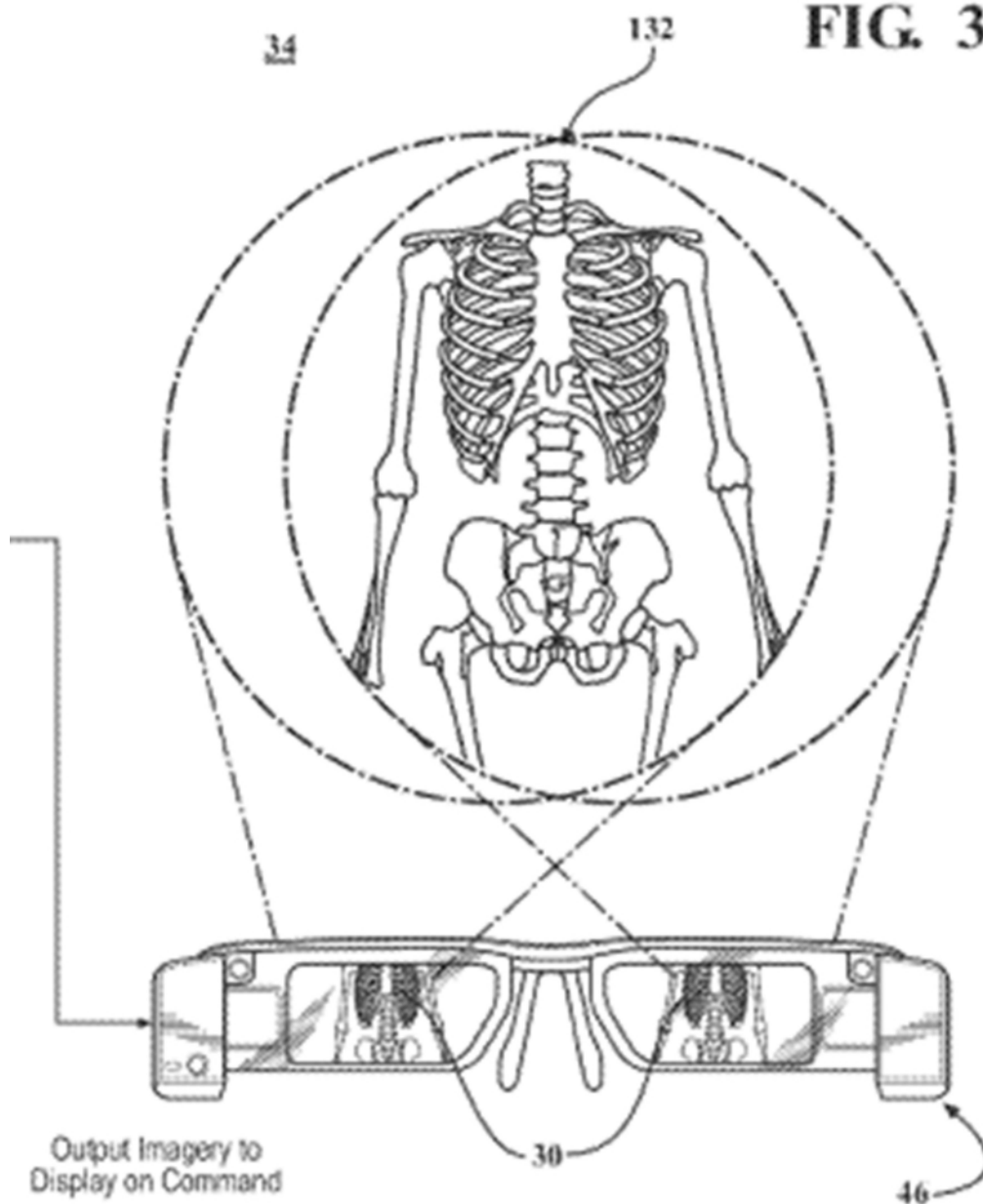
FIG. 3

Doo

“[M]edical image viewing system 34 can allow the surgeon 26 to maintain a viewing perspective on the patient 28 while concurrently obtaining relevant image-based (i.e., pictorial) information about the patient 28”

“The 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 28”

(Ex. 1008, ¶38).



Claim 1 Obvious over *Doo* and *Amira*

“[A]n intra-operative medical image viewing system 34 that maintains the registration of an image to an actual anatomical feature of the patient 28 despite head movement by the surgeon 26. The system 34 can allow the surgeon 26 to selectively register, i.e., lock, an image to an actual anatomical feature of the patient 28 For example, **the image can be overlaid on the patient's actual anatomical feature** and, ..., the image can be sized to match the actual anatomical feature, thus **creating the visual impression of a "true registration" and a form of augmented reality.**”

“Initial placement of an image in preparation for registration can be established by the surgeon 26 communicating image control inputs to the system, resulting in image changes such as positioning, scaling, rotating, panning, tilting, and cropping.”

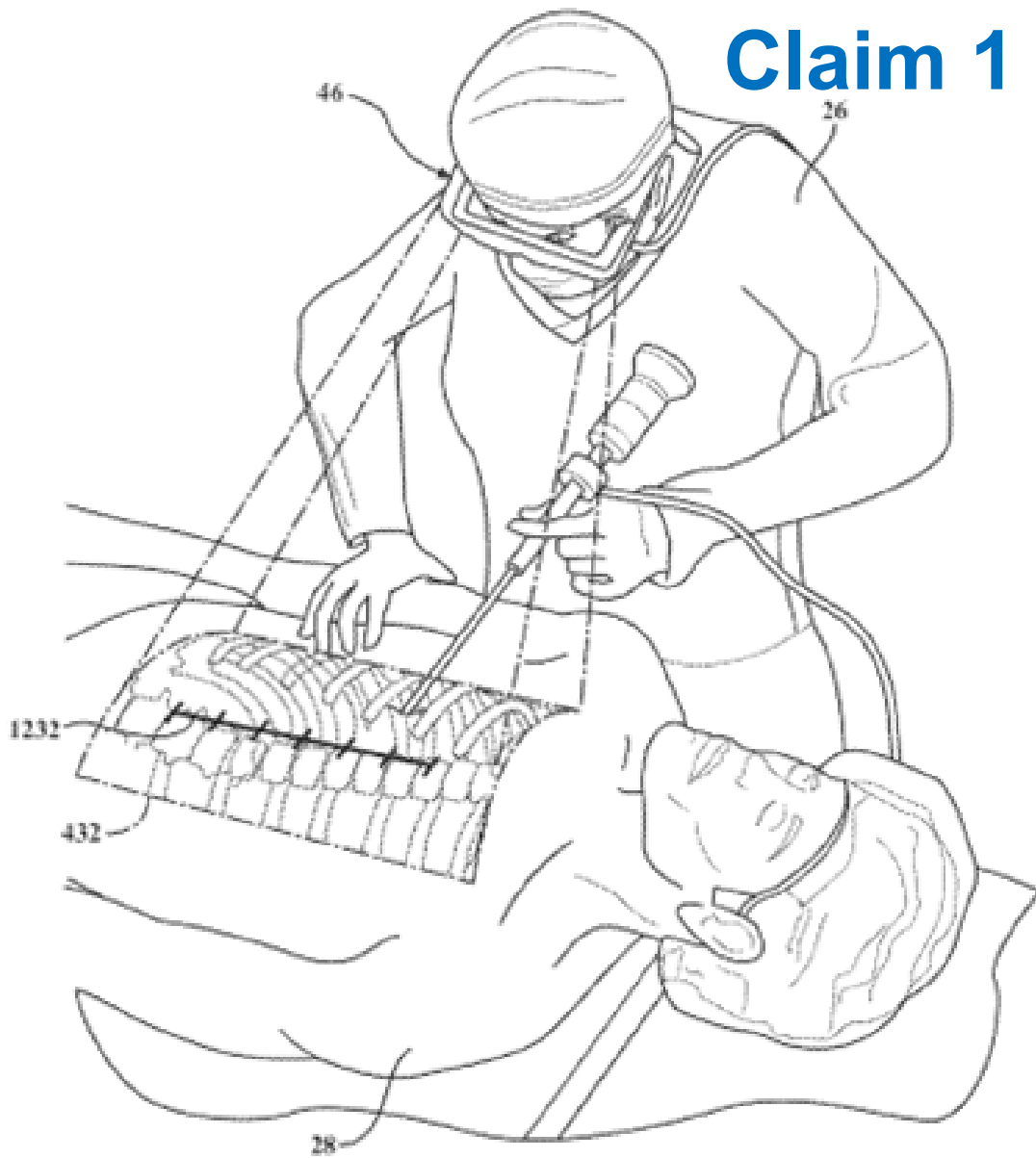
(Ex. 1008, ¶137).

