

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDIVIS, INC.
Petitioner

v.

NOVARAD CORP.
Patent Owner

US Patent No. 11,004,271

Inter Partes Review No. IPR2023-00042

REPLY IN
***INTER PARTES* REVIEW OF US PATENT NO. 11,004,271**

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Ex. 1001	US Patent No. 11,004,271, claiming priority to March 30, 2017 (the ‘271 Patent)
Ex. 1002	Excerpts of File history of Application No. 16/574,524, now the ‘271 Patent
Ex. 1003	Excerpts of File history of Application No. 15/894,595, now U.S. Patent No. 10,475,244, through which the ‘271 Patent claims priority
Ex. 1004	Excerpts of File history of Application No. 15/474,702, filed on March 30, 2017, and now U.S. Patent No. 9,892,564, through which the ‘271 Patent claims priority
Ex. 1005	Excerpt of Amira 5 User’s Guide title through Chapter 2 (Visual Imaging 2009) (“ <i>Amira</i> ”)
Ex. 1006	US Patent Application Publication No. US 2016/0191887 A1 to Casas, published on June 30, 2016 (“ <i>Casas</i> ”)
Ex. 1007	S. Pujol, Ph.D. et al., 3D Visualization of DICOM Images for Radiological Applications (Surgical Planning Laboratory, Brigham and Women’s Hospital, Boston, Massachusetts 2014) (“ <i>3D Visualization</i> ”)
Ex. 1008	International Publication No. WO 2015/164402 A1 to Doo et al., published on October 29, 2015 (“ <i>Doo</i> ”)
Ex. 1009	X. Chen et al., “Development of a Surgical Navigation System Based On Augmented Reality Using an Optical See-Through Head-Mounted Display,” 55 JOURNAL OF BIOMEDICAL INFORMATICS 124-131 (2015) (“ <i>Chen</i> ”)

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Ex. 1010	Main Application GUI for 3D Slicer < https://www.slicer.org/wiki/Documentation/4.6/Slicer/Application/MainApplicationGUI > (last edited 7 November 2016) (“3D Slicer”)
Ex. 1011	E. Azimi et al., “Augmented Reality Goggles with an Integrated Tracking System for Navigations in Neurosurgery,” IEEE VIRTUAL REALITY 123-124, 123 (IEEE 2012) (“AR Goggle for Neurosurgery”).
Ex. 1012	Declaration of Peter Kazanzides Ph.D.
Ex. 1013	Curriculum Vitae of Peter Kazanzides Ph.D.
Ex. 1014	Email message entitled “Novarad v. Medivis” and dated August 3, 2022, from counsel for Novarad, Brett Davis, to counsel for Medivis, Brian Lemon and others.
Exhibit 1015	Declaration of Christopher Fraiser (May 22, 2023) [served May 22, 2023]
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Exhibit 1020	A. Federov et al., “3D Slicer as an image Computing Platform for the Quantitative Imaging Network,” 30 MAGNETIC RESONANCE IMAGING 1323-1341 (2012) [served May 22, 2023]
Exhibit 1021	Supplemental Declaration of Peter Kazanzides Ph.D. (May 22, 2023) [served May 22, 2023]
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Exhibit 1025	The Britannica Dictionary Definition of “Confine” from < https://www.britannica.com/dictionary/confine > (downloaded 9/7/23).
Exhibit 1026	Merriam-Webster Dictionary Definition & Meaning of “Confined” from < https://www.merriam-webster.com/dictionary/confined > (downloaded 9/7/23).
Exhibit 1027	Cambridge English Dictionary Definition of “Confine” from < https://dictionary.cambridge.org/us/dictionary/english/confine > (downloaded 9/7/23).
Exhibit 1028	Declaration of Pamela Keyl (October 10, 2023)

I. INTRODUCTION

The Board preliminarily found that *Doo* anticipates Claims 1, 5, and 6 of the ‘271 Patent. Further, the combinations of *Doo* and *Amira* or *Chen*, *3D-Visualization*, and *3D Slicer-GUI* render Claims 1-6 and 11-20 obvious. Petition, 41-69. Nothing in Novarad’s response defeats these challenges.

To distinguish the cited prior art, Novarad relies on claim constructions that conflict with the ‘271 Patent and are thus improper. But even if the Board were to adopt Novarad’s improper constructions, the cited references still render the challenged claims obvious.

II. CLAIM CONSTRUCTION

Novarad originally contended, and its proffered-expert agreed, that the claims should be given their plain and ordinary meaning. Ex. 1014; Ex. 1022, 111:7-10. But, now facing an instituted IPR, Novarad proposes unordinary meanings that contradict the claims and specification.

A. The Response Does Not Qualify the Cited Opinions

Novarad disputes neither Medivis’s definition of the person of ordinary skill in the art (POSA) (*see* Petition, Section III.B) nor the general scope and content of the prior art detailed in the Petition, Section IV.B. Nonetheless, relying on the Mulumudi and Rosenberg Declarations (Exs. 2002, 2004), Novarad cites opinions as to the perspective of the POSA. But only a qualified expert may opine. FRE

702 (including new clarifying amendment). Novarad bears the burden to qualify its alleged experts and their opinions. *Id.* But Novarad failed to meet its burden because it has not cited in its response any evidence that its declarants are qualified or that their opinions are reliable. FRE 104(a). The Board should not be forced to “play arch[a]eologist with the record.” *General Access Solutions, Ltd. v. Sprint Spectrum L.P.*, 811 F. App'x 654, 657 (Fed. Cir. 2020) (unpublished); *see also DeSilva v. DiLeonardi*, 181 F.3d 865, 866-67 (7th Cir. 1999) (“A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record”). Accordingly, none of the statements in the Response attributed to Novarad’s declarants should be considered admissible evidence.

