

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MIM SOFTWARE INC.,
Petitioner,

v.

EXINI DIAGNOSTICS AB,
Patent Owner.

IPR2025-00827
U.S. Patent No. 11,941,817

PATENT OWNER'S PRELIMINARY RESPONSE

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PATENT OWNER'S EXHIBIT LIST

EXHIBIT	DESCRIPTION
EX2001	Defendant's Memorandum of Law in Support of its Motion to Stay Pending <i>Inter Partes</i> Review, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 89, Apr. 8, 2025.
EX2002	MIM's Invalidity and Noninfringement Contentions, Civil Action No. 1:24-cv-10437-PBS.
EX2003	PACER Docket, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS (as of June 30, 2025).
EX2004	Defendant's Motion to Dismiss the Second Amended Complaint, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 43, June 17, 2024.
EX2005	Motion to Dismiss Hearing Transcript (excerpted pp. 1, 4-6), <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Oct. 8, 2024.
EX2006	Order Granting in Part and Denying in Part Defendant's Motion to Dismiss the Second Amended Complaint, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 72, Jan. 14, 2025.
EX2007	Motion to Stay Hearing Transcript (excerpted pp. 1, 5-6), <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, May 12, 2025.
EX2008	Order Granting in Part and Denying in Part Defendant's Motion to Stay Pending <i>Inter Partes</i> Review, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 102, May 13, 2025.
EX2009	Scheduling Order, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 85, Mar. 5, 2025.

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EX2010	U.S. District Courts, Judicial Caseload Profile 2024 (D. Mass. excerpted).
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EX2012	<i>NIH Strategic Plan for Data Science FY 2025-2030</i> , Nat’l Institutes of Health.
EX2013	Rowe, S.P. et al., <i>PET Imaging of Prostate-Specific Membrane Antigen in Prostate Cancer: Current State of the Art and Future Challenges</i> , Prostate Cancer & Prostatic Diseases (2016).
EX2014	Declaration of Dr. Milan Sonka.
EX2015	Curriculum Vitae of Dr. Milan Sonka.
EX2016	RESERVED
EX2017	Crisan, et al., <i>Radiopharmaceuticals for PET and SPECT Imaging: A Literature Review over the Last Decade</i> , International Journal of Molecular Sciences 23(9):5023 (2022).
EX2018	<i>PET Scans</i> , CancerQuest, Emory Winship Cancer Institute (2025).
EX2019	Rowe, S.P., et al., <i>PSMA-Based [¹⁸F]DCFPyL PET/CT Is Superior to Conventional Imaging for Lesion Detection in Patients with Metastatic Prostate Cancer</i> , Molecular Imaging and Biology 18(3):411-419 (2016).
EX2020	<i>FDA Approves First PSMA-Targeted PET Imaging Drug for Prostate Cancer</i> , Oncology Practice Management (2020).
EX2021	<i>FDA Approves Second PSMA-Targeted PET Imaging Drug for Men with Prostate Cancer</i> , Food and Drug Administration (2021).
EX2022	<i>Atlas-Based vs. AI Auto-Contouring in Clinical Practice</i> , MIM Software Inc. (2023).
EX2023	Brown, <i>Machine Learning, Explained</i> , MIT Sloan (Apr. 21, 2021).
EX2024	RESERVED

EXHIBIT	DESCRIPTION
EX2025	Krizhevsky, et al., <i>ImageNet Classification with Deep Convolutional Neural Networks</i> , Advances in Neural Information Processing Systems 25 (2012).
EX2026	Deng, et al., <i>ImageNet: A large-scale hierarchical image database</i> , IEEE Conference on Computer Vision and Pattern Recognition (2009).
EX2027	Bushberg, J.T., et al., <i>The Essential Physics of Medical Imaging</i> (2012), Ch. 1, Sec. 1.1, pp. 3-15.
EX2028	Bushberg, J.T., et al., <i>The Essential Physics of Medical Imaging</i> (2012), Ch. 3, Sec. 3.1, pp. 33-38.
EX2029	Kelleher, <i>Deep Learning</i> (2019), Ch. 1, “What Is Machine Learning?,” pp. 9-17.
EX2030	Kelleher, <i>Deep Learning</i> (2019), Ch. 1, “The Key Ingredients of Machine Learning,” pp. 22-30.
EX2031	Kelleher, <i>Deep Learning</i> (2019), Ch. 3, “Neural Networks: The Building Blocks of Deep Learning,” pp. 65-67.
EX2032	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “The Era of Deep Learning,” pp. 143-145.
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EX2034	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “Weight Initialization and ReLU Activation Functions,” pp. 148-153.
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I. INTRODUCTION