Claim 1 Obvious over *Doo* and *Amira*

“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, ¶75).

“A 3D shape has a volume.” (Opp., 15).

“*Doo*’s Figure 7 ... illustrates the projection of bones of the patient from the 3D data being confined with the volume of the virtual 3D shape” (Ex. 1012, ¶75; Pet., 37).



Claim 1 Obvious over *Doo* and *Amira*

FIG. 11

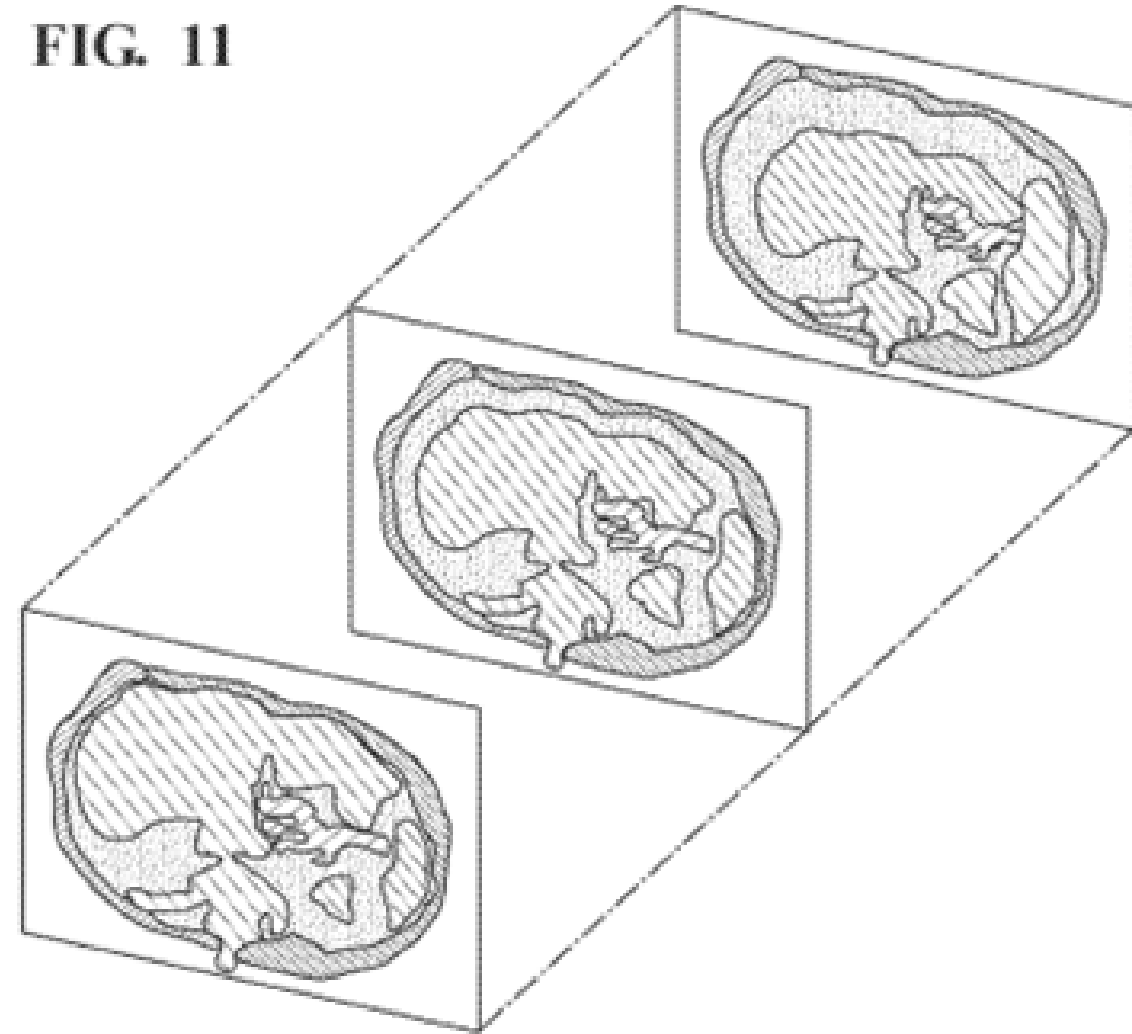


Figure 11 “is a series of three-dimensional tomographic slices of anatomical feature of a patient.” (Ex. 1008, [0026]; Pet., 36-37).

“A fusion of several tomographic slices can be stitched together to create a 3D image.” (Ex. 1008, [0078]; Pet., 36-37).

