UNITED STATES PATENT AND TRADEMARK OFFICE

Paper 7

Date: April 24, 2023

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDIVIS, INC.,

MEDIVIS, INC. Petitioner,

v.

NOVARAD CORP., Patent Owner.

IPR2023-00045 Patent 10,945,807 B2

Before MIRIAM L. QUINN, JO-ANNE M. KOKOSKI, and SCOTT RAEVSKY, *Administrative Patent Judges*.

KOKOSKI, Administrative Patent Judge.

DECISION
Granting Institution of *Inter Partes* Review 35 U.S.C. § 314

I. INTRODUCTION

Medivis, Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–7 (the "challenged claims") of U.S. Patent No. 10,945,807 B2 ("the '807 patent," Ex. 1001). Paper 3 ("Pet."). Novarad Corp. ("Patent Owner") did not file a Preliminary Response.

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see also* 37 C.F.R. § 42.4 (2022). For the reasons discussed below, we determine that Petitioner establishes a reasonable likelihood of prevailing with respect to the unpatentability of at least one claim of the '807 patent. Accordingly, for the reasons that follow, we institute an *inter partes* review of claims 1–7 of the '807 patent.

A. Real Parties in Interest

Each party identifies itself as the real party in interest. Paper 5, 2; Paper 6, 1.

B. Related Matters

The parties identify *Novarad Corp. v. Medivis, Inc.*, No. 21-1447-GBW (D. Del. 2021) as a related matter. Paper 5, 2; Paper 6, 1.

C. The '807 Patent

The '807 patent relates to "a system and method for using mixed reality or augmented reality devices to improve surgical, interventional radiologic, cardiac, or other medical procedures." Ex. 1001, 2:22–25. The '807 patent teaches that "[a]n augmented reality device, such as an augmented reality (AR) headset, may be used to overlay images onto a real world scene (e.g., what user is viewing in the real world) using images

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projected on lenses or a screen that is partially transparent," such as overlaying an MRI image in an area where an operation is going to occur. *Id.* at 2:25–30, 3:6–7. According to the '807 patent,

[a] facet of this ability to overlay images is the cameras that exist in the augmented reality headset to create a contextual map of the space in which the patient lies and allows 3D patient data such as a hologram of images obtained prior to surgery to be merged with the real world of patient anatomy.

Id. at 3:10–15.

Figure 1A of the '807 patent is reproduced below.

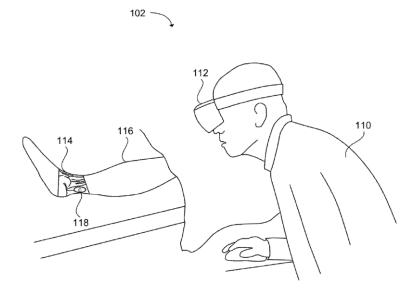


Figure 1A is an illustration of an example use of an augmented reality headset to augment a medical procedure with acquired medical images. Ex. 1001, 1:46–48. A medical professional sets up AR headset 112 in surgery area 102, and AR headset 112 receives an image of patient anatomy 116 using a visual image camera in AR headset 112. *Id.* at 3:16–21. Acquired medical image 114 associated with patient anatomy 116, such as an MRI or CT image, is fed via a wireless connection to AR headset 112, and is associated with or anchored to patient anatomy 116 in the real-world scene so that when a doctor moves, "acquired medical image 114 can remain

fixed in the correct spot with respect to the patient's anatomy and does not move around in the doctor's vision." *Id.* at 3:21–36. Augmentation tag 118 "may be configured to conform to a three dimensional (3D) structure in the acquired medical image 114 or radiological image to identify an anatomical structure associated with a medical procedure to be performed." *Id.* at 3:37–43. The '807 patent teaches that "[t]he augmentation tag may be a simple geometric shape such as a circle, square, triangle, or another more complex shape in two dimensions or three dimensions, such as an outline of the anatomy in question." *Id.* at 3:43–46. Acquired medical image 114 and augmentation tag 118 are then "projected onto the lenses of the augmented reality headset 112 to form a single graphical view of the medical professional(s) wearing the AR headset 112" and, as a result, "the acquired medical image 114 and augmentation tag 118 may appear as though the images are overlaid directly on the patient anatomy." *Id.* at 4:35–41.

D. Challenged Claims

Petitioner challenges claims 1–7 of the '807 patent. Pet. 15. Claim 1, the only independent challenged claim, is representative of the claimed subject matter and is reproduced below.

