

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MIM SOFTWARE INC.,
Petitioner.

v.

EXINI DIAGNOSTICS AB, INC.,
Patent Owner.

IPR2025-00827
Patent 11,941,817 B2

Before BARRY L. GROSSMAN, CHRISTOPHER G. PAULRAJ, and
RYAN H. FLAX, *Administrative Patent Judges*.

GROSSMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. *Background and Summary*

MIM Software, Inc. (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–5, 7–14, 16–19, 22–26, and 28–32 of U.S. Patent Number 11,941,817 B2 (Ex. 1001, “the ’817 patent”). Paper 2 (“Petition” or “Pet.”). EXINI Diagnostics AB (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 10 (“Prelim. Resp.”). Patent Owner filed a request for discretionary denial (Paper 9) and Petitioner filed an opposition (Paper 11). The request was denied and the Petition was referred to the Board and this panel. Paper 12.

We have jurisdiction under 35 U.S.C. § 314. Under § 314, an *inter partes* review may not be instituted “unless . . . 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(a). The Board determines whether to institute a trial on behalf of the Director. 37 C.F.R. § 42.4(a).

After considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner has demonstrated that there is a reasonable likelihood that at least one of the challenged claims is unpatentable. A decision to institute is “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.” *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018). Accordingly, we institute an *inter partes* review of all challenged claims and on all grounds asserted in the Petition. Our rationale is set forth below.

B. Real Parties in Interest

Petitioner identifies itself, MIM Software Inc., its parent company, GE HealthCare Technologies Inc., and its insurer, AIG Specialty Insurance Company, as real parties-in-interest. Pet. 1.

Patent Owner makes no objection to Petitioner’s notice, and identifies itself, Progenics Pharmaceuticals, Inc. (“Progenics”), and Lantheus Holdings, Inc. as the real parties-in-interest. Paper 4, 2. Patent Owner further states that Progenics is a co-plaintiff in the related district court litigation cited below in Section I.C. *Id.*

C. Related Matters

The parties identify *Progenics Pharmaceuticals, Inc. et al. v. MIM Software Inc.*, 1:24-cv-10437-PBS (D. Mass.), as a related matter. Pet. 1; Paper 4, 2. The parties also identify three other IPR proceedings as “related.” These are IPR2025-00630 (institution denied); IPR2025-00725 (institution denied); and IPR2025-00726 (institution denied).¹ Petitioner notes, however, that the challenged patents in these three IPR proceedings “contain subject matter that overlaps with the subject matter described in the [’817] Patent” but they are not “within the same patent family as the [’817] Patent and are not related to the [’817] Patent by any priority claim. Pet. 1.

D. Discretionary Denial

Patent Owner filed a request for discretionary denial (Paper 9). Petitioner filed an opposition (Paper 11). The Acting Director denied the

¹ These three related IPR proceedings were each denied for the same reason, which was that the “Petition fails to satisfy the requirement of 37 C.F.R. § 42.104(b) to set forth how the challenged claims are to be construed.” *See, e.g.*, IPR2025-00630, Paper 14, 9–10. The Petition before us does not include this defect.

request and referred the Petition to the Board “to handle the case in the normal course, including by issuing a decision on institution addressing the merits and other non-discretionary considerations, as appropriate.”

Paper 12, 2 (“Dir. Denial”).

In its Preliminary Response Patent Owner asserts that the “Board should deny institution under 35 U.S.C. § 325(d) because (a) every ground of the Petition is based on the same prior art that was presented to the Office and considered during prosecution, and (b) the Petition fails to show that the Examiner made any material error.” Prelim. Resp. 12–18. This Preliminary Response was filed on August 6, 2025, more than one month after Patent Owner filed on July 3, 2025, its Discretionary Denial brief.