B. The Patent Conflicts with Novarad’s Construction of “3D data”

Claim Term	Novarad’s Proposed Construction	Medivis’s Proposed Construction
“three-dimensional (3D) data” / “3D data” “three-dimensional (3D) data ... including an outer layer of the patient and multiple inner layers of the patient”	“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” ¹	“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” No “direct-volume-rendering” limitation applies

Novarad’s addition of “direct-volume-rendered” and “direct volume rendering” (both “DVR”) to the claims is wrong for two reasons: it (1) adds an unsupported limitation, (2) contradicts the claims and specification.

First, DVR is found nowhere in the claims or specification. If DVR were an essential part of the invention, as Novarad argues, the ’271 patent should have mentioned it. Novarad’s proffered-expert Mulumudi admitted that he could identify DVR only by the use of the phrase “direct volume rendering.” Ex. 1022,

¹Summary tables in Novarad’s Response do not fairly summarize the constructions that Novarad applies when seeking to distinguish the cited art. Medivis, therefore, summarizes all of Novarad’s argued constructions in the summary tables throughout this reply.

129:17-130:1 (“Q. Is there any way that you could tell whether the volume rendering referenced on page 49 of *Amira* is direct volume rendering without the words ‘direct’—the phrase ‘direct volume rendering’ being used? THE WITNESS: No”). Thus, it is unclear how Mulumudi could have found DVR in the ‘271 Patent, which does not mention “direct volume rendering.”

Second, a DVR requirement conflicts with the claims and specification. Claim 1 requires (1) “identifying 3D data,” which data includes, *inter alia*, “multiple inner layers of the patient,” and (2) displaying “one of the inner layers of the patient from the 3D data.” Ex. 1001, 18:60-61. Contrary to Claim 1, Novarad’s proposed DVR limitation, which requires an image of the *entire* anatomical volume that is neither feature-specific nor segmented, would seemingly require that all inner layers be displayed.

Relying on a conflation of “slices” and “layers,” Novarad argues that “3D data must have height, width, and depth.” Response, 13. But Claim 3 recites “slices of the projected inner layer,” thus differentiating slices from layers. Indeed, Novarad’s proffered expert admitted that “slices” and “layers” are different. Ex. 1022, 32:7-16.²

² Even if slices were conflated with layers, as Novarad suggests, the specification teaches the possible “display [of] a slice of the 3D data **instead of a volume** of the 3D data.” Ex. 1001, 5:34-35 (emphasis added).

Contrary to Novarad's argument, Professor Kazanzides explained that, "depending on context, [3D] has different meanings." Ex. 2006, 57:20-58:10. He clarified that "[o]ne meaning [of 3D] is that it has ... three coordinates, X, Y, and Z." Ex. 2006, 57:20-58:10. Accordingly, Professor Kazanzides explained that "multiple x-ray images would be considered 3D data." *Id.*, 59:19-60:13. "[A]s one example, you can have a biplane x-ray where you take x-ray images from orthogonal direction, and based on that you ... identify 3D points in the anatomy" *Id.*, 60:6-13. Alternatively, each slice in a stack of 2D slices may provide information "common to the slice" but "relative to the other slices." *Id.*, 62:17-66:1. *Amira* confirms that "[a] common way to store 3D image data is to write a separate 2D image file for each slice." Ex. 1005, 39. Importantly, Novarad's proffered-expert Mulumudi admitted that "3D data can be stored as a plurality of 2D images." Ex. 1022, 127:12-14.

Finally, the '271-specification conflicts with Novarad's construction that "3D data" excludes X-ray images. Response, 11-12. The '271-specification explains that **"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 (emphasis added). Indeed, "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.**" *Id.*, 12:4-7 (emphasis added).

C. The Patent Refutes Novarad’s Construction of “Inner Layer(s) of The Patient”

Claim Term	Novarad’s Proposed Construction	Medivis’s Proposed Construction
“inner layer(s) of the patient” (proposed by Novarad)	“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”	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

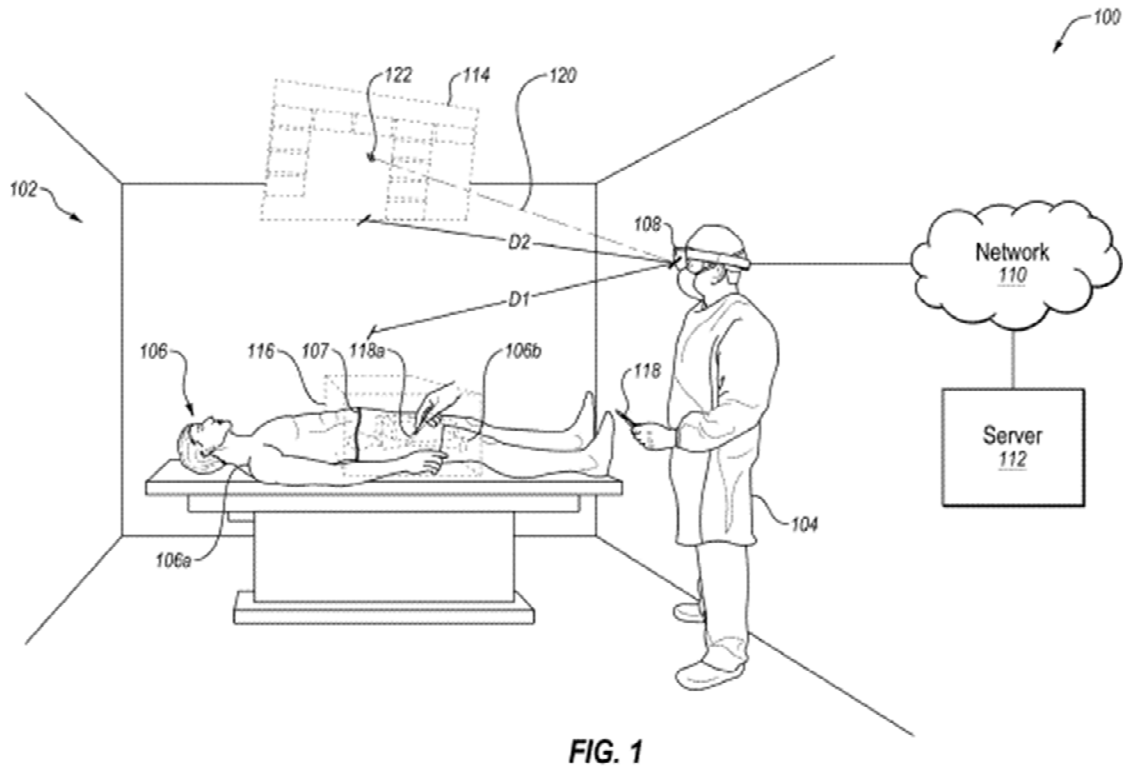
Novarad’s proposal to add a 3D-DVR limitation through its construction of “inner layer(s) of the patient” likewise conflicts with the ’271 Patent. Because Novarad links its proposed construction to “the projection” of one of the inner layers and “an ‘inner layer’” (Response, 15 (emphasis added)), Medivis understands that Novarad seeks to limit the following terms in Claims 1 and 11:

- The step in both claims of “displaying ... **one of the inner layers** of the patient from the 3D data **projected** onto real-time, non-image actual views of the patient”;
- Claim 1’s “**the projected inner layer** of the patient ... being confined within a volume of a virtual 3D shape”; and

- Claim 11's "**the projected inner layer** of the patient ... being having the altered color gradient."

Novarad's proposed "3D-DVR" limitation conflicts with the preferred embodiments of the foregoing limitations. For instance, method 600 in FIGS. 6A-6E is the exemplary method for "augmenting views of a patient with 3D data." Ex. 1001 11:19-20. According to the specification, "method 600 may employ still X-ray images of the skeletal system of the patient 106 (as illustrated in FIG. 1)." *Id.*, 11:53-55. Block 612 of method 600 is "[d]isplay[ing] one of the inner layers of the patient from the 3D data projected onto real-time views of the outer layer of the patient." *Id.*, FIG. 6A, 13:25-27. The preferred embodiments of a projected inner layer illuminate the scope of the "displaying" step.

The first example of block 612 is displaying "bones 106b of the patient 106 ... projected" in FIG. 1 (shown below). Ex. 1001, 13:27-31.

**FIG. 1**

Id. 14:26-34, FIG. 1. Figure 1's exemplary projected bones 106b refute Novarad's proposed 3D-DVR limitation in two ways:

- (a) contrary to Novarad's exclusion of X-ray images from "3D data" (Response, 11), Figure 1 illustrates the "employ[ment of] still X-ray images of the skeletal system" (Ex. 1001, 11:53-55);
- (b) contrary to Novarad's "DVR" definition, which is "unsegmented" and "not feature specific" (Response, 39-40, 5), bones 106b are a specific feature segmented from the whole volume.

The second example of block 612 displays "a CT scan image of the brain of the patient ... 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." Ex. 1001, 13:31-34.

Novarad admits that a CT scan image is 2D. Response, 2.

FIGS. 2C and 2E each illustrate a 2D CT image projected and confined within a virtual box.

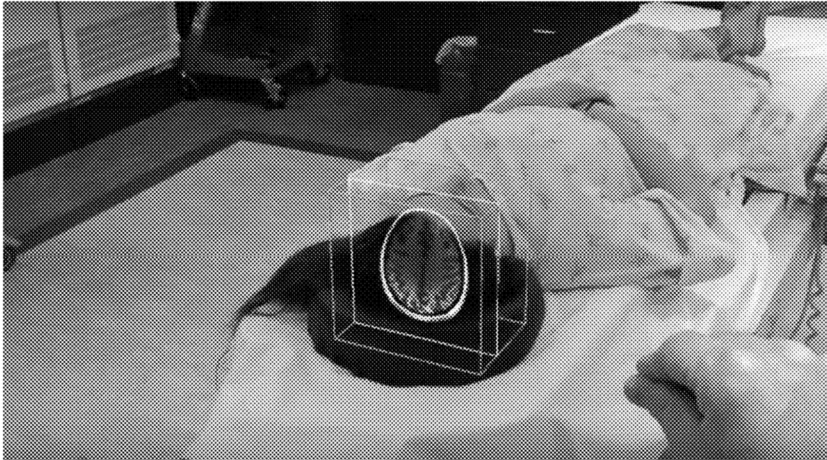


FIG. 2C

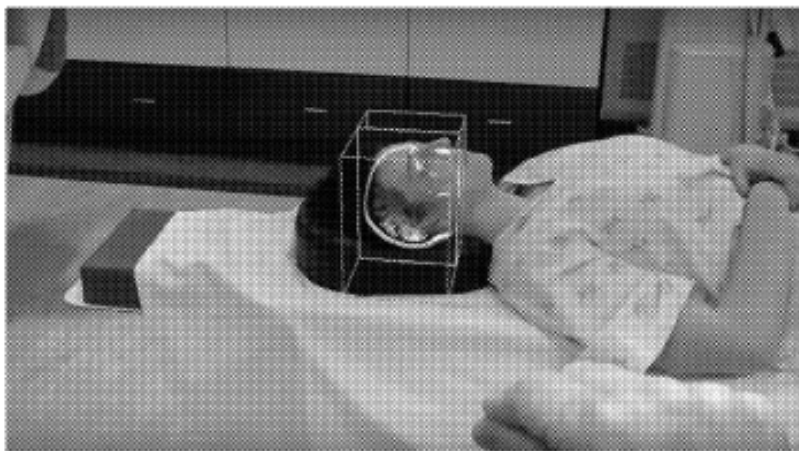


FIG. 2E

Ex. 1001, 8:36-39, FIGS. 2C, 2E. Contrary to these examples, Novarad argues that “the projection ... must have height, width, and depth.” Response, 15; *see also id.* 12 (same). Except to the extent that projection of a 2D image imbues it with the

requisite volume, as the ‘271 patent explains (Ex. 1001, 12:4-7), each exemplary CT scan lacks the volume Novarad’s proposed 3D-DVR construction requires.