U.S. Patent No. 11,941,817 (the “’817 Patent”) discloses a novel solution to serious challenges faced by doctors when analyzing medical images for cancer diagnosis and treatment. More specifically, the ’817 Patent claims an inventive system and method for automatically segmenting medical images using machine learning modules tailored to identify specific volumes of interest (VOIs) across multiple tissue regions, and then using those segmented anatomical volumes to create a 3D segmentation map of the subject’s medical image that helps physicians analyze the image for cancer detection and assessment. The result is a robust, automated framework for identifying and tracking cancerous lesions throughout the body with improved accuracy, consistency, and clinical utility.

Key innovations of the ’817 Patent include: (a) the use of machine learning modules customized to identify specific tissue regions to perform detailed whole-body segmentation of anatomical images; (b) the creation of a unified 3D segmentation map for representing multiple VOIs that accommodates the use of multiple machine-learning modules; and (c) the integration of such anatomical and functional imaging data to automatically detect and classify cancerous lesions. These advances go well beyond conventional medical image processing techniques that existed as of the priority date (January 7, 2019).

None of the Petition's cited references disclose the innovative techniques that are described in the '817 Patent and recited in the challenged claims. To begin with, the Petition relies primarily on the same prior art references that were already cited and considered during prosecution of the '817 Patent. The Petition briefly suggests that the Examiner could or should have combined the asserted references to find the patent obvious, but the Petition fails to sufficiently explain how the Examiner made any clear and material error. *See* Pet., 4-5. The Petition's arguments do not support any such conclusion. To the contrary, the Petition fails to show that the references it asserts disclose or render obvious key claim elements. For example, as discussed in more detail below, 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 detection in functional images, as recited in the claims of the '817 Patent. Because the asserted references do not disclose the claimed techniques, the Petition attempts to stretch vague and inapt statements in those references to cover the claimed limitations, but these efforts fail to fill the references' critical gaps.

Therefore, Patent Owner requests that the Board deny institution of the Petition.

II. TECHNOLOGY BACKGROUND

One of the longstanding challenges in diagnosing and managing cancer, as well as other serious diseases, is the difficulty of accurately and consistently interpreting medical imaging data. *See* EX2014, ¶35. Both anatomical scans (such as X-rays or CT scans) and functional scans (like PET or single-photon emission computed tomography (SPECT)) are valuable tools. EX2014, ¶¶26-28. However, before the inventions described in the '817 Patent, physicians faced significant obstacles in using these scans to form a complete and reliable picture of a patient's condition.

One difficulty was that each type of scan could only capture part of the relevant picture for any given patient. Simply put, anatomical scans show the anatomy or structure of organs and tissues within the body (but not the function); functional scans show the activity and function of those organs or tissues (but not the anatomy/structure). *See* EX2014, ¶¶27-28. As applied to cancer, an anatomical scan thus cannot reliably detect the activity of a tumor, whereas a functional scan can struggle to differentiate between the organs and tissue surrounding a tumor. *See id.* As a result, physicians were left to parse two different types of scans to try to piece together the full picture, which often led to inaccurate or inconsistent diagnoses or treatments.

While radiologists and physicians have various medical imaging modalities and techniques at their disposal, the selection of which types of images to obtain, and how to interpret these images is not straightforward. EX2014, ¶35. To the contrary, the task of determining, for example, whether a particular patient has cancer, how severe it is, and what course of action to take is laborious, error prone, and highly subjective, often varying from physician to physician. *Id.* Without effective automated integration, mapping, and assessment of those scan results, a physician might miss a critical diagnostic insight.

III. CITED REFERENCES

A. Renisch

Renisch discloses “diagnostic imaging systems and methods” for analyzing PET/CT images on a dedicated computer workstation. EX1005, [0001], [0020]; EX2014, ¶50. Where Renisch addresses image segmentation, it focuses on conventional atlas-based techniques. EX1005, [0028] (“The segmentation unit 76 can also employ an atlas of normal anatomical structures which is mapped to the actual anatomical image.”); EX2014, ¶50.