The issue of a discretionary denial was resolved in the Acting Director’s determination that “discretionary denial of institution is not appropriate in this proceeding.” Dir. Denial 2. Among other factors, the Acting Director’s determination to refer this case to the panel for a determination on the merits was based on the conclusion that “Petitioner provides persuasive reasoning, supported by evidence, that discretionary denial under 35 U.S.C. § 325(d) is not appropriate.” *Id.* (citing Paper 11, 21–29).

Our delegated authorization in this proceeding is limited to addressing “the merits and other non-discretionary considerations.” Dir. Denial 2. Accordingly, we do not consider Patent Owner’s argument under Section 325(d) in its Preliminary Response.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–5, 7–14, 16–19, 22–26, and 28–32 would have been unpatentable on the following nine grounds²:

Ground	Claim(s) Challenged	35 U.S.C. §³	Reference(s)/Basis
A	1–5, 7, 10–14, 16, 19, 26	102	Renisch ⁴
B	1–5, 7, 10–14, 16, 19, 26	103	Renisch, Zhao ⁵
C	8, 9, 17, 18, 22– 25, 29–32	103	Renisch, or Renisch in view of Zhao, each in view of Baker ⁶
D	8, 9, 17, 18, 22, 24, 25, 29, 31, 32	103	Renisch, or Renisch in view of Zhao, each in view of Eiber ⁷

² Grounds C and D each include two different, distinct grounds. Ground C, for example, includes grounds: (1) Renisch and Baker *or* (2) Renisch, Zhao, and Baker.

³ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Because the ’817 patent claims priority to a provisional application filed in 2019, after the effective date of the applicable AIA amendments (March 16, 2013), we refer to the AIA versions of the statutes throughout this Decision.

⁴ U.S. Patent Application Publication No. 2012/0123253 (Ex. 1005) (“Renisch”).

⁵ U.S. Patent No. 10,140,544 (Ex. 1007) (“Zhao”).

⁶ U.S. Patent Application Publication No. 2018/0144828 (Ex. 1008) (“Baker”).

⁷ M. Eiber et al., Prostate Cancer Molecular Imaging Standardized Evaluation (PROMISE): Proposed miTNM Classification for the Interpretation of PSMA-Ligand PET/CT, 59(3) J. Nuclear Med. 469–78 (2018) (Ex. 1009) (“Eiber”).

Ground	Claim(s) Challenged	35 U.S.C. §³	Reference(s)/Basis
E	1, 2, 7–11, 16– 18, 22–25, 29– 32	103	Baker, Zhao
F	3–5, 12–14	103	Baker, Zhao, Eiber
G	19, 26, 28	103	Baker, Zhao, Suehling ⁸

Pet. 8. To support these challenges, Petitioner relies, *inter alia*, on the declaration of Dr. Bruce Rosen (Ex. 1002). In its Preliminary Response, Patent Owner relies, *inter alia*, on the declaration of Dr. Milan Sonka (Ex. 2014). At this stage of the proceeding, there is no dispute that each witness is competent to testify as to the subject matter of their declaration.

II. THE '817 PATENT

A. *Specification*

The '817 patent is titled “Systems and Methods for Platform Agnostic Whole Body Image Segmentation.” Ex. 1001, code (54). As stated in the Abstract, the '817 patent discloses “systems and methods that provide for automated analysis of three-dimensional (3D) medical images of a subject in order to automatically identify specific 3D volumes within the 3D images that correspond to specific anatomical regions (e.g., organs and/or tissue).” Ex. 1001, code (57). According to the written description, the capability of the disclosed systems and methods to handle 3D images “is an important advantage over certain other image analysis that only identify 2D regions in 2D images.” *Id.* at 3:21–24.

⁸ U.S. Patent Application Publication No. 2011/0007954 (Ex. 1006) (“Suehling”)

The disclosed invention is described as using “automated analysis of combinations of anatomical and functional images in order to accurately identify and grade cancerous lesions within a subject.” *Id.* at 3:49–52. As explained by Patent Owner, “anatomical scans (such as X-rays or CT scans) and functional scans (like PET [“positron emission tomography” (Ex. 1001, 1:44–45)] or single-photon emission computed tomography (SPECT)) are valuable tools.” Prelim. Resp. 3 (citing Ex. 2014 ¶¶ 26–28). As noted in the ’817 patent, however, “[t]here are limitations” with these known procedures. Ex. 1001, 2:44.