**D. The Patent Refutes Novarad’s Proposed Construction of
“Confined Within a Volume of a Virtual 3D Shape”**

Claim Term	Novarad’s Proposed Construction	Medivis’s Proposed Construction
“virtual 3D shape” (proposed by Medivis) “confined within a volume of a virtual 3D shape” (proposed by Novarad)	“confined within ... a virtual 3D shape” means “navigated along any axis ... a virtual control;”	“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

To distinguish the art, Novarad argues that “confined” means “navigated ... along any axis.” Response 18; *see also id.* 27, 28. The specification, however, does not suggest that “confined” has any meaning outside the ordinary. To Novarad’s proffered-expert, “confine” is not a technical term. Ex. 1022, 19:12-16. The plain and ordinary meaning of “confined” is, simply, “kept.” Exs. 1025, 1026, 1027. In context, “confined within a volume” means “kept within a volume.”

Contrary to the specification, Novarad argues that “the virtual 3D shape is a ‘virtual control’ that ‘controls’ what portion of the volume of the projected 3D layers are visible to the user.” Response, 17; *see also id.* 58 (“the ‘virtual 3D shape’ is a ‘virtual control’”), 30, 41. But the specification uses the ordinary meaning of “shape.” *See, e.g.*, Ex. 1001, 6:56-61 (“a specific **shape** to be more easily sensed (**such** as by shaping the tip ... **as a sphere**)”), 12:34-45 (“measurements ... to determine the size and **shape** of the outer layer”) (emphasis added). Moreover, Novarad’s proffered-expert testified that “shape” is not a technical term and that the only meaning of “shape” he could identify is “form.” Ex. 1022, 17:5-18:13.

Nothing in the specification’s limited disclosure of “virtual 3D shape” suggests that it is a control. For instance, the step disclosed in block 626 is “[d]isplay[ing] a virtual spatial difference box projected onto real-time views of the outer layer of the patient.” Ex. 1001, FIG. 6C, 14:26-34. The first example of block 626 is displaying “a virtual spatial difference box 116 [that] confine[s] within [its] volume ... the projected inner layer of the patient 106 ..., such as the projected bones 106b of FIG. 1.” Figure 1 (below) illustrates “virtual user interface 114” and “virtual cursor 122” as the virtual control elements, both of which are distinct from “virtual spatial difference box 116.” *Id.*, FIG. 1; *see also id.*

3:63-4:7, 5:18-49, 7:18-31. Accordingly, the specification discloses that controls, such as user interfaces and cursers, are distinct from the virtual 3D shape.

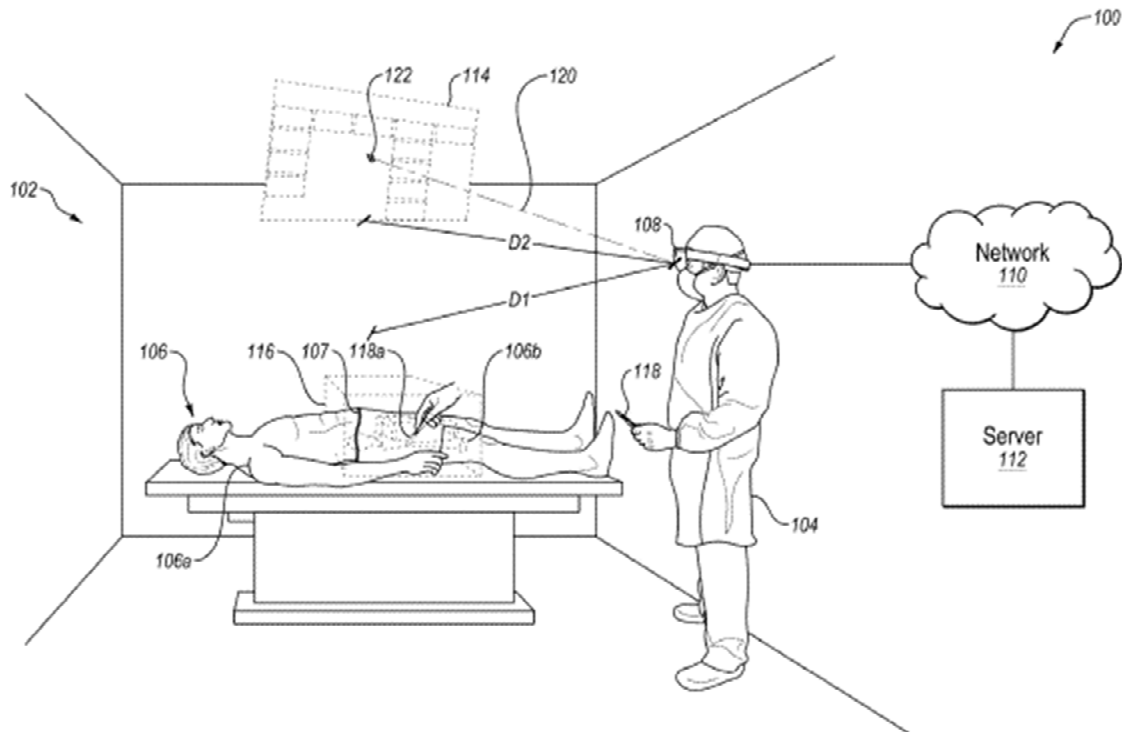


FIG. 1

Contrary to Novarad's interpretation, the patent at most suggests using a "virtual 3D shape" as a frame of reference. It does not suggest that the virtual 3D shape itself be a control. According to the specification, "box 116 *may also assist* the user when navigating the projected 3D data *by providing a frame of reference.*" *Id.*, 6:11-13 (emphasis added). "[T]his frame of reference 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." *Id.*, 6:14-17. A user

may move the slices and control the view using hand gestures or voice commands, for example. *Id.*, 6:21-26, 7:57-8:25.

Finally, Novarad cites Claim 3’s requirement that the virtual 3D shape be “configured to be controlled to reposition ... slices of the projected inner layer.” But Claim 3 at most requires the shape to “be controlled”—not to be a control. Something that is controlled need not itself be a control. Accordingly, a “virtual 3D shape” is better understood in the context of the specification as a “virtual 3D shape (i.e., form) as simple as a box and as complex as the outer layer of the patient,” **not** a control.