B. Zhao

Zhao discloses a method for analyzing digital images using a predictive model and loss functions implemented via processing circuitry. EX1007, 1:32-62;

EX2014, ¶51. Zhao’s approach is limited to segmenting individual 2D images. EX1007, 7:56-64, 8:63-9:3; EX2014, ¶51.

C. Baker

Baker discloses a network-based (e.g., cloud-based) platform and supported graphical user interface (GUI) decision-making tool that supports clinical decision-making and treatment tracking for cancer patients. EX1008, [0011]; EX2014, ¶52.

D. Eiber

Eiber discloses a standardized reporting framework for PET/CT and PET/MRI scans, which he refers to as the molecular imaging TNM (miTNM) system. EX1009, 469; EX2014, ¶53. Eiber’s approach involves manual measurement of reference values for lesion grading, such as placing circular regions of interest in specific anatomical locations. EX1009, 471 (“The liver SUV can be measured by placing a 3-cm-diameter circular region of interest in the normal inferior right liver lobe in the axial plane; the blood pool, by centering a 2-cm-diameter circular region of interest in the aortic arch in the axial plane; the parotid gland, by centering a 1.5-cm-diameter circular region of interest in the right parotid gland in the axial plane; and a tumor lesion, by centering a 1-cm-diameter circular region of interest over the voxel with maximum uptake in the axial plane.”); EX2014, ¶53.

E. Suehling

Suehling discloses a method and system for detecting lesions in medical images using region-specific lesion detectors. EX1007, [0030]-[0031]; EX2014, ¶54. Suehling's lesion detection approach focuses on anatomical images, rather than functional images. *See* EX1007, [0020]-[0021], [0033].

IV. THE '817 PATENT

A. The Invention

As of the priority date (January 7, 2019), there remained a critical unmet need for more accurate, reliable, and consistent methods of performing detailed whole-body segmentation of medical images — particularly for cancer diagnosis and treatment. *See* EX2014, ¶¶55-63.

The '817 Patent describes how to use software modules that implement machine learning techniques, like convolutional neural networks (CNNs), to segment 3D anatomical images and identify specific target tissue volumes of interest (VOIs). EX1001, 31:60-32:21, 34:41-37:10, 42:5-48:41; EX2014, ¶55. Among other things, the machine-learning-based 3D image segmentation techniques described in the '817 Patent allow accurate and robust full-body segmentation and automated analysis of cancerous lesions across multiple tissue regions. EX1001, 4:66-5:11; EX2014, ¶56. The claimed methods support both early detection and monitoring of disease progression or metastasis. EX1001, 4:66-5:11, EX2014, ¶56.

These innovations provide tools for automated, image-based cancer detection and longitudinal tracking of disease evolution and treatment response. EX2014, ¶56.

A key claimed advancement is the creation of a 3D segmentation map using machine learning-based segmentation of 3D anatomical images. EX1001, 31:64-32:21; EX2014, ¶57. The claimed 3D segmentation map is a specific element that is created and used to represent multiple volumes of interest (VOIs) that are identified via the techniques described in the '817 Patent. EX1001, 34:27-39; EX2014, ¶57. In particular, the '817 Patent describes how accurate 3D image segmentation can be performed throughout a subject's body (e.g., whole-body 3D image segmentation) using customized CNN modules, each trained to segment a particular set of tissues (e.g., organs or bones) within a specific anatomical subregion of the body, where the specific anatomical subregion is a group of related tissue, such as a pelvic region, a chest region, a head and/or neck region, a spine region, an upper body region, a lower body region, and the like. EX1001, 6:40-42, 42:66-46:51, 34:27-29; EX2014, ¶58. For example, the specification of the '817 Patent describes training a first machine learning module (CNN) for the pelvic region to segment the left and right ilium, the prostate, the urinary bladder, the sacrum, and the coccyx; training a second CNN for the abdomen to segment the liver, the left and right kidneys, and the gallbladder; and training five other CNNs to segment tissues

within those corresponding five additional anatomical subregions. EX1001, 46:17-51; EX2014, ¶58.