As explained in the ’817 patent,

Functional images such as SPECT and PET provide detailed and specific information on biological processes in the body, but their potential is only realized when combined with a detailed anatomical map so that function can be localized to individual organs and structures. Although CT and MRI provide detailed anatomical information, conventional (e.g., manual) identification of organs and structures is difficult, subjective and time consuming, making certain assessment infeasible without computer support.

Id. at 3:34–43.

According to the written description in the ’817 patent, “the full body segmentation approaches described [in the ’817 patent] allow for automated analysis of combinations of anatomical and functional images in order to accurately identify and grade cancerous lesions within a subject.”

Id. at 3:49–52. The “automated, machine learning-based segmentation” is used to identify “target volumes of interest (VOIs)” representing target tissue regions where cancerous lesions may be found. *Id.* at 3:55–60. Thus, as stated in the ’817 patent, “the AI-based systems and methods described [in

the '817 patent] allow for analysis of a variety of cancers at various stages.”
Id. at 5:2–4.

As further explained in the '817 patent,

The AI-based segmentation technologies described herein utilize machine learning techniques, such as Convolutional Neural Networks (CNNs) to automatically to identify [sic] a plurality of target 3D volumes of interest (VOIs) each corresponding to a specific target tissue region, such as one or more organs, portions of organs, particular bone(s), a skeletal region etc. Each identified 3D VOI may be represented via a segmentation mask. The multiple segmentation masks, identifying multiple target tissue regions across a patient's body, can be stitched together to form a segmentation map. The segmentation map, and/or various segmentation masks that it comprises, may be used compute various quantities from medical images, such as useful indices that serve as measures and/or predictions of cancer status, progression, and response to treatment. Segmentation maps and masks may also be displayed, for example as a graphical representation overlaid on a medical image to guide physicians and other medical practitioners.

Id. at 32:3–21.

Patent Owner acknowledges that “[a] key claimed advancement is the creation of a 3D segmentation map using machine learning-based segmentation of 3D anatomical images.” Prelim. Resp. 7 (citing Ex. 1001, 31:64–32:21; Ex. 2014 ¶ 57).

B. Prosecution History

The application that matured into the '817 patent was allowed via an initial Office Action by the Examiner (i.e., a first-action allowance). Ex. 1004, 323; *see also* Prelim. Resp. 11 (citing Ex. 1004, 323) (stating “On October 13, 2023, the Examiner allowed the application after considering all the references and stated, in the Notice of Allowance, that ‘**the closest prior art** is **Hamadeh et al. (US 8,855,387)**.’”) (emphasis in original).

Hamadeh discloses that the technical field of the Hamadeh patent is “two-dimensional bone scan images.” Ex. 1014, 1:14–20. Hamadeh discloses that “[t]he present invention relates to the field of medical imaging and to the field of automated processing and interpretation of medical images. In particular, it relates to automated processing and interpretation of *two-dimensional bone scan images* produced via isotope imaging.” *Id.* (emphasis added).

The Examiner’s focus on the distinction between the three-dimensional images of the invention claimed in the ’817 patent and the two-dimensional images in Hamadeh is mirrored in the ’817 patent itself. The ’817 patent states:

The capability of the approaches described herein to handle 3D images is an important advantage over certain other image analysis that only identify 2D regions in 2D images. For example, one approach relevant for cancer detection, EXINI Diagnostics AB’s Bone Scan Index (BSI) software, detects regions of suspected bone cancer (see also U.S. Pat. No. 8,855,387, issued Oct. 7, 2014) [this is the Hamadeh reference on which the Examiner relied, Ex. 1014 in this IPR proceeding, cited by the Examiner as the “closest prior art”]. However, the BSI analysis is carried out on **two-dimensional** scintigraphy images, **as opposed to on three dimensional** images.