E. Novarad Fails to Show that its Inclusion of “Being Having” Is a Correctable Error

Claim Term	Novarad’s Proposed Construction	Medivis’s Proposed Construction
“being having”	“having;” (delete “being”)	“being or having”

Novarad’s inclusion of “being having” was its own error. Ex. 1002, 22, 80; Response 18. But Novarad fails to prove that its error was merely clerical and offers no explanation as to why deleting “being” is the obvious correction. According to Novarad’s proffered-expert, “being” and “having” are not synonyms. Ex. 1022, 16:10-12. Novarad thus fails to satisfy the statutory requirements (35 USC §255) to allow correction of its allegedly-clerical error.

III. *DOO* ANTICIPATES CLAIMS 1, 5, AND 6

A. *Doo* Anticipates Claim 1

Novarad argues against anticipation by ignoring *Doo*'s disclosure and by applying claim constructions that conflict with the '271 Patent's disclosure.

1. **Preamble: “[a] method for augmenting real-time, non-image actual views of a patient with three-dimensional (3D) data”**

Doo discloses a “method for displaying ... three-dimensional visual data in real-time and in perceived three-dimensional space.” Ex. 1008, [00030]. *Doo* further discloses that an “image can be overlaid on the patient's actual anatomical feature and, ... sized to match ..., thus creating the visual impression of a ‘true registration’ and a form of *augmented* reality.” *Id.*, [00037] (emphasis added).

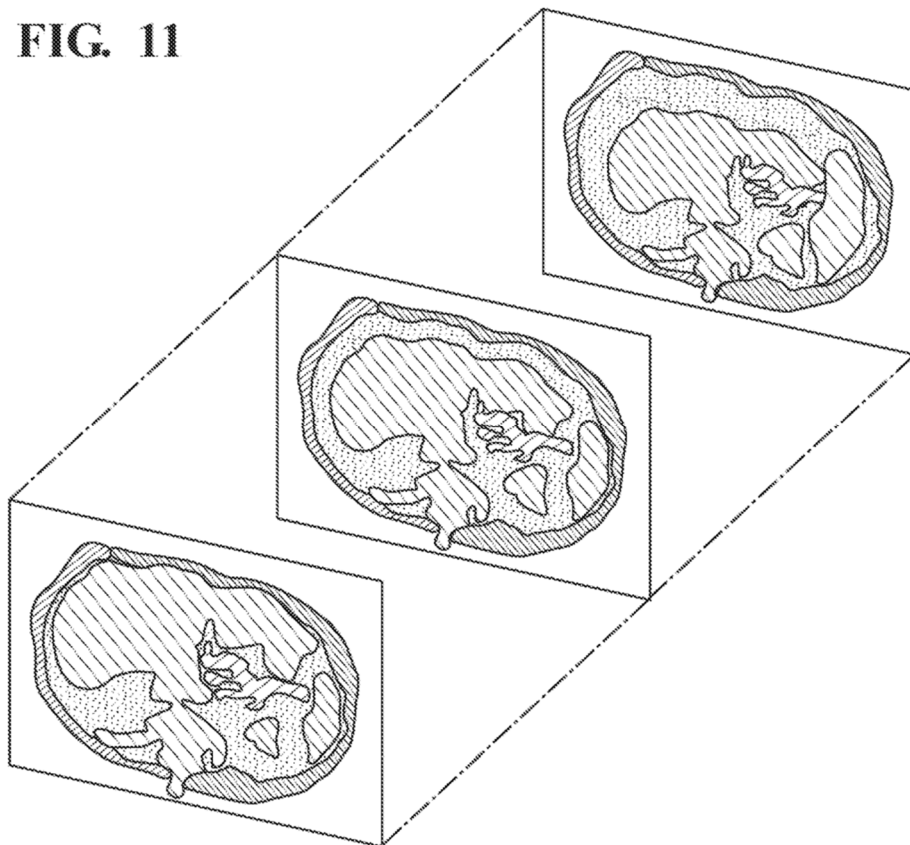
In its discussion of Figure 2, *Doo* discloses that “display 30 can be selectively ... transparent and configured to exhibit at least one medical image 32 to the surgeon 26 that is overlaid on the patient 28.” *Id.*, [00038]; *see also* Decision, 8. In other words, *Doo* discloses augmenting the view of the patient with 3D data.

2. **Claim 1's first step: “identifying 3D data for the patient, the 3D data including an outer layer of the patient and multiple inner layers of the patient”**

Novarad's attempt to distinguish *Doo* based on its unreasonably narrow construction of “3D data” fails because, as explained above, Novarad's

construction conflicts with the '271 Patent's disclosure and with the testimony of Novarad's own declarant. For example, Novarad's proffered-expert admitted that "3D data can be stored as a plurality of 2D images." Ex. 1022, 127:12-14. Novarad admits that *Doo* discloses the same "potential sources of 3D data for the patient, including [CT] and [MRI]," as the '271-specification discloses. Response 26; *also compare* Ex. 1001, 11:34-55, with Exhibit 1008, [0040]. *Doo's* Figure 11 (below), for example, illustrates 3D data, including an outer layer and multiple inner layers of the patient.

FIG. 11



3. **Claim 1's second step: "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"**

Contrary to Novarad's argument, Medivis's evidence is not limited to *Doo*'s Figures 2 and 3. *Doo* also discloses that "[d]isplay 30 can be a component of a head mountable unit 46 ... worn by the surgeon." Decision 8-9, 10 (quoting Exhibit 1008, [0038], [00044], FIG. 3). *Doo* discloses "render[ing] a medical image] from a [different] perspective." Exhibit 1008, [0033]. *Doo* discloses "position[ing] and scal[ing] a medical image relative to the patient 28 from the perspective of the surgeon 26." Ex. 1008, [0033]. Thus, *Doo* discloses an "image ... overlaid on the patient's actual anatomical feature ..., thus creating ... augmented reality." *Id.*, [0037].