The outputs of the CNN modules are then combined to generate a unified 3D segmentation map. EX1001, 35:10-26, 49:7-10, 50:20-21; *see also id.*, 5:37-48, 32:1-21, 34:27-29; EX2014, ¶¶58-59. See, for example, FIGs. 6A and 6B of the '817 Patent:

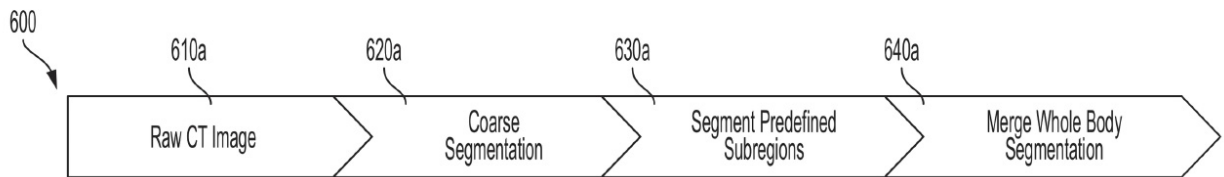


FIG. 6A

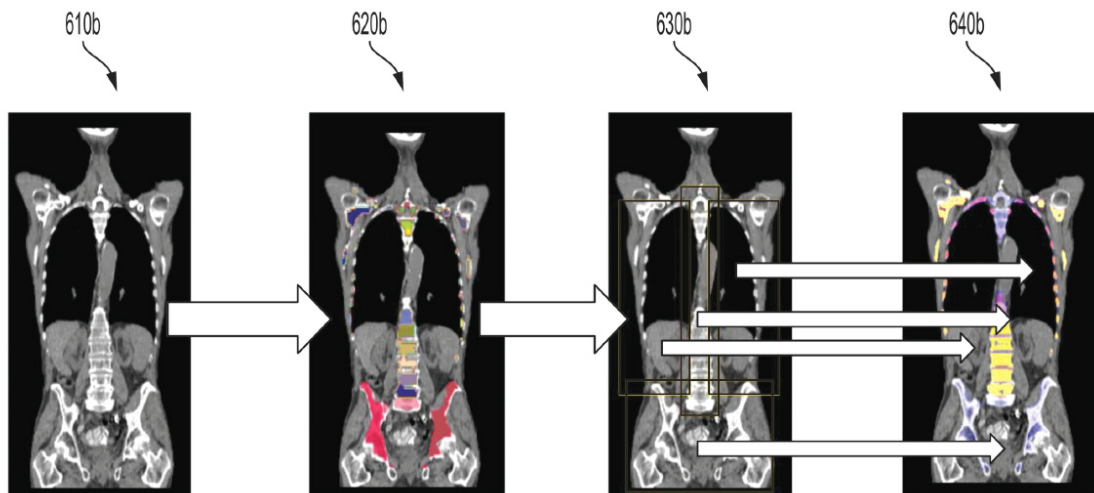


FIG. 6B

FIGs. 6A and 6B of the '817 Patent

And, as illustrated in FIG. 8 of the '817 Patent, the 3D segmentation map provides 3D information about anatomical geometry of various organs and bones within a subject:

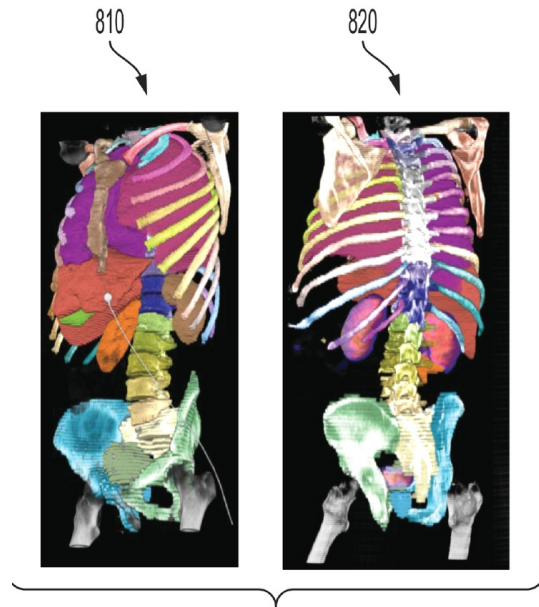


FIG. 8

FIG. 8 from the '817 Patent

As reflected above, the 3D segmentation map serves as a foundational layer for further analysis. EX1001, 31:65-33:40; EX2014, ¶60. For example, the '817 Patent describes combining the anatomical segmentation map with 3D functional imaging data (e.g., PET or SPECT scans) to provide anatomical context for functional signals. *See* EX1001, 32:65-33:40; EX2014, ¶60. *See*, for example, FIG. 3 of the '817 Patent:

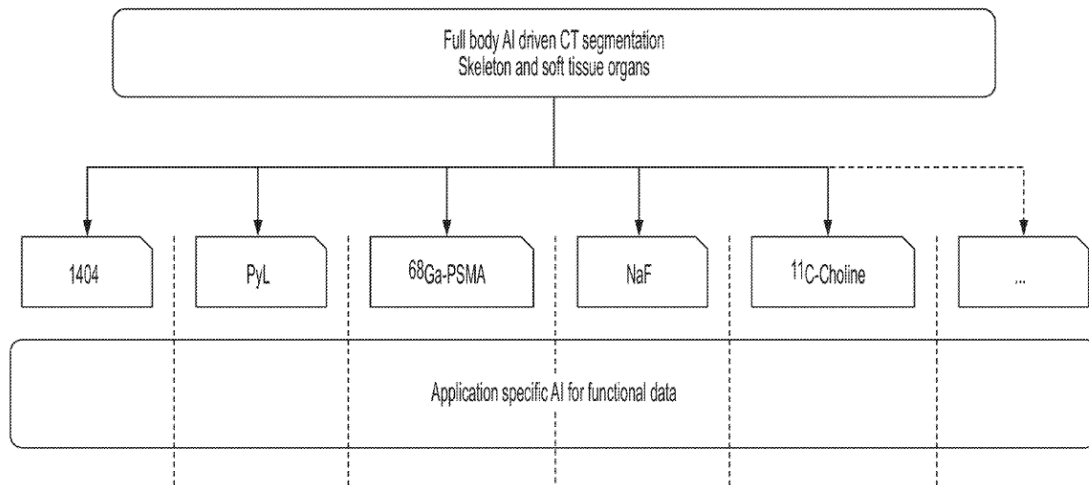


FIG. 3

FIG. 3 of the '817 Patent.

One can thus access and use the 3D segmentation map to provide anatomical context for functional images, where it is often difficult to obtain. EX1001, 33:9-34:39; EX2014, ¶61. This integration enables more accurate lesion detection, classification (e.g., primary tumor vs. metastasis), and quantification of lesion severity—especially in complex tissues like the bladder or kidneys where physiological uptake can obscure pathology. EX1001, 3:49-5:11; EX2014, ¶62.

By providing for automated, whole-body, 3D segmentation and functional-anatomical integration, the claimed methods offer significant advantages over prior art. EX2014, ¶63.

B. Prosecution History

The Application for the '817 Patent was filed on March 29, 2023 as a divisional application, claiming earliest priority to U.S. Provisional Application 62/789,155 filed on January 7, 2019. EX1004, 224; EX2014, ¶64. The '817 Patent issued on March 26, 2024. EX1004, 464; EX2014, ¶64. During prosecution of the '817 Patent, the Patent Owner cited three of the Petition's references, Renisch, Baker, and Eiber, in an IDS submitted to the Office on June 26, 2023. *See* EX1004, 246, 251; EX2014, ¶66. On October 4, 2023, the Examiner signed the IDS, noting at the bottom that "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.M.S./." The Examiner did not line through the Renisch, Baker, or Eiber references, thus indicating that those references (among others) were considered. EX1004, 280, 285; *see also* EX2014, ¶66. On October 13, 2023, the Examiner allowed the application after considering all the references and stated, in the Notice of Allowance, that "[t]he closest prior art is **Hamadeh et al. (US 8,855,387)**." EX1004, 323 (emphasis in original); EX2014, ¶67. After this Notice of Allowance was issued, on October 30, 2023, the Patent Owner filed a Request for Continued Examination with an IDS citing additional references and an amendment to the specification addressing informalities identified in a Notice to File Corrected Application Papers issued by the Office. EX1004, 327-51; EX2014, ¶67. The

Examiner issued a second Notice of Allowance on November 21, 2023, presenting the same reason for allowance. EX1004, 421-31; EX2014, ¶67.