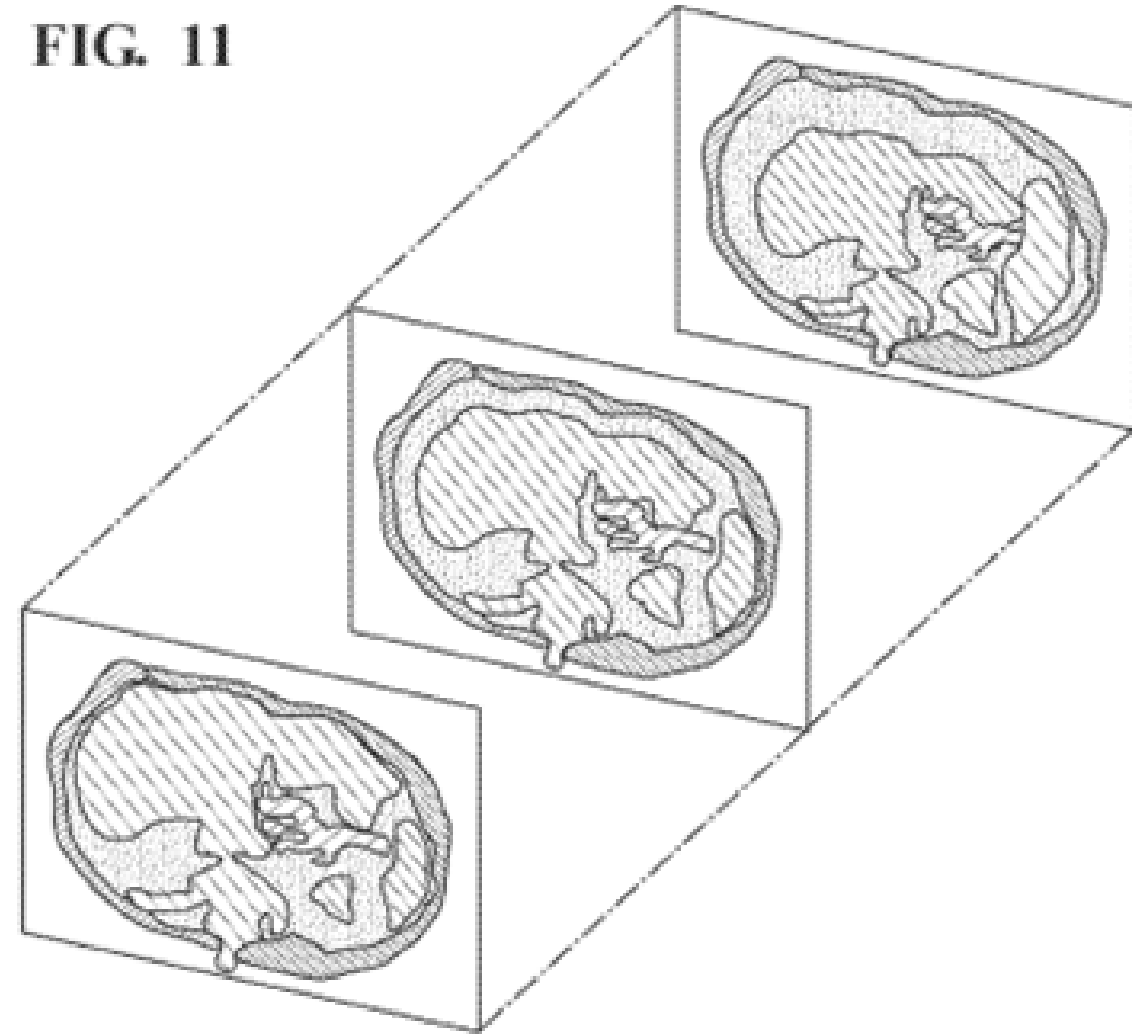
Figure 11 illustrates in part by dashed lines a virtual 3D shape in the form of a virtual box having top, bottom left, right, front, and back sides (Ex. 1012, ¶¶76-77; Pet., 38).

Claim 1 Obvious over *Doo* and *Amira*

Each of the inner layers is confined within a Figure 11's virtual box illustrated in part by dashed lines (Ex. 1012, ¶¶76-77; Pet., 38).

POSA would understand that any projected inner layer would be confined within a volume of a virtual 3D shape, whether the virtual 3D shape were displayed or not (Ex. 1012, ¶¶76-77; Pet., 38).

FIG. 11



Claim 5 Obvious over *Doo* and *Amira*

‘271 Patent Claim 5: “The method of claim 1, wherein lines of the virtual 3D shape are hidden.”

“[T]he technique of hiding or showing the lines of a virtual 3D shape was well known.” (Ex. 1012, ¶¶42-47; Pet., 39).

“[D]ashed lines in *Doo*’s Figure 7 ... do not seem to be visible to the surgeon.” (Ex. 1012, ¶¶42-47; Pet., 39).

“POSA would conclude that the lines of the virtual 3D shape illustrated in *Doo*’s Figure ... 7 ... are hidden.” (Ex. 1012, ¶¶42-47; Pet., 39).

Claim 6 Obvious over *Doo* and *Amira*

‘271 Patent 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.”

Doo discloses:

- “System programming can be stored in and accessed from memory 72.”
- “Any combination of one or more ... computer-readable media may be utilized in various embodiments of the invention.”
- “Computer program code for carrying out operations of this invention may be written in any combination of one or more programming languages.”
(Ex. 1008, [0063], Ex. 1012, ¶79; Pet., 40).

“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 of more processors to perform the method recited in Claim 1.” (Ex. 1012, ¶79; Pet., 40).

“CONFINED WITHIN A VOLUME OF A VIRTUAL 3D SHAPE”

Novarad argues the “virtual 3D shape” is a box:

“a virtual 3D shape, *i.e.*, a virtual spatial difference box 116”

(Sur-reply, 7).

Amira discloses virtual a virtual 3D bounding box that can be controlled to reposition slices

(Ex. 1005, 28/40, 79/91-80/92; Pet., 42-45).

Claim 1 Obvious over *Doo* and *Amira*

Amira (Exhibit 1005):

Amira illustrates exemplary bounding boxes as yellow lines (Ex. 1005, 36/48; Ex. 1012, ¶46; Pet., 22).

Amira discloses a user may “[d]eactivate and activate the display of ... BoundingBox module using the toggle viewer (Ex. 1005, 25/37; Ex. 1012, ¶47; Pet., 22).

Amira’s “3D viewer lets you look at the model from different positions.” (Ex. 1005, 23-24/35-36; Ex. 1012, ¶48; Pet., 23).