Moreover, "*Doo*'s Figures 2 and 3 ... show that 'the projected display may be inner layers of the patient from the 3D data.'" Decision 11. The '271-specification's preferred embodiments of projected inner layer(s) are remarkably similar to exemplary projected inner layer(s) disclosed in *Doo*. For example, whereas the '271-specification discloses Figure 1's projected bones 106b as one preferred embodiment (Ex. 1001, 13:25-31), *Doo* illustrates the projection of bones in Figure 3 and describes them as "overlaid on patient 28" (Ex. 1008, [0040]-[0041], [0041]). Novarad articulates no real distinction between the two sets of projected bones.

The other preferred embodiments disclosed in the '271-specification comprise 2D "CT scan image of the brain ... projected onto ... the head of the patient." Ex. 1001, 13:25-34. *Doo* projects similar images. Contrary to Novarad's argument that *Doo*'s projected "two-dimensional 'x-ray of the chest of the patient ... [lacks] any three-dimensional significance" (Response 27), the '271-specification explains that "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.**" Exhibit 1001, 12:1-7 (emphasis added).

4. **Claim 1's final limitation: "the projected inner layer of the patient from the 3D data being confined within a volume of a virtual 3D shape"**

While Novarad argues that *Doo*'s figures "Cannot Confine a 3D Volume" (Response 29-32), Claim 1 requires an inner layer "confined *within* a volume," not a confined volume. The '271-specification's preferred embodiments of a projected inner layer (all disclosed with respect to block 612) are not reasonably distinguishable from *Doo*'s exemplary projected inner layers.

Despite the '271 Patent's reliance on conventional medical imaging (Ex. 1001, 2:49-51), Novarad argues that what was known in the art is conjecture (Response 28-29). But among other features of conventional medical imaging systems, the Petition discusses the bounding boxes of *Amira* and *3D-Visualization*.

Petition 16-23. By definition, a bounding box confines 3D data within a volume. *See, e.g.*, Ex. 1005, 40.

Doo's shape 532 in Figure 9 and shape 432 in Figure 7 are virtual 3D shapes. A body's surface is a 3D shape. *Doo* discloses that Figure 9's shape 532 "mimic[s] the surface curvature of the patient's body." Ex. 1008, [00076]. *Doo*'s Figure 7 illustrates projection of inner layers that are confined within the volume of shape 432.

As to *Doo*'s Figure 11, Novarad argues that some processing must be done before 3D slices may be obtained. Response 31. To the contrary, *Doo*'s "Figure 11 **is** a series of [3D] tomographic slices of an anatomical feature of a patient." Ex. 1008, [0026] (emphasis added). Further, *Doo*'s "Figure 11 illustrates ... 'fly through 3D' in which a series of **three-dimensional ... slices** can be sequentially exhibited." *Id.*, [0078] (emphasis added). Also, *Doo*'s "fusion [of 3D slices] create[s] a 3D image" within a bounding box. *Id.*, [0078]. *Doo* further discloses modifying the overlaid image to "adapt[] the image as it is perceived by the surgeon. *Id.*, [0041].

B. *Doo* Anticipates Claim 5 and 6

Doo discloses that "[t]he image ... is selectively and/or variably transparent[;] the surgeon 26 controls the image opacity [up to] fully transparent" Ex. 1008, [0030]. As such, *Doo* discloses hiding the lines of the 3D shape.

IV. *DOO* AND *AMIRA* RENDER CLAIMS 1-6 AND 11-20 OBVIOUS

The discussion above, as to how *Doo* anticipates Claims 1, 5 and 6, is incorporated by reference. *Doo* plus *Amira* renders those and all other challenged claims obvious.

A. *Amira* Is Prior Art

As a preliminary matter, *Amira* (Ex. 1005) is a user guide that was publically available in 2009. Copyrighted “1999-2009,” it was available on the internet on October 4, 2012. Ex. 1005 4; Ex. 1024, ¶¶ 5-6, 4-406. *See International Business Machines 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); *Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1374-75 (Fed. Cir. 2021) (Wayback Machine® *prima facie* evidence of public availability); MPEP §2128.II.E.

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

Novarad admits that “*Amira* is software for displaying medical imaging” and that “*Amira* generally displays images ... on 2D computer monitors.” Response 43, 44. *Amira* also discloses a “Virtual Reality Option,” including

“[t]racking capabilities [that] allow for ... interaction with the visualization.” Ex. 1005, 14/26.³

Doo teaches that, conventionally, “[a]n operating room ... with many display screens ... presenting ... anatomical ... image data to the surgeon causes several problems,” such as distraction and cognitive load. Ex. 1008, [0003], [0004]-[0007]. *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. *Id.*, [0010]. Thus, similar to the ‘271 Patent, but contrary to Novarad’s argument, *Doo* suggests an improvement on conventional medical imaging displays, such as disclosed in *Amira*.

C. *Doo* and *Amira* Render Claim 1 Obvious

Amira remedies alleged deficiencies in *Doo*. For example, contrary to Novarad’s arguments, *Amira* discloses “direct volume rendering” of “3D image data.” Ex. 1005, 6/18-7/19; *see also id.* 26/38-27/39, 32/44-39/51.

“In *Amira* the bounding box of an object is the smallest rectangular, axis-aligned volume in 3D space that encompasses the object.” Ex. 1005, 28/40. In other words, *Amira* discloses an object that is confined within the volume of its bounding box. Novarad admits that “*Amira*’s bounding box ... represents the

³ Each page of *Amira* contains two page numbers. To avoid confusion, Medivis cites both as “#/#.”

space in which the displayed data set exists” and that “*Amira* shows ... bones and skin[] surrounded by a box.” Response, 39.

“*Amira*[‘s] Virtual Reality Option ... enable[s] the use of *Amira*’s advanced data visualization and analysis features on immersive VR systems” Ex. 1005, 14/26. That option includes VR “tracking capabilities [that] allow for ... interaction with the visualization.” *Id.* Like the ‘271-specification’s preferred embodiment of a virtual 3D shape (box 116), *Amira*’s axis-aligned bounding box may assist the user when navigating the projected 3D data by providing a frame of reference.