V. PERSON OF ORDINARY SKILL

Petitioner argues that a POSA “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; EX2014, ¶15.

For purposes of this preliminary response, Patent Owner does not dispute Petitioner’s definition of a POSA. EX2014, ¶¶13-16.

VI. CLAIM CONSTRUCTION

The term “3D segmentation map” appears in claims 1, 3, 10, 12, 19, and 26 of the ’817 Patent. While the Petition proposes an incorrect construction of this term (*see* Pet., 9-10), that issue is not material to the grounds for denying institution that Patent Owner presents below. Patent Owner expressly reserves all rights to challenge the construction should the Board institute the Petition.

VII. ARGUMENT

A. The Board should deny institution as to all grounds under 35 U.S.C. § 325(d).

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.

Section 325(d) provides that the Board may reject a petition if, as in this Petition, “the same or substantially the same prior art or arguments previously were presented to the Office.” Per *Advanced Bionics*, the Board applies a two-step test when deciding whether to deny institution pursuant to Section 325(d). First, the Board determines whether the Petition presents the same or substantially the same art (or arguments) previously presented to the Office. If so, the Board then asks whether the Petition demonstrates that the Office materially erred in its consideration of that same art. If the Petition fails to show a material error, the Board defers to the earlier examination and denies institution. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8-9 (PTAB Feb. 13, 2020) (precedential). As the Board emphasizes, “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred.” *Id.*, 9. Section 325(d) reflects a strong “commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* When applying the two-part *Advanced Bionics* test, the Board also considers the non-exclusive *Becton, Dickinson* factors, which assist in the evaluation of whether the same or substantially the same prior art or arguments were previously presented to the Office. *Advanced Bionics*, IPR2019-01469, Paper 6, 7; *Becton*,

Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8, 17-18 (PTAB Dec. 15, 2017).

1. The Petition presents the same or substantially the same art that the Examiner already considered.

The Patent Owner undisputedly cited the Petition's primary references, Renisch and Baker, during prosecution of the '817 Patent. EX1004, 246; EX2014, ¶¶65-68. Petitioner acknowledges as much. Pet., 4. The Patent Owner also undisputedly cited one of the secondary references, Eiber, during prosecution and even discussed it in the specification of the '817 Patent. *See* EX1004, 251; EX1001, 62:24-25; EX2014, ¶¶65-68.

In particular, the Patent Owner listed Renisch, Baker, and Eiber on the IDS filed on June 26, 2023. *See* EX1004, 246, 251; EX2014, ¶66. On October 4, 2023, the Examiner signed the IDS, noting at the bottom that "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.M.S./." The Examiner did not line through the Baker, Renisch, or Eiber references, thus they were considered. EX1004, 280, 285; EX2014, ¶66. *See Skechers U.S.A., Inc. v. Nike, Inc.*, IPR2025-00141, Paper 20, 13 (PTAB June 3, 2025) (holding first step of *Advanced Bionics* test satisfied where the reference "was cited on an IDS by the applicant, and the Examiner indicated that all references were considered"). The Examiner thus allowed the claims after considering the Renisch and Baker primary references (as well as the secondary Eiber reference). EX2014, ¶¶67-68. Therefore,

the Petition runs afoul of the first prong of the *Advanced Bionics* framework because the Petition presents “the same or substantially the same prior art” previously presented to the Office. Petitioner does not argue otherwise. *See* Pet., 3-5.

Although two of the Petition’s three secondary references (Zhao and Suehling) were not presented to the Examiner, their absence does not change the *Advanced Bionics* step 1 analysis at least because the Petition does not contend that any claim is invalid exclusively based on the secondary references; every claim depends on at least some combination of Renisch and/or Baker (both of which the Examiner considered). In *ClearH2O v. Ceva Animal Health*, the Board recognized that, “[a]lthough the examiner did not consider [these] secondary references . . . during prosecution, because Petitioner’s primary references . . . were also the primary references involved during the original examination, this factor weighs in favor of denying institution.” *ClearH2O, Inc. v. Ceva Animal Health Inc.*, IPR2020-00039, Paper 21, 25 (PTAB Mar. 18, 2020). Here, the Petition does not even argue that the secondary references add anything to Renisch and/or Baker that the Examiner did not consider during prosecution. Pet., 3-5. Therefore, the secondary references make no difference to the ultimate analysis under Section 325(d).