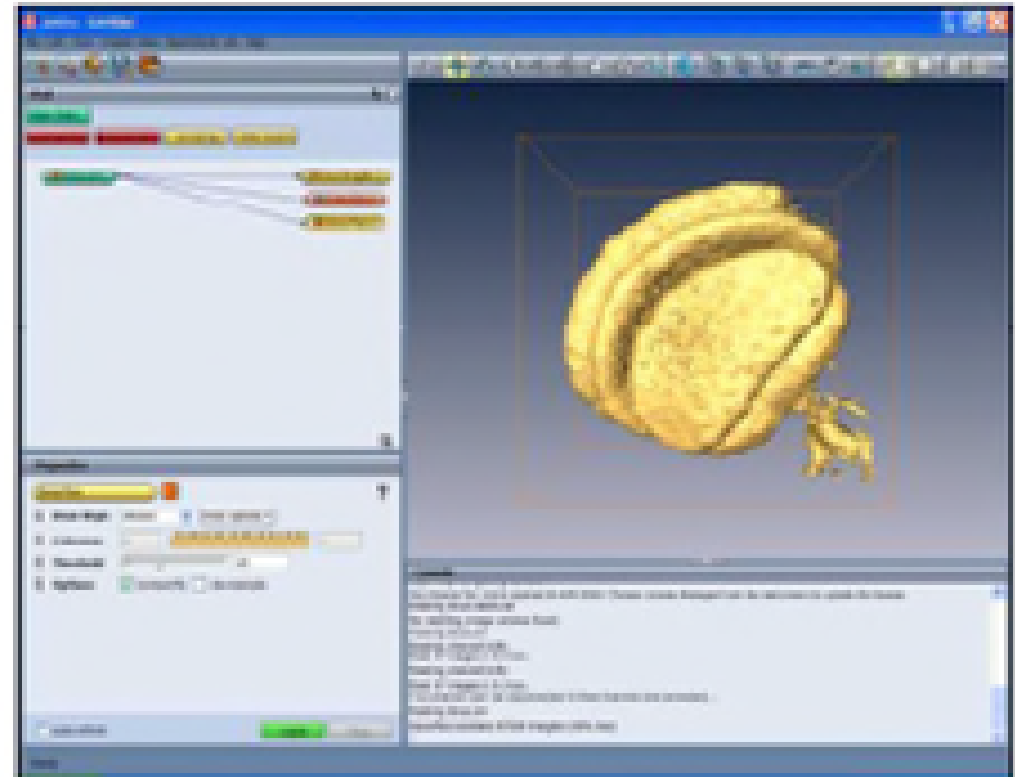
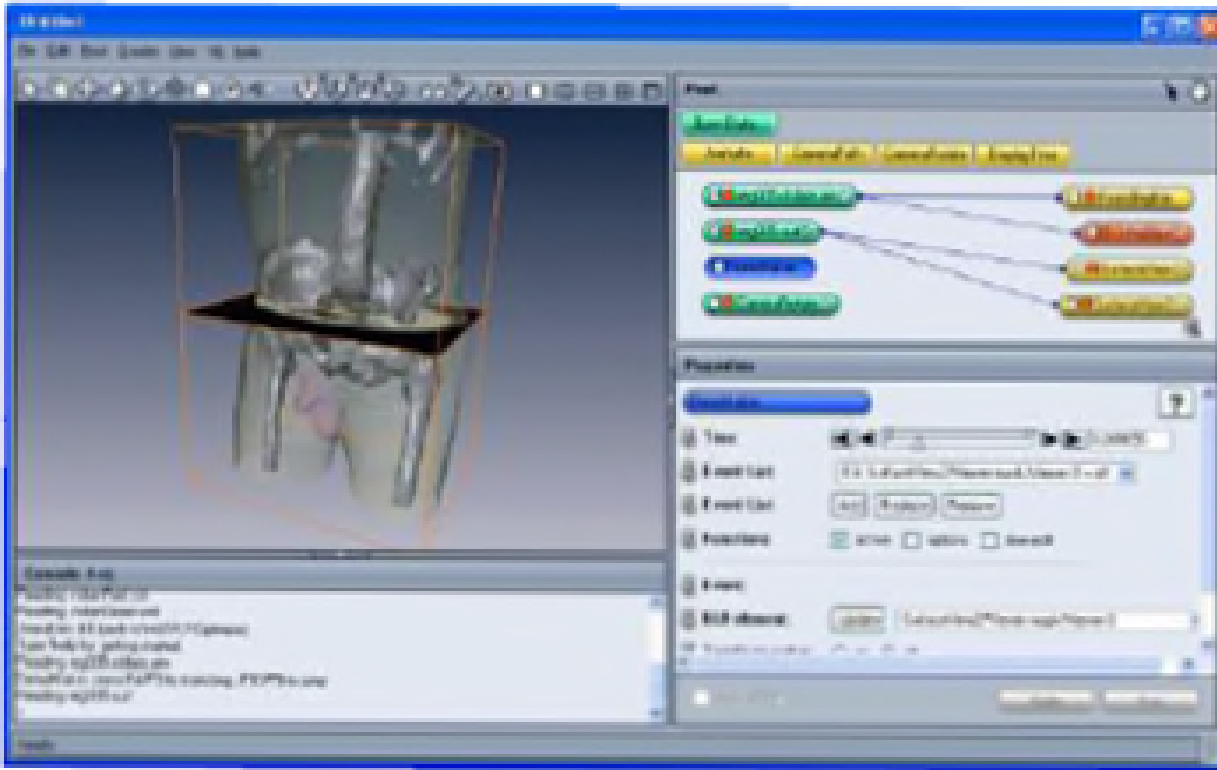


Figure 2.14: Lobus data set visualized in 3D using an isosurface.

Claim 1 Obvious over *Doo* and *Amira*



Like *Doo*, *Amira* “[o]perat[es] on 3D data.”

(Ex. 1005, 11/23; Ex. 1012, ¶¶81-83; Pet., 42).

Amira illustrates exemplary bones within skin within the yellow lines of a bounding box

(Ex. 1005, 80/92; Ex. 1012, ¶83; Pet., 43).

Claim 1 Obvious over *Doo* and *Amira*

Amira discloses displaying direct volume rendering:

“One of the most powerful techniques for visualizing 3D image data is *direct volume rendering*.”

(Ex. 1005, 6/18-7/19 (emphasis original); MTE, 5-6).

2.3.6 Volume Rendering

Volume Rendering is a visualization technique that gives a 3D impression of the whole data set without segmentation. The underlying model is based on the emission and absorption of light that pertains to every voxel of the view volume. The algorithm simulates the casting of light rays through the volume from pre-set sources. It determines how much light reaches each voxel on the ray and is emitted or absorbed by the voxel. Then it computes what can be seen from the current viewing point as implied by the current placement of the volume relative to the viewing plane, simulating the casting of sight rays through the volume from the viewing point.

You can choose between two different methods for these computations: *maximum intensity* projections or an ordinary emission-absorption model.

- Remove all objects in the Pool other than the *lobux.am* data record.

37

Medivis Exhibit 1005

49

(Reply, 3-4 (discussing Mulumudi’s testimony about Ex. 1005, Section 2.3.6 beginning on 37/49)).

CLAIM 11

11. [1pre] A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:

[1a] 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;

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

[1b] 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.

Claim 11 Obvious over *Doo* and *Amira* (1 of 3)

According to Kazanzides, Claim 11 would have been obvious to a POSA at the relevant time over *Doo* in view of *Amira*.

(Ex. 1012, ¶¶ 81, 90; Pet., 47).

Doo discloses “adjusting the transparency of the overlaid image.”

(Ex. 1008, 28 (claim 5); Ex. 1012, ¶¶ 91-96; Pet., 47-48).

“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.”

(Ex. 1008, [0030]; Ex. 1012, ¶¶ 91-96, Pet., 48).

Claim 11 Obvious over *Doo* and *Amira* (2 of 3)

- *Amira* discloses the use of colormaps to alter color gradients (Pet., 50).
- *Amira* discloses “colormaps [with] special-purpose interactive editors.” (Ex. 1005, 4/16; Pet., 50).
- *Amira* recommends users “experiment with changing the color maps.” (Ex. 1005, 103/115; Pet., 51).
- *Amira* directs users to “[c]hange the minimum and maximum values of the Overlay color map.” (Ex. 1005, 102-103/114-115; Pet., 51).
- *Amira* discloses a user can “change the contrast ... or change the brightness.” (Ex. 1005, 101/113; Pet., 51).

Claim 11 Obvious over *Doo* and *Amira* (3 of 3)

- *Amira* discloses “[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, 102/114; Pet., 50).
- *Amira* discloses a user can “visualize one or two data set at the same time using a Multi Planar reconstruction (MPR) and a 3D viewer.” (Ex. 1005, 100/112; Ex. 1012, ¶ 97; Pet., 52).
- According to Kazanzides, a POSA would have appreciated that *Amira*’s color adjustment technology applies to improving visibility of a virtual image overlaid on an actual patient view. (Ex. 1012, ¶¶91-96; Pet., 51).