Ex. 1001, 3:21–29 (emphases added).

As noted above, Patent Owner asserts that “[a] key claimed advancement [of the claimed invention in the ’817 patent] is the creation of a 3D segmentation map using machine learning-based segmentation of 3D anatomical images.” Prelim. Resp. 7 (citing Ex. 1001, 31:64–32:21). Notwithstanding this emphasis on three-dimensional images, Patent Owner did not bring to the Examiner’s attention, or comment on, the Renisch reference, discussed in detail below, which was before the Office in the

prosecution of the '817 patent, and discloses three-dimensional images/imaging. *See, e.g.*, Ex. 1005, ¶ 21 (“A reconstruction processor 34 reconstructs 3D image representations from the acquired imaging data, and the reconstructed image representations are stored in a diagnostic anatomical image memory 36.”). Instead, Renisch was merely included in a 12-page listing of 260 cited documents submitted in an Information Disclosure Statement. Ex. 1004, 243–256 (Renisch is listed as item A57 at Ex. 1004, 246). This Information Disclosure Statement was submitted as required by applicable rules. *See* 37 C.F.R. §§ 1.56, 1.97.

C. Illustrative Claim

Petitioner challenges claims 1–5, 7–14, 16–19, 22–26, and 28–32 of the '817 patent. Claims 1 and 10 are independent claims. Claim 1, reproduced below, is representative for purposes of our analysis:

1. A method for automatically processing 3D images to automatically identify cancerous lesions within a subject, the method comprising:
 - (a) receiving, by a processor of a computing device, a 3D anatomical image of a subject obtained using an anatomical imaging modality, wherein the 3D anatomical image comprises a graphical representation of tissue within the subject;
 - (b) automatically identifying, by the processor, using one or more machine learning modules, for each of a plurality of target tissue regions, a corresponding target volume of interest (VOI) within the 3D anatomical image;
 - (c) determining, by the processor, a 3D segmentation map representing a plurality of 3D segmentation masks, each 3D segmentation mask representing a particular identified target VOI;
 - (d) receiving, by the processor, a 3D functional image of the subject obtained using a functional imaging modality;

- (e) identifying, within the 3D functional image, one or more 3D volume(s), each corresponding to an identified target VOI, using the 3D segmentation map; and
- (f) automatically detecting, by the processor, within at least a portion of the one or more 3D volumes identified within the 3D functional image, one or more hotspots determined to represent lesions based on intensities of voxels within the 3D functional image.

Ex. 1001, 79: 5–33. Independent claim 10 is directed to a “system” rather than a “method,” as stated in claim 1. Claim 10 differs from claim 1 in that claim 10 includes a “memory” having stored instructions that, when executed, causes a processor to perform the actions corresponding to clauses (a)–(f) in claim 1. Claim 1 does not recite a “memory.”

III. ANALYSIS

A. *Petitioner’s Burden*

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (“In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.”).

This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat’l. Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).⁹

⁹ We may refer to Patent Owner’s arguments or positions as unpersuasive; however, this is in the context of the record as a whole. We do not shift the ultimate burden from Petitioner.

B. Anticipation

“To anticipate a claim, a prior art reference must disclose each and every element of the claim, either explicitly or inherently.” *Adasa Inc. v. Avery Dennison Corp.*, 55 F.4th 900, 910 (Fed. Cir. 2022) (citing *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006)). “While those elements must be arranged or combined in the same way as in the claim, the reference need not disclose the elements in the very same terms used by the patent.” *Id.* (citing *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (“[T]he reference need not satisfy an *ipsissimis verbis* test.” (citing *In re Bond*, 910 F.2d 831, 832–33 (Fed. Cir. 1990)))). “And ‘[e]ven if a reference’s teachings are insufficient to find anticipation, that same reference’s teachings may be used to find obviousness’ where it suggests some reason to modify the prior art to obtain the claimed limitations.” *Id.* (citing *CRFD Rsch., Inc. v. Matal*, 876 F.3d 1330, 1345 (Fed. Cir. 2017)). “The question of what a reference teaches and whether it describes every element of a claim is a question for the finder of fact.” *Id.* (citing *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1221 (Fed. Cir. 2003)). In an *inter partes* review, the Board is the finder of facts.