- 1. [Preamble] A method for augmenting medical imaging of a patient, the medical imaging displayed using an augmented reality headset worn by a medical professional, the method comprising:
- [1a] receiving a visual image of patient anatomy captured by a visual image camera, the visual image comprising a viewable portion of the patient anatomy;
- [1b] retrieving an acquired medical image associated with the patient anatomy from data storage, the acquired medical image comprising imaging acquired of one or more anatomical structures at a plurality of anatomical layers of the patient anatomy;

- [1c] associating the acquired medical image to align with the viewable portion of the patient anatomy captured by the visual image camera, wherein the one or more anatomical structures of the medical imaging at the plurality of layers are aligned with the visual image of the patient anatomy;
- [1d] retrieving an augmentation tag from data storage, the augmentation tag associated with a location in one layer of the acquired medical image, the augmentation tag identifying at least one anatomical structure of the acquired medical image found at the location; and
- [1e] projecting the acquired medical image and the augmentation tag using the augmented reality headset to form a single graphical view as an overlay to the patient anatomy viewable through a lens of the augmented reality headset.

Ex. 1001, 15:23–50 (bracketed material added).

E. Asserted Grounds

Petitioner asserts that claims 1–7 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1–7	102	Jones ²
1–7	103	Jones
1–7	102	Doo ³
1–7	103	Doo

Pet. 15. Petitioner relies on the Declaration of Peter Kazanzides, Ph.D. (Ex. 1009) in support of its contentions.

¹ The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), revised 35 U.S.C. §§ 102 and 103 effective March 16, 2013. Because the earliest claimed priority date of the '807 patent is February 21, 2017, the AIA version of §§ 102 and 103 apply.

² Jones, US 2016/0225192 A1, published August 4, 2016 (Ex. 1007).

³ Doo, WO 2015/164402 A1, published October 29, 2015 (Ex. 1008).

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person having ordinary skill in the art would have had

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

Pet. 10 (citing Ex. 1009 ¶¶ 19–24).

On this record, we determine that the level of ordinary skill in the art is reflected in the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (specific findings on the ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prod., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))). A more specific definition is not necessary for purposes of deciding whether to institute review.

B. Claim Construction

We construe each claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). Under this standard, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). Only those terms in controversy need to be construed,

and only to the extent necessary to resolve the controversy. *Realtime Data LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019).

Relying on Dr. Kanzanzides's supporting testimony, Petitioner proposes the following constructions for the terms "acquired medical image" and "augmentation tag." Pet. 10–13; Ex. 1009 ¶¶ 28–35.

"acquired medical image"	an MRI, fMRI, fluoroscopy, mammography, CT, sonography, X- rays, nuclear medicine, ultrasound, computer generated images (CGI),
	photos, video, or other types of acquired or synthesized medical images
"augmentation tag"	any annotation, mark, selection, extraction or highlighting associated with a location in an acquired medical image

Pet. 13. For purposes of this Decision, and based on the record now before us, we adopt Petitioner's constructions of "acquired medical image" and "augmentation tag," which are undisputed at this stage of the proceeding.

C. Asserted Anticipation by Doo

Petitioner contends that claims 1–7 are anticipated by Doo. Pet. 51–69; Ex. 1009 ¶¶ 106–151.

1. Overview of Doo

Doo is directed to "an intra-operative medical image viewing system that can allow the surgeon to maintain a viewing perspective on the patient while concurrently obtaining relevant information about the patient." Ex. $1008 \, \P \, 11$. Doo's system "can present a selectively or variably transparent image of an anatomical feature of a patient" to a surgeon during surgery as the surgeon views, or maintains a viewing perspective generally toward, the actual anatomical feature of the patient. *Id.* $\P \, 30$.

Figure 2 of Doo is reproduced below.

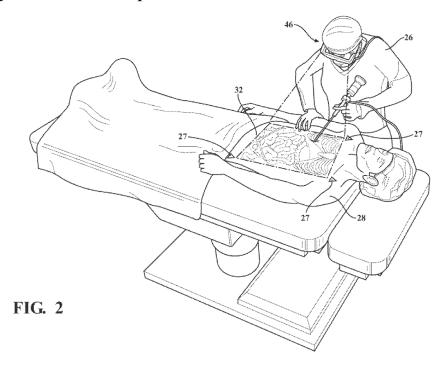


Figure 2 is a perspective view of an embodiment described in Doo in a first surgical environment. Ex. $1008 \, \P \, 17$. Surgeon 26 wears display 30 suitable for implementing intra-operative medical viewing system while operating on patient 28. $Id. \, \P \, 38$. The viewing system allows surgeon 26 to maintain a viewing perspective on patient 28 while concurrently obtaining relevant image-based information about patient 28 on demand. Id. Display 30 is positioned between surgeon 26 and patient 28, and is "configured to exhibit at least one medical image 32 to the surgeon 26 that is overlaid on the patient 28 [as shown in Figure 2] or that is positioned in an adjacent hovering location as perceived by the surgeon 26." Id. "[D]isplay 30 can be a component of a head mountable unit 46 . . . worn by the surgeon 26 while the surgeon 26 is operating on the patient 28." $Id. \, \P \, 44$.