CLAIMS 12 to 19

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] “echogenicity”

[15] “enhancement amount”

[16] “enhancement speed”

[17] “density”

[18] “radioactivity”

[19] “water content”

Claims 12-19 Obvious over *Doo* and *Amira*

- According to Kazanzides, 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; Pet., 52).
- *Amira's* multi-modal imaging typically includes “magnetic resonance (MR), computer tomography (CT), and positron emission tomography (PET/SPECT).” (Ex. 1005, 102/114 (Section 2.15.2); Pet., 52).

Motive to Combine *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

Chen provides **motive to combine** its disclosure with *3D Slicer*, as described in *3D Slicer-Visualization & 3D Slicer-GUI*:

- “Currently, 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, 131:1).
- “It has been developed as a common research multi-platform with plenty of extension modules to support a wide-variety of clinical applications such as visualization, segmentation, ...” (*Id.*).
- “[W]e ... 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.*).

Motive to Combine *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

Kazanzides confirms the **motive to combine** *Chen* with *3D Slicer-GUI* and *3D Slicer-Visualization*:

- “A [POSA] would understand that *Chen*[, Ex. 1009] expressly suggests combination of the systems and method disclosed therein with the features and capability described in [*3D Slicer-GUI*, Ex. 1010] and [*3D Slicer-Visualization*, Ex. 1007].”
(Ex. 1012, ¶106).

Expectation of Success Combining *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

Chen provides a **reasonable expectation of success** in combining its disclosure with *3D Slicer*, as described in *3D Slicer-Visualization & 3D Slicer-GUI*:

- “[D]uring the past several years, many research groups have developed loadable extension modules based on 3D Slicer, for example, DicomRtExport module enables basic DICOM RT studies to local storage [30] and iGyne module for MR-guided interstitial gynecological brachytherapy [31].” (Ex. 1009, 131:1).
- “Therefore, 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.*).

Expectation of Success Combining *Chen*, 3D Slicer-Visualization & 3D Slicer-GUI

3D Slicer-Visualization confirms the **reasonable expectation of success** in combining *Chen's* features with 3D Slicer package:

- “[3D] Slicer is distributed ... with no restriction on use”
(Pet., 16; Ex. 1007, Slide 7).
- “A software platform that is both easy to use for clinical researchers and easy to extend for programmers”
(Pet., 16; Ex. 1007, Slide 8).
-

Claim 1 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

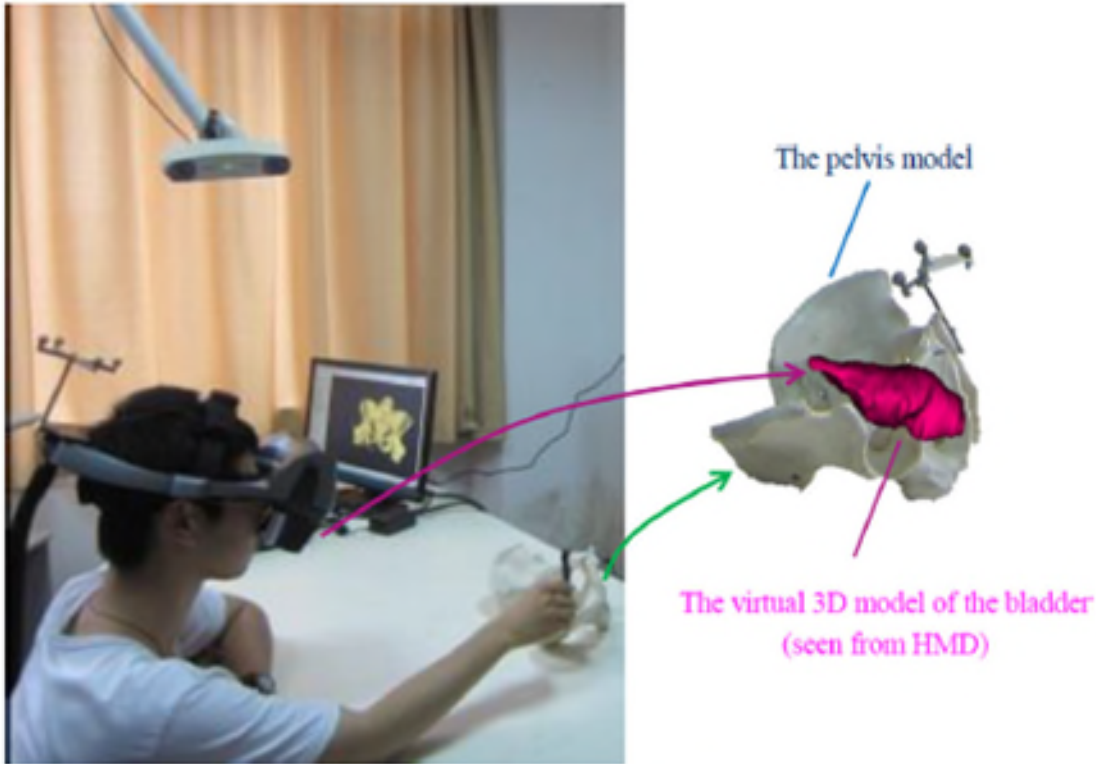


Fig. 6. Wearing HMD to conduct a phantom experiment.

- *Chen* discloses “an AR-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.” (Ex. 1009, Abstract; Pet., 56).
- With the use of *Chen’s* system, “3D virtual critical anatomical structures in the head-mounted display are aligned with the actual structures of patient in real-world scenario” (Ex. 1009, Abstract; Pet., 56).

Claim 1 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

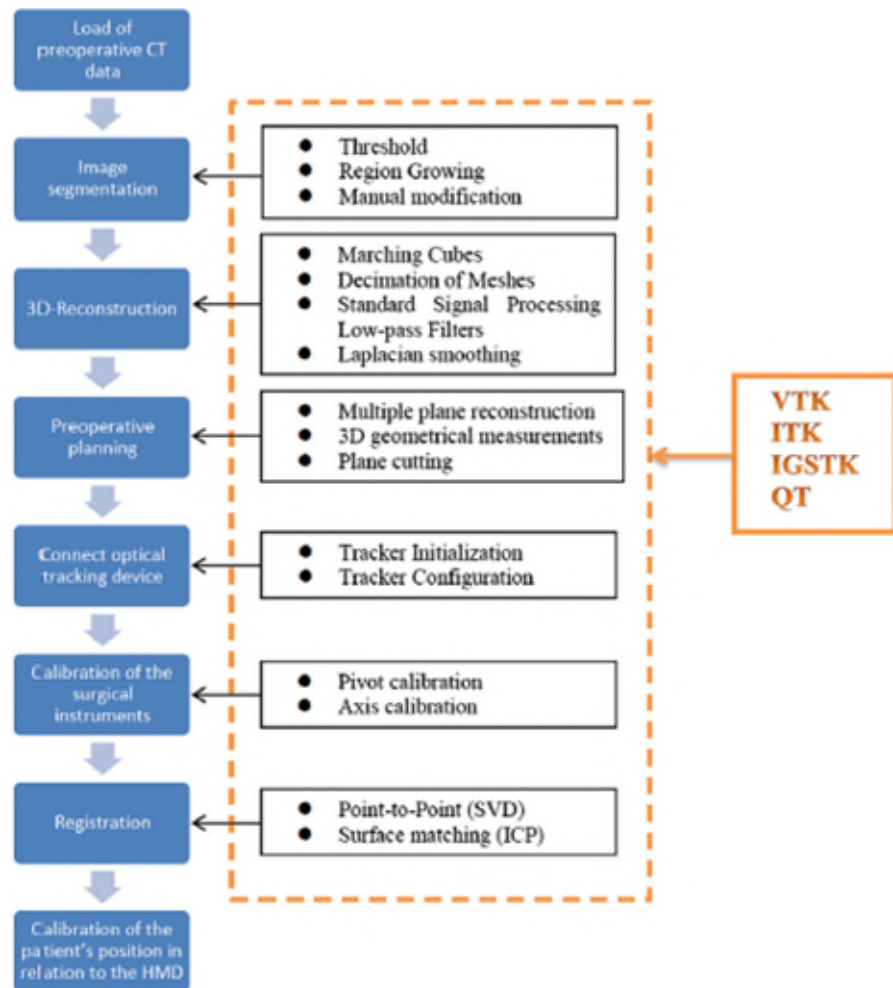


Fig. 2. The framework of AR-SNS.