Furthermore, as explained in more detail below, the two secondary references that were not presented to the Examiner – Zhao and Suehling – fail to disclose

limitations missing from the references that *were* considered by the Examiner – Renisch, Baker, and Eiber. *Infra*, Sections VII.C.2, VII.C.7.

The Petition thus satisfies the first step of the *Advanced Bionics* framework.

2. The Petition fails to show that the Examiner materially erred.

Because the Petition relies on the same prior art that the Examiner already considered, the burden shifts to the Petitioner to demonstrate that the Examiner *materially erred* when it considered the art during prosecution. *Advanced Bionics*, IPR2019-01469, Paper 6, 8. Material error is a high bar. The Petition must identify specific errors by the Examiner, such as “misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.” *Id.*, 8 n.9. The Petition cannot simply identify room for reasonable disagreement with the Examiner’s reasoning. Absent clear and material error, the Board will not second-guess the Examiner. *See id.*, 9 (“If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability . . . this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.”).

The Petition fails to carry its heavy burden. The Petition does not (and cannot) identify any clear and material error by the Examiner. Instead, the Petition briefly and cursorily argues that the Examiner must have misunderstood the Petition’s two

primary references (Renisch and/or Baker) because those references teach the elements that the Examiner found lacking in the prior art. Pet., 4-5. Notably, though, the Petition does not quote the Examiner’s full explanation for what he concluded was missing:

However, Hamedia **fails to teach** a cancerous lesion automatic[] identification method for (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.

EX1004, 324 (emphasis in original). Rather than explain in detail why Renisch and Baker teach this long list of limitations, the Petition dedicates a *single sentence* to why Renisch and Baker satisfy these elements. Pet., 4-5 (“This Petition presents two alternative primary references, US2012/0123253 (‘Renisch’) and US2018/0144828 (‘Baker’), both of which – unlike Hamadeh – automatically identify cancerous lesions in 3D medical images by: (i) segmenting 3D anatomical images using machine learning; and (ii) mapping the segmented regions, e.g., organs, to a corresponding 3D functional image to identify the anatomical locations of lesions detected in the functional image.”). Such cursory assertion is insufficient to demonstrate clear material error. *See Ecto World, LLC v. Rai Strategic Holdings*, IPR2024-01280, Paper 13, 5 (PTAB May 19, 2025) (precedential) (reaffirming that

“a petitioner must provide an analysis” specific to step two of the *Advanced Bionics* test). Where the “Petitioner argues only that the Petition presents grounds of unpatentability not previously considered and/or applied by the Examiner,” but the Petition fails to provide “further analysis,” it “cannot persuade [the Board] of “material error.” *Vital Connect, Inc. v. Bardy Diagnostics, Inc.*, IPR2023-00381, Paper 7, 19 (PTAB July 11, 2023) (denying institution at step 2). Petitioner cannot rely on its cursory assertion to satisfy its burden at step two of *Advanced Bionics*. *Id.* The Petition thus fails to show clear error in the Examiner’s analysis.

Therefore, the Board should deny institution under Section 325(d).

B. Institution should be denied as to all Petitioner’s proposed grounds because the Petition fails to meet the particularity requirements of 35 U.S.C. § 312(a)(3).

Under 35 U.S.C. § 312(a)(3), a petition must identify “with particularity each claim challenged, the grounds on which the challenge is based, and the evidence that supports the grounds.” This standard ensures that the Patent Owner and the Board have a clear, complete, and specific understanding of the Petitioner’s unpatentability theories at the institution stage. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (“It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’”) (quoting 35 U.S.C. § 312(a)(3)); *Apple Inc. v. Gesture Tech.*

Partners, LLC, 129 F.4th 1367, 1375 (Fed. Cir. 2025) (“Ultimately, it is the petitioner’s burden to present a clear argument.”) (citation omitted).

The Petition fails to meet the particularity standard in two ways. First, it fails to provide a particularized explanation of how the asserted references allegedly map to the claim elements. Second, the Petition improperly over-relies on overlapping grounds and internal cross-references. These defects prevent the Board from making a threshold determination of patentability under Section 314(a), and thus require denial of institution. *See* 35 U.S.C. § 314(a).