Also, as explained in *Net MoneyIN*,

unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.

Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008).

“The requirement that the prior art elements themselves be arranged as in the claim means that claims cannot be treated . . . as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and

that give the claims their meaning.” *VirnetX Inc. v. Mangrove Partners Master Fund, Ltd.*, No. 2020-2271, 2023 WL 2708975, at *5 (Fed. Cir. Mar. 30, 2023) (citing *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010) (internal quotation marks omitted)), cert. denied, 144 S. Ct. 1001 (2024).

Applying these general principles, we consider the evidence and arguments of the parties concerning Ground A.¹⁰

C. Level of Ordinary Skill in the Art

Petitioner asserts that the person of ordinary skill in the art (or ordinarily skilled artisan) involved in this proceeding “would include a person with a medical (MD) degree and/or an advanced degree in Computer Engineering, Computer Science, Physics, or other field related to computer imaging, and at least 3 years of field experience with medical imaging devices, such as PET/CT or SPECT/CT systems.” Pet. 8–9 (citing Ex. 1002 ¶ 39).

Patent Owner states “[f]or purposes of this preliminary response, Patent Owner does not dispute Petitioner’s definition” of a person of ordinary skill. Prelim. Resp. 12 (citing Ex. 2014 ¶¶ 13–16).

For purposes of this Decision, based on the prior art, the sophistication of the disclosed technology in the ’817 patent, and the declaration testimony of each party’s proffered expert witness, we adopt

¹⁰ For the purposes of institution, we consider only Ground A. However, we will address all asserted grounds and all challenged claims in any final decision.

Petitioner’s unchallenged definition of the education and experience level of a person of ordinary skill in the art.¹¹

D. Claim construction

We construe each claim in this proceeding “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b) (2021). Under this standard, claim terms are generally given their ordinary and customary 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, 1312–14 (Fed. Cir. 2005) (en banc) (“We have frequently stated that the words of a claim ‘are generally given their ordinary and customary meaning.’” (citations omitted)).

Petitioner proposes a construction for the claim term “3D segmentation map,” which is recited in claims 1, 3, 10, and 26. Pet. 9–10; *see also* Ex. 1001 79:3–82:40 (claims). According to Petitioner the ’817 patent claims “internally define a 3D segmentation map as “representing a plurality of 3D segmentation masks, each 3D segmentation mask representing a particular identified target VOI [volume of interest].” Pet. 9–10 (citing Ex. 1001, 79:19–22 [independent claim 1, clause(c)], 80:27–30 [independent claim 10, clause (c)]). Notwithstanding this asserted “internal definition” in all the challenged claims, Petitioner proposes a slightly modified construction, which is “a plurality of 3D segmentation masks

¹¹ Our determinations in this Decision (except our decision to institute), are preliminary and non-binding. Any final decision will be based on a fully developed record of arguments and evidence and will state our binding determinations, findings, and conclusions.

distinguishing a plurality of regions within a 3D image.” *Id.* (citing Ex. 1002 ¶¶ 108–110).

Patent Owner asserts that “[w]hile the Petition proposes an incorrect construction of [the term 3D segmentation map], that issue is not material to the grounds for denying institution that Patent Owner presents below.” Prelim. Resp. 12 (internal citation omitted). Patent Owner also “expressly reserves all rights to challenge the construction should the Board institute the Petition.” *Id.*

The written description of the ’817 patent contains a lengthy section titled “Definitions.” Ex. 1001, 29:5–31:58. The term “3D segmentation map,” however, is *not* defined in this section.