Doo teaches that the system "can allow the surgeon 26 to selectively register, i.e., lock, an image to an actual anatomical feature of the patient 28 or to some other fiducial marker associated with the patient 28." Ex. 1008

¶ 37. "For example, the image can be overlaid on the patient's actual anatomical feature and, by using commands in a selected user-interface modality, 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." *Id.* Doo also teaches that the system "can be configured to automatically present a true registration, or registration at a predetermined hovering distance, such as by calibrating to one or more strategically arranged markers or fiducials 27 placed directly on the body of' patient 28. *Id.* Doo further teaches that the system can monitor the movement of surgeon 26 and change the displayed image so to maintain that registration. *Id.*

2. *Claim 1*

Petitioner contends that Doo discloses all of the limitations of claim 1. Pet. 51-65; Ex. 1009 ¶¶ 106-139.

For the Preamble ("A method for augmenting medical imaging of a patient, the medical imaging displayed using an augmented reality headset worn by a medical professional"), ⁴ Petitioner relies on Doo's "intraoperative medical image viewing system [that] can allow a surgeon to maintain a viewing perspective on the patient while calling up visual images on the fly." Pet. 53 (quoting Ex. 1008, code (57)). Petitioner also relies on Doo's teachings that "[a] display is worn by the surgeon . . . during surgery," and "[t]he display is selectively transparent, and exhibits to the surgeon an image derived from the image file." *Id.* (quoting Ex. 1008, code (57)). Petitioner further points to Doo's description of display 30 as "a goggle-type system worn by the surgeon 26." *Id.* (quoting Ex. 1008 ¶ 38). Petitioner

⁴ We do not express an opinion on whether the preamble is limiting.

also relies on Doo's teaching that "the image can be overlaid on the patient's actual anatomical feature and . . . sized to match the actual anatomical feature, thus creating the visual impression of a 'true registration' and a form of augmented reality." Id. at 54-55 (quoting Ex. $1008 \, \P \, 37$).

For limitation 1a ("receiving a visual image of patient anatomy captured by a visual image camera..."), Petitioner relies on Doo's description of one or more cameras in head mountable unit 46 that "can be configured to generate a streaming image or video signal" and "can be oriented to generate a video signal that approximates the field of view of the surgeon 26 wearing the head mountable unit 46." Pet. 55 (quoting Ex. 1008 ¶ 46). Petitioner further relies on Doo's teaching that "[f]orward-facing cameras may stream image data for pattern-recognition logic to determine anatomical features... and use those for alignment." *Id.* (quoting Ex. 1008 ¶ 48). Petitioner also points to Doo's teaching that "[p]rocessing of the one or more forward-facing video signals can also be applied to determine the identity of the object. Determining the identity of the object, such as the identity of an anatomical or landmark feature of the patient 28, can be executed by the processor 48." *Id.* at 56 (quoting Ex. 1008 ¶ 48; citing Ex. 1009 ¶¶ 112–115).

For limitation 1b ("retrieving an acquired medical image associated with the patient anatomy from data storage . . . "), Petitioner states that, "according to Doo, '[t]he intra-operative medical image viewing system 34 can also include an image control unit 38 configured to retrieve the image file from the image source 44 cdots." Pet. 56-57 (quoting Ex. 1008 cdot 41; citing id. cdot 11-13, 41, 44). Petitioner asserts that

Doo discloses "[t]he inter-operative medical image viewing system 34 can include a plurality of image sources 44. Each

image source 44 can have at least one digital image file representative of an anatomical or pathological feature of a patient 28. An image file can be of static data such as a picture or an x-ray or can be dynamic such as a video feed . . . In practice, it is likely each image source 44 will have many digital image files of the patient 28 . . . By way of example and not limitation, the system 34 can utilize images generated by radiography, computer-aided tomography, positron emission tomography, single-phase emission tomography, magnetic resonance imaging (MRI), ultrasound, . . . and spectroscopy. Each image source 44 can be a collection (or archive or database) of previously-created digital images "

Id. at 57 (quoting Ex. 1008 ¶ 40; citing Ex. 1009 ¶ 117); see also Ex. 1009 ¶ 119 (Dr. Kanzanzides testifying that "[a] person of ordinary skill in the art would understand that at least some of the exemplary medical images disclosed by Doo would typically include a plurality of images of different layers of the patient anatomy.").