- Figure 2 of *Chen* illustrates “Load of preoperative CT data” as the first step in the framework of the AR-SNS.” (Ex. 1009, Fig. 2; Pet., 56; Ex. 1012, ¶¶111-112).
- *Chen* discloses “3D models including hard and soft tissues, especially critical anatomical structures such as blood vessels and nerves can be reconstructed.” (Ex. 1009, 125:2:1-5; Pet., 56-57).

Claim 1 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

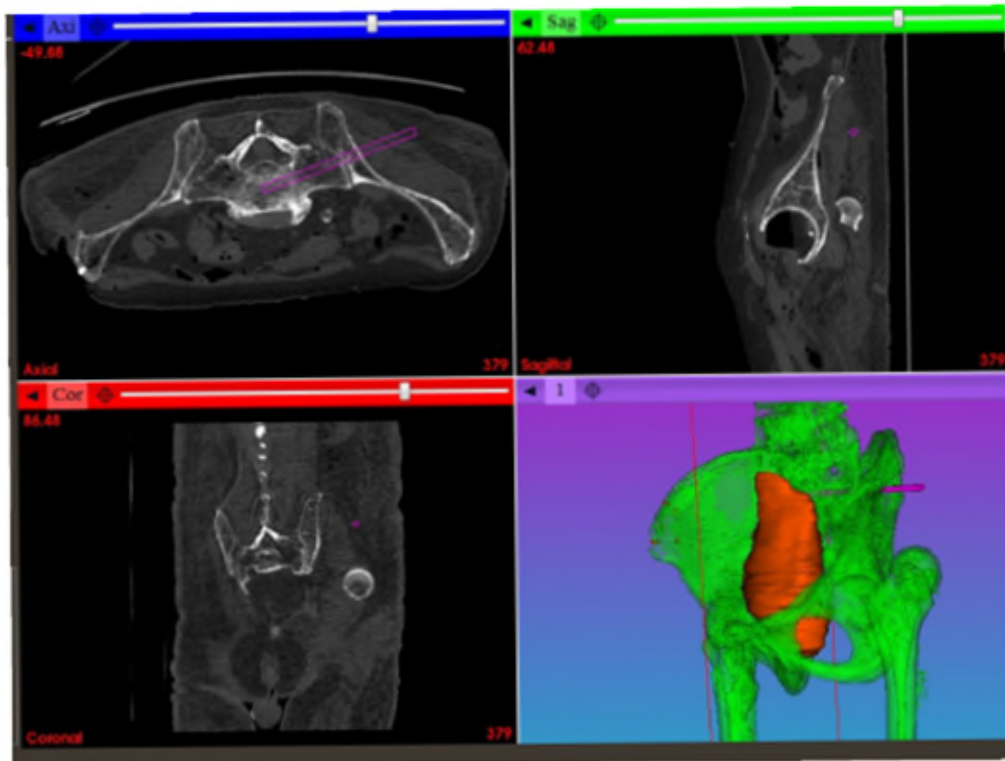


Fig. 4. A virtual path for the surgical drill rendering on all of the 2D/3D views.

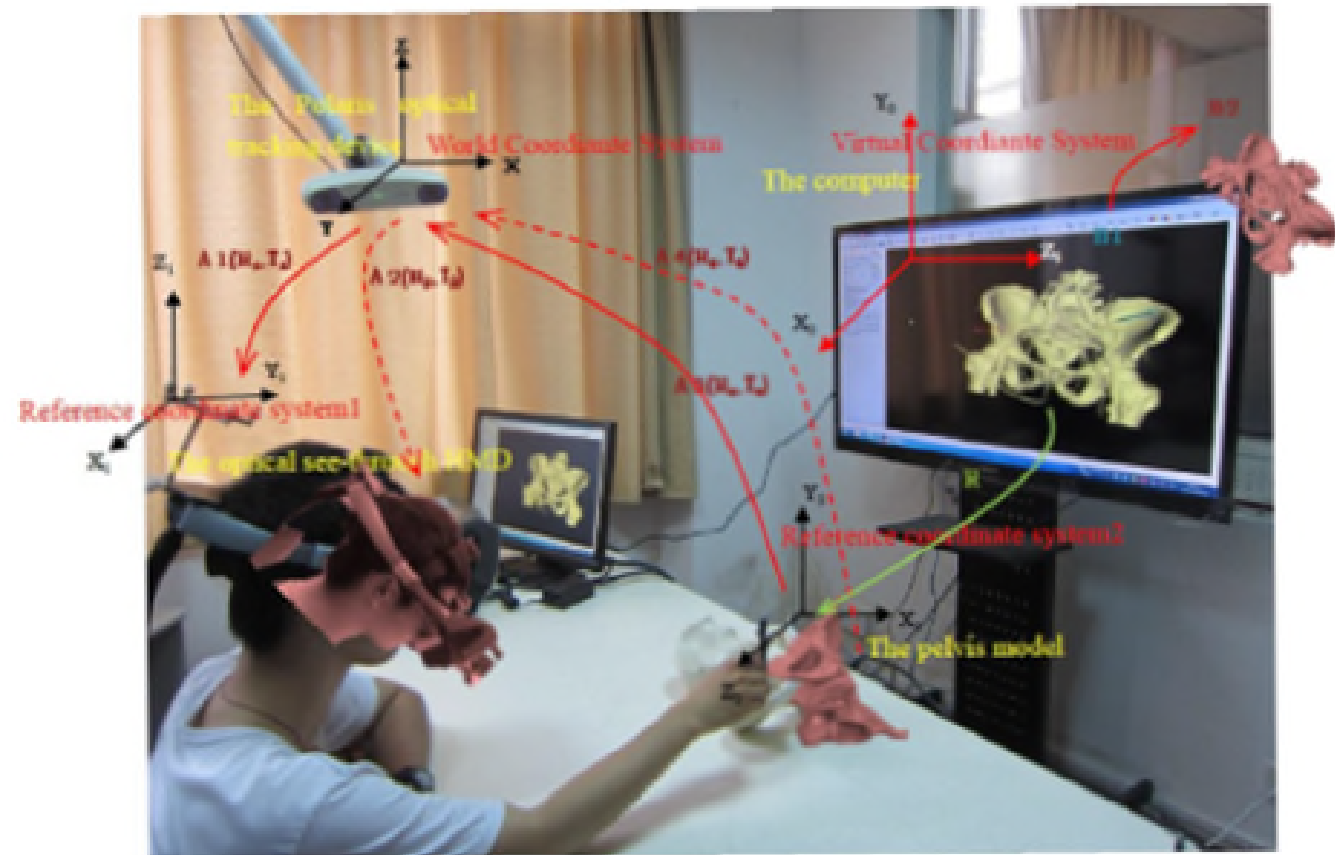


Fig. 5. The establishment of coordinate systems in AR-SNS.