“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

We do not perceive a need to construe any claim limitation at this time. This, however, does not preclude the parties from arguing proposed constructions of the claims during trial. Indeed, the parties are hereby given notice that any disputed claim construction, in general, should be addressed at trial and, if so, should be addressed clearly in a designated section of briefing rather than relegated to arguments on the merits of patentability. Claim construction, if necessary, will be determined at the close of the evidentiary record and after any hearing.

*E. Compliance with the Particularity Requirements
of 35 U.S.C. § 312(a)(3)*

Patent Owner asserts that the Petition fails to meet the particularity requirements of 35 U.S.C. § 312(a)(3). Prelim. Resp. 18–26. According to Patent Owner, “Petitioner’s excessive internal cross-referencing impermissibly forces the Board and Patent Owner to piece together scattered portions of the Petition (and exhibits).” *Id.* at 26. Patent Owner concludes that “the Petition fails to adequately map the references to the claim elements with particularity.” *Id.* We disagree.

Using claims 1 and 10 as an example, Petitioner asserts:

Claim 10 recites a “system for automatically processing 3D images” that is substantively identical to the “method for automatically processing 3D images” recited in claim 1, addressed above. Whereas claim 1 (the method claim) recites a series of steps, each performed “by a processor,” claim 10 (the system claim) recites a “processor” with stored instructions that perform the same steps recited in claim 1. Similarly, dependent claims 11–14, 16, and 26 are substantively identical to dependent claims 2–5, 7, and 19.

Pet. 41–42.

Claims 1 and 10 contain similar elements and limitations. Petitioner’s reference, for example, in the Petition’s analysis of claim 10, back to the analysis of claim 1 concerning nearly identical elements and limitations (*id.* at 42) is a matter of efficiency and is sufficiently clear for us to determine the basis for Petitioner’s challenges. We determine that the Petition does not violate the statutory requirement for particularity.

F. Ground A

1. Summary of Renisch

Renisch discloses a method and system for hot spot detection that includes a segmentation unit that segments an *anatomical* first image

representation into regions corresponding to anatomical structures of a subject or patient and a hot spot detection unit that detects regions of high uptake from a *functional* second image representation. Ex. 1005 ¶¶ 6–7.

As shown in Renisch's Figure 1, diagnostic system 10 includes a first imaging system, shown as diagnostic imaging scanner 12. *Id.* ¶ 20. Scanner 12, for example, could be a computed tomography (CT) imaging scanner or a magnetic resonance imaging (MRI) scanner for obtaining *anatomical* diagnostic images. Scanner 12 is operated by controller 30 to perform selected imaging sequences of a selected target area. *Id.* ¶ 21. The imaging sequences acquire diagnostic imaging data of the target area. *Id.* Reconstruction processor 34 reconstructs 3D image representations from the acquired imaging data, which are stored in diagnostic anatomical image memory 36. *Id.*

Diagnostic system 10 also includes a second imaging system, shown in Figure 1 as *functional* imaging scanner 40. *Id.* ¶ 22. Scanner 40, for example, could be a Positron Emission Tomography (PET) scanner or a Single Photon Emission Computed Tomography (SPECT) scanner for obtaining functional images. *Id.*

Diagnostic system 10 also includes a hot spot detection system 70 for automatic detection of a region of interest (ROI) pertaining to a lesion and automatic quantification of metabolic activity in detected lesions based on anatomical images 72 and functional images 74. *Id.* ¶ 25.

The disclosed system and method in Renisch also include segmentation unit 76, which is capable of employing different types of segmentation methods. During segmentation, the models act as templates to identify and define the boundary of the structure of interest. *Id.* ¶¶ 27–28.