For limitation 1c ("associating the acquired medical image to align with the viewable portion of the patient anatomy captured by the visual image camera..."), Petitioner relies on Doo's description of forward-facing cameras that stream image data to determine anatomical features in the patient field and then use those features for alignment. Pet. 58 (quoting Ex. 1008 ¶ 48). Petitioner further relies on Doo's teaching that "video signals generated by the camera 50 can be processed by the landmark detector 80 to identify an anatomical feature of the patient 28," and that landmark detector 80 "can be configured to determine the identity of an object within the field of view of the surgeon 26." *Id.* (quoting Ex. 1008 ¶ 65). Petitioner also relies on Doo's description of registering or locking an image to an actual anatomical feature of the patient, such as by overlaying the image on the patient's actual anatomical feature and matching the size of

the image to the anatomical features, "thus creating the visual impression of a 'true registration' and a form of augmented reality." *Id.* at 59 (quoting Ex. $1008 \, \P \, 37$).

For limitation 1d ("retrieving an augmentation tag from data storage ..."), Petitioner relies on Doo's teaching "that '[t]he image can include portions indicating a three-dimensional nature of the anatomical feature of the patient 28" and "that the image can be displayed 'in any one of a plurality of different two-dimensional, 2-1/2 dimensional, or three-dimensional modalities." Pet. 60 (quoting Ex. 1008 ¶ 73). Petitioner asserts that "Doo also discloses 'treatment guide 1232 can be overlaid on (i.e., combined or rendered with) the image 332 that is visible to the surgeon 26 so that the two images 332, 1232 are aligned in true registry," and "the treatment guide 1232 could take many different forms including that of a scale (FIGS. 7 and 12), a radiologic study, pre-operative sketches or notes made by the surgeon 26 herself or perhaps by a teacher or a consulting practitioner or a medical student." *Id.* at 61 (quoting Ex. 1008 ¶ 74); *see also* Ex. 1009 ¶ 131 (Dr. Kanzanzides testifying that "[t]he treatment guide is a type of augmentation tag, as described in the '807 patent.").

For limitation 1e ("projecting the acquired medical image and augmentation tag using the augmented reality headset to form a single graphical view as on overlay to the patient anatomy..."), Petitioner points to Doo's teaching that the displayed image is overlaid directly on, or projected inside, the patient's body, and sized to match the actual anatomical feature to create a form of augmented reality. Pet. 62–63 (citing Ex. 1008 ¶¶ 11–13, 30, 35, 37, 39). Petitioner also relies on Doo's description of treatment guide 1232 (which represents a tumor boundary) overlaid with image 332 (described above with respect to limitation 1d), and Doo's

example of a radiologist "draw[ing] guiding lines or annotations preoperatively for a surgeon to study." *Id.* at 64-65 (quoting Ex. $1008 \, \P \, 74$).

Having reviewed Petitioner's arguments and supporting evidence for all of the elements of independent claim 1, and based on the record before us, we determine that Petitioner establishes a reasonable likelihood that it would prevail in showing that claim 1 is anticipated by Doo. Pet. 31–38; Ex. 1012 ¶¶ 63–77.

3. Dependent Claims 2–7

Petitioner contends that Doo discloses all of the limitations of claims 2–7, which directly depend from claim 1. Pet. 65–69; Ex. 1009 ¶¶ 140–151. We have reviewed Petitioner's arguments and supporting evidence, including those summarized above with respect to claim 1, and determine that Petitioner also establishes a reasonable likelihood that it would prevail in showing that claims 2–7 are anticipated by Doo.

D. Remaining Grounds

Petitioner contends that claims 1–7 are anticipated by Jones, would have been obvious over the teachings of Jones in view of what was known in the art, and would have been obvious over the teachings of Doo in view of what was known in the art. Pet. 25–50, 69–70; Ex. 1009 ¶¶ 57–105, 152–153. Having determined that Petitioner establishes a reasonable likelihood of showing that at least one of the challenged claims is unpatentable as set forth above, we institute an *inter partes* review based on these grounds as well. *See* 37 C.F.R. § 42.108(a) ("When instituting inter partes review, the Board will authorize the review to proceed on all of the challenged claims and on all the grounds of unpatentability asserted for each claim.").

III. CONCLUSION

Taking into account the arguments in the Petition and the evidence of record, we determine that Petitioner establishes a reasonable likelihood that it will prevail on its challenge to at least one claim of the '807 patent. Thus, we institute an *inter partes* review of the challenged claims on the grounds presented in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that an *inter partes* review is instituted with respect to the grounds asserted in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which shall commence on the entry date of this Decision.

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