Claim 1 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

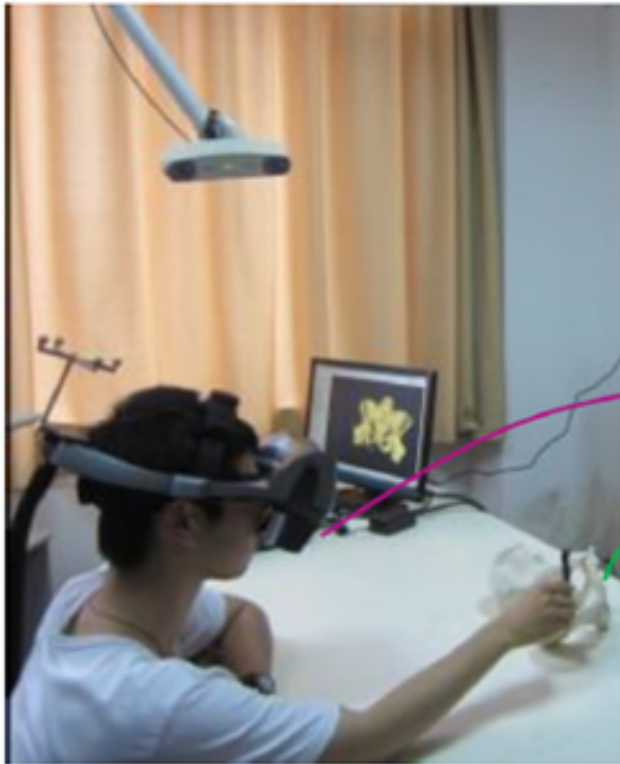
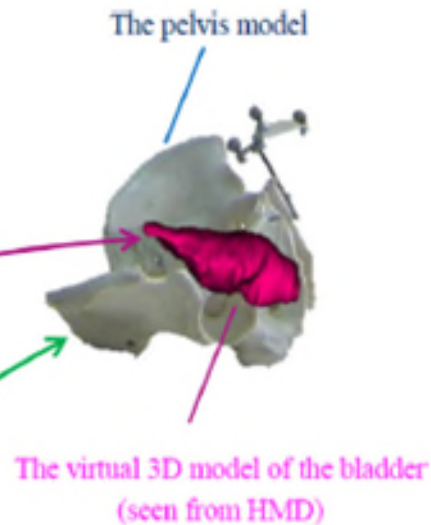
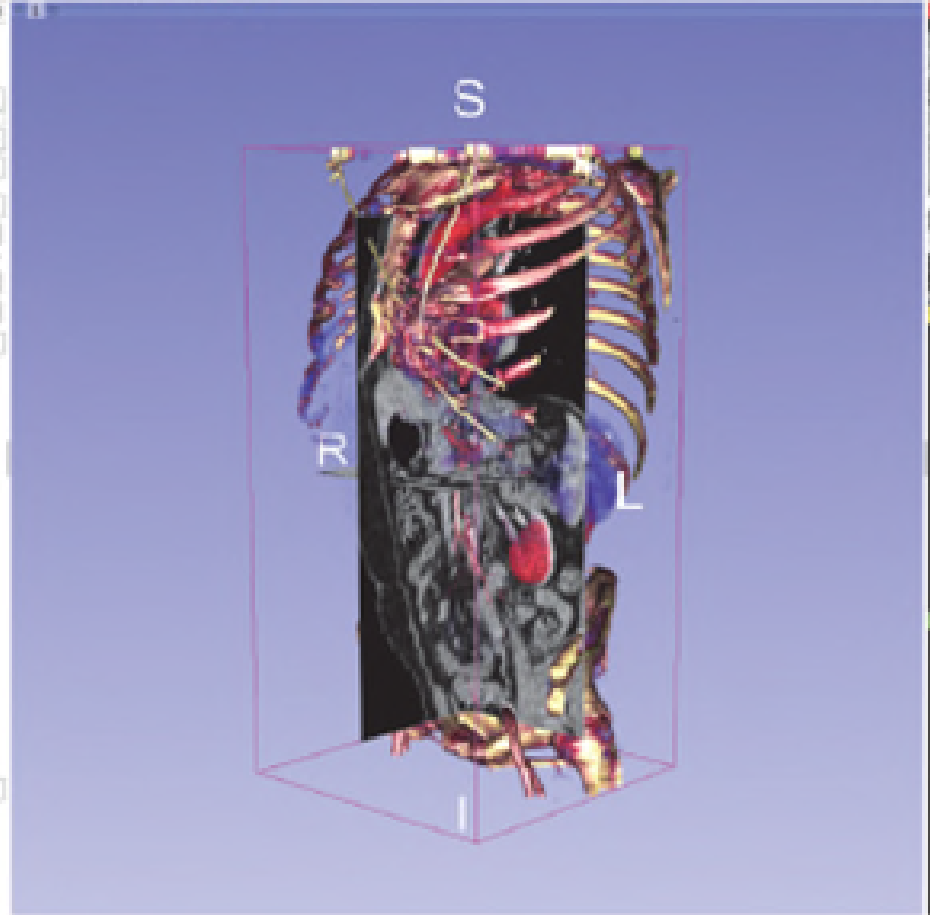


Fig. 6. Wearing HMD to conduct a phantom experiment.



- “[A]n 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, 125:2:14-17; Pet., 57; Ex. 1012, ¶¶113-117).
- “[A]lso conducted a cadaver experiment ... in an operating room.” (Ex. 1009, 129:2:19-21; Pet., 58).

Claim 1 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*



3D Slicer-Visualization discloses how to interact in 3D with structural images (Ex. 1007, Slide 2; Pet., 59-60).

3D Slicer-Visualization illustrates the 3D volume rendered image of the aorta and rib cage along with other 2D CT slices of the thorax and abdomen (Ex. 1007, Slide 44; Pet., 59-60; Ex. 1012, ¶118).