Additionally, Renisch discloses hot spot detection unit 90, which uses an algorithm to detect from functional second image representation 74 hot spots or regions of high intensity 92 (*see* Fig. 3A). *Id.* ¶¶ 29. The algorithm “sorts all the voxels” of second image representation 74.¹² *Id.*

2. *Anticipation by Renisch*

In Ground A, Petitioner asserts that Renisch anticipates claims 1–5, 7, 10–14, 16, 19, and 26. We focus on independent claim 1. Because independent claim 10 is substantially identical to claim 1, our analysis of claim 1 also applies to claim 10.

Petitioner provides a clause-by-clause analysis of claim 1 stating where in Renisch each claimed step or limitation is disclosed in Renisch. Pet. 10–31.¹³ Throughout its analysis, Petitioner relies on the declaration testimony of Dr. Rosen (Ex. 1002). We need not duplicate this detailed and extensive analysis for purposes of this Decision. We determine that the Petition sufficiently covers Renisch’s disclosure of the subject matter recited by independent claim 1 (and claim 10) and we find no gaps therein.

Patent Owner asserts that “the Petition fails to show that any reference (or combination thereof) teaches the creation of a 3D segmentation map using machine learning modules, or the use of such a map to guide lesion

¹² The word “voxel” is used to describe a graphic simulation of a three-dimensional object. It is similar to the word “pixel” used to describe graphic simulation of a two-dimensional object. *See, e.g.*, Ex. 2014 (distinguishing voxels from pixels).

¹³ Petitioner also discusses, specifically for claim 1’s clause 1(c), the alternative ground of obviousness based on Renisch combined with Zhao, which we do not address in this decision.

detection in functional images, as recited in the claims of the '817 Patent.”
Prelim. Resp. 2. Patent Owner focuses on the claimed “segmentation map.”

As discussed above, the '817 patent states the disclosed invention identifies “a plurality of target 3D volumes of interest (VOIs) each corresponding to a specific target tissue region, such as one or more organs, portions of organs, particular bone(s), a skeletal region etc.” Ex. 1001, 32:6–9. These VOIs are areas, or regions, of interest for imaging (by “areas” or “regions” we do not suggest this is limited to or includes 2D areas). Each of these areas of interest or VOIs are “represented via a segmentation mask,” e.g., a mask may represent an organ, a portion of an organ, an anatomical system or a portion thereof, etc. *Id.* at 32:9–10. The claimed “segmentation map” is simply a combination of multiple “segmentation masks.” *Id.* at 32:11–13 (“multiple segmentation masks, identifying multiple target tissue regions across a patient’s body, can be stitched together to form a segmentation map”). Thus, a map may represent more of an imaged subject’s anatomy than a mask, e.g., the entire body, or multiple organs or tissues together.

Patent Owner’s primary argument regarding anticipation by Renisch is that “the Petition does not point to an actual, specific step in Renisch as equivalent to step (c) of claim 1.” *Id.* at 21 (citing Ex. 2014 ¶¶ 79. 82–83).

Step (c) in claim 1 states:

(c) determining, by the processor, a 3D segmentation map representing a plurality of 3D segmentation masks, each 3D segmentation mask representing a particular identified target VOI

Ex. 1001, 79:19–22.

Petitioner asserts that “[l]imitation [1(c)] is merely an explicit statement of a routine implementation detail in digital image segmentation.”

Pet. 23 (citing Ex. 1002, ¶¶ 159–172). According to Petitioner, “Renisch discloses [limitation 1(c)] to a POSITA even though Renisch does not use the same terminology.” *Id.* at 24 (citing sections from Ex. 1005 and also citing Ex. 1002 ¶¶ 163–167).

Petitioner asserts that “Renisch segments a 3D anatomical image into multiple VOIs corresponding to different anatomical structures, such as the brain, heart, liver, and bladder.” *Id.* (citing Ex. 1005 ¶ 25, Fig. 3B). Each segmented VOI is represented by its own image, or “segmentation mask,” to use the terminology of the ’817 patent; each segmented organ is represented by its own image, i.e., its own “segmentation mask.” Pet. 24 (citing Ex. 1002 ¶ 165).