Contrary to Novarad’s arguments, *Amira* discloses Claim 1’s step of “displaying ... one of the inner layers of the patient from the 3D data, ... confined within a volume of a virtual 3D shape,” such as the bones surrounded by skin surrounded by a bounding box. Ex. 1005, 79/91-80/92.

Similar to the ‘271 Patent, *Doo* discloses improvements on conventional imaging technology, such as disclosed in *Amira*. As Novarad explains, in “an augmented reality environment[,], virtual objects are projected onto a real-life object.” Response 37. *Doo*, however, discloses displaying one of the inner layers of the patient, such as bones, in an augmented reality (AR) headset. As previously discussed, *Doo* also discloses overlaying an image “sized to match the actual

anatomical feature, thus creating the visual impression of a ‘true registration’ and a form of augmented reality.” Ex. 1008, [00037].

D. *Doo* and *Amira* Render Claims 2-6 Obvious

Novarad’s challenges to Claims 2 and 4-6 are based on alleged deficiencies relating to Claim 1, which Medivis addressed above. Novard’s only specific quarrel relates to Claim 3. Contrary to Novarad’s argument, Claim 3 requires only that something “be controlled.” *Amira* discloses that its bounding box, and an object encompassed therein, may “be controlled” through various user interfaces. Petition 44-45.

Moreover, *Amira* is not limited to a conventional 2D mouse interface but rather discloses imaging navigation through user interaction with a 3D virtual interface. *Amira* discloses a “Virtual Reality Option Users Guide.” Ex. 1005, vi/10-vii/11. *Amira* discloses that part of its VR option is “3D User Interaction” involving “Navigation Modes.” *Id.* Medivis previously served a complete version of *Amira* including that VR Users Guide. Ex. 2024, 280-341.

Nor is *Doo*’s disclosure reasonably distinguishable from the requirements of Claim 3. *Doo* discloses “an image control input can be [the surgeon’s] voice ..., ... hand gesture ..., [or] eye movements.” Exhibit 1008, [0042]. “*Doo*[/] teach[es] that ‘an image control unit ... controls the display so that at least a portion of an image can be exhibited’ and ‘a plurality of peripheral devices are each configured

to ... generate an image control signal.” Decision 10 (quoting Ex. 1008, Abstract). In other words, like *Amira*’s display, *Doo*’s display is configured to be controlled.

E. *Doo* and *Amira* Render Claim 11 Obvious

Claim 11 is similar to Claim 1 but adds an “altering” step and an “altered” limitation. Medivis thus incorporates by reference its discussion above on the obviousness of Claim 1 and addresses only Claim 11’s additional limitations.

1. Claim 11’s second step: “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”

Novarad’s own proffered-expert, Mulumudi, admitted that it was known in the art how to change the brightness of an image. Ex. 1022, 150:22-151:3. Indeed, Mulumudi admitted that the brightness of an image could be predictably altered by changing its contrast:

Q. At the beginning of 2017, how would one change the brightness of a medical image?

A. By changing the contrast.

Q. Okay. At the beginning of 2017, was changing the brightness of the medical image something that could be done predictably?

A. Yes.”

Ex. 1022, 151:4-10.

Doo discloses altering a medical image’s contrast. Petition 47-48. According to *Doo*, “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]. *Doo* discloses that “[t]he display 30 can be ... variable along the spectrum ... depending on user preference.” *Id.*, [0051]. Moreover, “[i]n some situations, the surgeon may prefer full opacity, ... where high-contrast is beneficial.” *Id.*, [0051]. An image that is brighter, more opaque would inherently be “lighter” and “better visible.”

Similarly, as explained below, *Amira* discloses the use of editable color maps to alter color gradients in a 3D data set.

2. Claim 11’s final limitation—“the projected inner layer of the patient from the 3D data being having the altered color gradient”

As explained above, altering the color gradient was disclosed in *Doo* and *Amira* and could have predictably been done before the assumed priority date.

F. *Doo* and *Amira* Render Claims 12-20 Obvious

Contrary to Novarad’s argument (Response 47), although *Amira*’s altered color gradients are not limited to surface renderings, they can and do represent

tissue properties of the multiple inner layers of the patient, as Claims 12-19 require. For example, according to Novarad, “surface rendering ... common[ly] ... distinguish[es] types of tissues” Response 5.

In any event, Medivis’s challenge was never limited to altered color gradients of surface renderings. *Amira* also discloses “direct volume rendering” of “3D image data.” Ex. 1005, 6/18-7/19; *see also id.* 26/38-27/39, 32/44-39/51. Novarad admits that “DVR ... involve[s] assigning colors to create a visual representation of the 3D data.” Response 48.

Amira also discloses the use of colormaps to alter color gradients and editable colormaps in the context of image volumes. For example, starting with “3D Volume Rendering” as the default, *Amira* discloses a user can “change the contrast ... or change the brightness.” Ex. 1005, 101/113.

Amira further discloses several examples of “using different color mappings” to fuse images derived from different 3D data sources, such as MRI, CT, and PET/SPECT. Ex. 1005, 102/114. *Amira* recommends “experiment[ing] with changing the color maps.” *Id.*, 103/115. In that context, the different color mappings inherently represent different tissue properties revealed by the relevant 3D data sources. Indeed, according to Novarad, “[t]he value of [each CT scan] pixel corresponds to the radiodensity of the tissue within the pixel.” Response 3.

Moreover, *Amira* discloses “Segmentation of 3D Images.”⁴ Ex. 1005, 40/52-45/57 (Section 2.4). Novarad admits that segmentation is a necessary precursor to surface rendering. Response 4, 39. Segmentation “identif[ies] the voxels within the original 3D dataset that belong to an anatomical structure of interest” (Response 4) by “distinguish[ing] between different types of tissues” (Response 5). *Amira* similarly explains that “segmentation assigns to each pixel of the image a label describing which region or material the pixel belongs, e.g., bone or the kidney.” Ex. 1005, 40/52. According to Novarad, “colors are typically determined by the segmentation step, where different structures are labeled with different colors.” Response 47-48.⁵ In sum, segmentation is a process of distinguishing anatomical structures within 3D data based on tissue properties and assigning colors that can be adjusted.