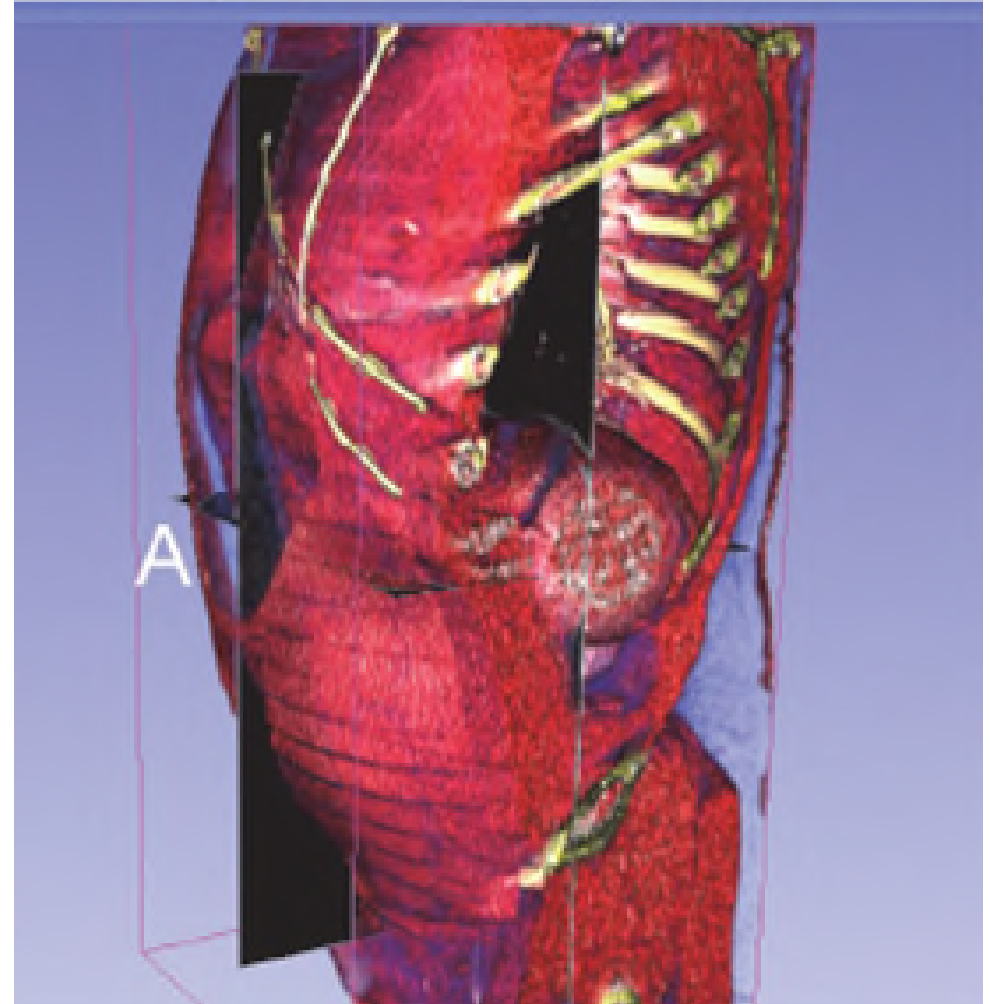
3D Slicer-Visualization discloses display of inner layer of the patient within a volume of a virtual 3D shape (Ex. 1007, Slide 44; Pet., 59-60; Ex. 1012, ¶118).

3D Slicer-Visualization's 3D Rendered Volume

Novarad argues: “The prior art only displays 2D images, stacks of 2D images, and 3D surface models.” (Sur-reply, 1).

3D Slicer-Visualization discloses display of “3D rendered volume”

(Ex. 1007, Slide 42 (figure to right); Pet., 18; see also Pet., 59-60, 62, 65-66, 68 (all citing *3D Slicer-Visualization* for volume rendering)).



Claim 1 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

Novarad **wrongly** suggests “[3D Slicer-GUI and 3D Slicer-Visualization] do not disclose ... manipulating 3D slices of a rendered image ...” (Sur-reply, 26).

- *3D Slicer-Visualization* discloses:
 - “display[ing] three [orthogonal] anatomical slices in the 3D viewer,”
 - rotating and translating the slices in the 3D viewer, and
 - “us[ing] ... slice sliders to slice through the volume in all three anatomical directions” (Ex. 1007, Slides 31-36).
- *3D Slicer-GUI* discloses “[a] Slice Scrollbar is provided for manually sweeping through slices” (Ex. 1010, 5).

Claim 1 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

- Novarad **wrongly** argues “*3D Slicer[-GUI]* and *3D [Slicer-]Visualization* cannot display medical imaging in an AR environment at all.”

(Sur-reply, 26 (citing Ex. 2004, Rosenberg)).

- Novarad’s argument is contradicted by pre-IPR evidence of record

CLAIM 11

11. [1pre] A method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data, the method comprising:

[1a] 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;

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

[1b] 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.

Claim 11 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

- *Chen* illustrates different color gradients for the same inner layers in Figures 4 and 6. (Ex. 1009, FIG. 4 (bladder gray and orange), FIG. 6 (bladder pink); Pet., 64-65; Ex. 1012, ¶¶ 127, 129).
- *Chen* discloses that, “surgeons and human-machine interaction experts ... found that the bright colors of virtual anatomical models with the black background in the HMD had a more vivid mixed reality effect.” (Ex. 1009, 131/1:11-15; Pet., 64-65; Ex. 1012, ¶¶ 127, 129).
- POSA would understand *Chen* discloses altering color gradient for better visibility (Ex. 1012, ¶ 127; Pet., 64-65).
- POSA would understand that *Chen* illustrates display of altered color gradient for a better effect. (Ex. 1012, ¶¶ 127, 129; Pet. 67).

Claim 11 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

- *3D Slicer-Visualization* illustrates a right kidney volume rendered in bright red to enhance visibility. (Ex. 1007, Slide 53; Pet., 65-66; Ex. 1012, ¶128).
- *3D Slicer-Visualization* illustrates coloring brain's white matter and the right and left optic nerves. (Ex. 1007, Slide 73; Pet., 66-68; Ex. 1012, ¶128).
- POSA would understand that *3D Slicer-Visualization* illustrates altering original color gradient for better visibility (Ex. 1012, ¶128-130; Pet. 65-68).
- POSA would understand that *3D Slicer-Visualization* discloses display of altered color gradient for better effect (Ex. 1012, ¶129-130; Pet., 65-68).

CLAIMS 12-19

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] “echogenicity”

[15] “enhancement amount”

[16] “enhancement speed”

[17] “density”

[18] “radioactivity”

[19] “water content”

Claim 12-19 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

Novarad argues “Chen Combination does not disclose altering the color gradient to identify any of the characteristics specifically identified in claims 12-19.” (Sur-reply, 27).

- The ‘271 Patent neither discloses nor claims altering color gradient to identify a tissue property:
 - Claim 11: “altering the original color gradient ... to be lighter than the original color gradient in order to be better visible when projected”
 - Claim 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.”

Claim 17 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

Novarad **admitted:**

- “The value of [each CT scan] pixel corresponds to the radiodensity of the tissue within the pixel” (POR, 3).
- *Chen* and *3D Slicer-Visualization* each disclose altering color gradient. (POR, 60-61).

Chen discloses:

- “[A]fter registration ..., surgeons can superimpose the virtual CT data onto the patient’s anatomy.” (Ex. 1009, 124:2:13-16).
- “[B]right colors of virtual anatomical models with the black background in the HMD had a more vivid mixed reality effect.” (*Id.*, 131:1:11-15; Reply, 29).

3D Slicer-Visualization discloses “a contrast-enhanced CT abdominal scan” (Ex. 1007, Slide 83).

Claims 12-19 Obvious Over *Chen, 3D Slicer-Visualization & 3D Slicer-GUI*

According to Kazanzides, 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; Pet., 52).

“Conventional 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; Pet., 4-5).

3D Slicer-Visualization discloses 3D data loading and visualization of DICOM images. (Ex. 1007, Slide 3).

Chen and *3D Slicer-Visualization* each disclose altering color gradient. (POR, 60-61).