Dr. Rosen also testifies that “[c]ollectively, the image segmentation results produced by Renisch are a segmentation map representing a plurality of 3D segmentation masks.” Ex. 1002 ¶ 166. As explained by Dr. Rosen,

Renisch states that “[t]he anatomical regions identified in the anatomical first image representation 72 can be carried over to the functional second image representation 74 in order to delineate anatomical structures in the second image representation 74.” *Id.* at [0034]. Additionally, Renisch states that “the outline of the segmented anatomical structures of the anatomical first image representation can be superimposed on the functional second image representation.” *Id.* at [0037]. These descriptions are essentially identical to the [’817] Patent.

Id. (citing Ex. 1001, 37:58–64).

We have considered Patent Owner’s arguments, but, on this record, are not persuaded. We recognize that Dr. Sonka provides a different opinion than Petitioner and Dr. Rosen. Dr. Sonka testifies that in his opinion “the distinctions between Renisch and claim 1 go beyond terminology.”

Ex. 2014 ¶ 79. At this stage, in the absence of a full record, we need not

resolve this difference between the expert opinions. Moreover, on this record, it appears that Renisch discloses the elements of limitation [1(c)] at paragraphs 26–31, where it discloses obtaining a scanned 3D image of a fuller anatomy, i.e., a segmentation map, and then using a segmentation unit (76) to define the boundaries of anatomical structures of interest within that fuller anatomy, i.e., creating a plurality of segmentation masks, using a library, models, clustering, edge detection, region growing, neural networks, and/or an atlas of normal anatomical structures, and then identifying hot spots of interest within those anatomical structures of interest, and identifying organs with lesions and those without. Ex. 1005 ¶¶ 26–31.

Based on the record before us and the specific disclosures in Renisch, as discussed in this Decision, we determine that Petitioner has met the “reasonable likelihood” standard necessary to institute an *inter partes* review proceeding. Although we address only Ground A and claims 1 and 10 herein for the purposes of institution, as noted above, we will address all asserted grounds and challenged claims in any final decision.

IV. CONCLUSION

We have determined that there is a reasonable likelihood that Petitioner will prevail on at least one challenged claim. Accordingly, we institute an *inter partes* review on all challenged claims on each asserted ground. A decision to institute is “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.” *PGS Geophysical*, 891 F.3d at 1360.

Our review of the Petition under 35 U.S.C. § 314 is not to determine whether an individual asserted fact is indisputable or whether a preponderance of the evidence supports Petitioner. Our review is to determine whether the totality of the information presented in the Petition

and Preliminary Response shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. “The ‘reasonable likelihood’ standard is a somewhat flexible standard that allows the Board room to exercise judgment.” Patent Trial and Appeal Board Consolidated Trial Practice Guide at 53 (Nov. 2019), *available at* www.uspto.gov/sites/default/files/documents/tpgnov.pdf.¹⁴

This is a decision to institute an *inter partes* review under 35 U.S.C. § 314. Our determinations at this stage of the proceeding are preliminary, and based on the evidentiary record developed thus far. This is not a final decision as to any fact or the patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record as fully developed during trial, including all arguments and evidence in any patent owner’s response,¹⁵ or submitted otherwise during trial, as permitted by our rules.

¹⁴ The Trial Practice Guide is also available as a web-version at www.uspto.gov/patents/ptab/trial-practice-guide. The parties’ familiarity with the Guide is expected.

¹⁵ See *In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (explaining that a patent owner waives an issue presented in its preliminary response if it fails to renew the issue in its response after trial is instituted).

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review is instituted as to claims 1–5, 7–14, 16–19, 22–26, and 28–32 of the '817 patent on each ground set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '817 patent shall commence on the entry date of this Decision, and notice is hereby given of the institution of a trial.

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