V. *CHEN, 3D-VISUALIZATION, AND 3D-SLICER-GUI* RENDER CLAIMS 1-6 AND 11-20 OBVIOUS

A. Motive to Combine *Chen, 3D-Visualization, and 3D-Slicer-GUI*

Chen planned integration with “a well-known software package named 3D Slicer (<http://slicer.org/>) for visualization and medical image computing.” Ex. 1009, 131:1:29-41. Both *3D-Visualization* and *3D-Slicer-GUI* were available from

⁵ Novarad argues that the ‘271 Patent does not involve segmentation. Response 39-40, 45. But if that were the case, the claimed invention could not represent any tissue property with an altered color gradient.

3D Slicer's URL. Ex. 2021. Both describe an application for clinical investigators and practice. Ex. 1007, 9, 16. *Chen* discloses that "many research groups have developed [3D Slicer] extension modules ..., for example, ... for MR-guided interstitial gynecologic brachytherapy." Ex. 1009, 131:1:34-39. Accordingly, a POSA would have had a reasonable expectation of success in combining *Chen* with 3D Slicer as described in *3D-Visualization* and *3D-Slicer-GUI*.

B. *Chen, 3D-Visualization, and 3D-Slicer-GUI Are Prior Art*

Chen, 3D-Visualization, and 3D-Slicer-GUI were publicly available before the priority date. Public availability rests on whether the reference was, more likely than not, available to interested persons. *See In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). A copyright notice "prima facie establishes a prior art date." *FLIR Systems, Inc. v. Leak Surveys, Inc.*, 2014-00411, Paper 9 at 18 (Sept. 5, 2014).

1. *Chen*

Copyrighted "2015," *Chen* (Ex. 1009) appeared online on April 13, 2015, and in print in June 2015. Ex. 1009 at 1; Ex. 1028, ¶¶ 6-14, 16. *Chen* was cited by seven publications by January 2017. *Id.*, ¶ 15.

2. *3D-Visualization*

3D-Visualization (Ex. 1007), a tutorial by 3D Slicer's Director of Training, like previous trainings given at 22 conferences to more than 2700 people, was

written to help people use 3D Slicer. Ex. 1007, 1-2, 7-8, 14-15, 20, 46-47, 98-103, 114-120; *see also* Ex. 1021, ¶¶ 11-23. Copyrighted “©2012-2014,” it was available on the internet on September 30, 2014. Ex. 1007, 2-124; Ex. 1019; Ex. 1021, ¶¶ 25-29.

3. **3D-Slicer-GUI**

3D-Slicer-GUI (Exhibit 1010) was “last edited on 7 November 2016, at 08:06.” Ex. 1010, 7. Kazanzides therefore opined that it is documentation that became available on November 8, 2016. Ex. 1021, ¶¶ 34-40.

C. **The *Chen* Combination Renders Claim 1-6 Obvious**

Contrary to Novarad’s arguments, the combination of *Chen*, *3D-Visualization* and *3D-Slicer-GUI* (the *Chen* combination) need not satisfy Novarad’s proposed inappropriate claim constructions to render the challenged claims obvious.

Chen discloses “a fused image [of] virtual anatomical structures such as soft tissues, blood vessels and nerves integrated with the intra-operative real-world scenario.” Ex. 1007, 125:1:8-12. As previously explained (Petition 54-59), that includes “displaying ... one of the inner layers of the patient ... projected onto ... the patient,” as Claim 1 requires. Novarad cannot reasonably distinguish *3D-Visualization*’s virtual bounding box (Ex. 1007, 22-121) from its own virtual box 116, which is the ‘271-specification’s preferred embodiment of the virtual 3D

shape. Novarad cannot explain why its virtual box can be used in an AR environment but *3D-Visualization*'s virtual bounding box cannot.

D. The *Chen* Combination Renders Claims 11-20 Obvious

In addition to everything that the *Chen* combination discloses as to Claims 1-6, *Chen* discloses a successful study in which “real- and virtual-world views are fused directly in the optical see-through HMD.” Ex. 130:1:36-46. Contrary to Novarad’s argument (Response 60-61), *Chen*’s black background does not obscure the real-world view through the HMD. Novarad admits that *Chen* and *3D-Visualization* each disclose altering color gradient. Response 53, 61. And according to *Chen*, third parties “found that ... bright colors ... had a more vivid ... effect.” Exhibit 131:1:11-15.

Novarad also admits that *Chen* discloses segmentation. Response 53. As seen in Section IV.F above, and as Novarad acknowledges, segmentation involves distinguishing anatomical structures within 3D data based on tissue properties and assignment of colors that can be adjusted. Thus, different color assignments inherently represent different tissue properties. *Chen* discloses segmentation of CT data (Response 53) and, according to Novarad, “[t]he value of [each CT scan] pixel corresponds to the radiodensity of the tissue within the pixel” (Response 3). Accordingly, altered color gradients representing various tissue properties would have been obvious.

VI. CONCLUSION

Novarad has failed to rebut the evidence that Claims 1-6 and 11-20 of the '271 Patent are anticipated or obvious. The Board should thus cancel those claims.

Respectfully submitted,

Dated: October 10, 2022

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CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing reply in support of the *inter partes* review of the '271 patent—excluding the Table of Contents, the Table of Authorities, the Table of Exhibits, this Certificate of Word Count, and the Certificate of Service (which are excluded from the word count by 37 CFR 42.24(c))—includes less than 5,600 words based on a word count using that feature of the WORD software.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Reply (including Exhibits 1015-1028 and the Certificate of Word Count) was served on October 10, 2023 by transmitting a copy by e-mail to the email addresses of the patent owner's attorneys of record in the patent owner's latest mandatory notice:

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