The Board’s regulations require that the Petition “(1) specify sufficiently where each element of the claims is found in the applied references, and (2) include a detailed explanation of the significance of the quotations and citations from the applied references.” *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12, 11 (PTAB Aug. 29, 2014); 37 C.F.R. § 42.104(b)(4) (requiring that every petition explain with particularity “where each element of the claim is found in the prior art patents or printed publications relied upon”).

Petitioner fails to explain with particularity “where each element of the claim is found in the prior art patents or printed publications relied upon” as required. *See* 37 C.F.R. § 42.104(b)(4). As explained below, Petitioner glosses over many critical claim elements, failing to explain where or how the references allegedly teach these elements. Thus, “the Petition places a significant and unfair burden on the Patent

Owner to respond adequately to underdeveloped arguments for numerous asserted grounds.” *Zetec, Inc. v. Westinghouse Elec. Co., LLC*, IPR2014-00384, Paper 10, 14 (PTAB July 23, 2014) (denying institution); *see also id.*, 15. This approach impermissibly leaves the Board and Patent Owner to guess at Petitioner’s case. *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1001-02 (Fed. Cir. 2023) (“The IPR petition, thus, must provide an understandable explanation of the element-by-element specifics of the patentability challenges, including the identification of particular portions of prior art on which the petitioner is relying.”) (citation omitted); *see also Microsoft Corp. v. FG SRC, LLC*, 860 F. App’x 708, 713 (Fed. Cir. 2021) (“It is not the Board’s job to cobble together assertions from different sections of a petition or citations of various exhibits in order to infer every possible permutation of a petitioner’s arguments. Arguments in a petition must be made with particularity, not opacity[.]”).

For example, under Ground A, the Petition asserts that Renisch anticipates independent claim 1, even though the asserted reference fails to disclose an entire step of the claimed method – namely, step (c), which states “determining...a 3D segmentation map representing a plurality of 3D segmentation masks, each 3D segmentation mask representing a particular identified target VOI”. EX1001, 79:19-22; EX2014, ¶¶78-83.

The Petition attempts to argue that “Renisch discloses [1(c)] to a POSITA even though Renisch does not use the same terminology.” Pet., 24; EX2014, ¶79. Were this accurate, however, the Petition would still be able to point to specific portions of the reference and identify them as equivalent to the particular claim elements, just by another name (“terminology”). The Petition does not do this; for example, the Petition does not point to an actual, specific step in Renisch as equivalent to step (c) of claim 1. *See* Pet., 24; EX2014, ¶¶79, 82-83. Instead, the Petition attempts to infer the presence of this step of claim 1 from passages of Renisch that describe entirely different steps and which, as explained in further detail below, are inapt. Pet., 24; EX2014, ¶¶82-83. Thus, contrary to the Petition’s assertion, the distinctions between Renisch and claim 1 are more than a difference in terminology, and the Petition’s arguments at Ground A fail to specify sufficiently where each element of claim 1 is found in the applied reference. *See* EX2014, ¶¶82-83.

The Petition offers an alternative, second challenge to the independent claims under Ground B, alleging they are obvious based on Renisch and Zhao. Pet., 25; EX2014, ¶96. The Petition attempts to rely on a secondary reference, Zhao, to supply limitation 1(c), which, as explained above, is plainly missing from Renisch. Pet., 25; EX2014, ¶97. However, here too the Petition fails to show where each

individual element of this particular claim limitation is allegedly disclosed in the cited art (here, Zhao). *See* EX2014, ¶¶97-100.

In particular, limitation 1(c) states, “determining...a **3D** segmentation map representing a plurality of **3D** segmentation masks, each **3D** segmentation mask representing a particular identified target VOI” (emphasis added). EX1001, 79:19-22. Thus, the claim specifies a *three-dimensional (3D)* segmentation map. *See id.*; EX2014, ¶96. The Petition, however, does not point to a specific portion of Zhao as disclosing a **3D** segmentation map, as recited in claim 1. *See* Pet., 25-26; EX2014, ¶¶97-98. Instead, the Petition points to a “multi-value mask” described in Zhao (EX1007, 5:30-42) and states “[t]he ‘multi-value mask’ corresponds to a segmentation map, as claimed. Accordingly, Zhao discloses [1(c)].” Pet., 25-26; EX2014, ¶97. This statement of the Petition, however, skirts the requirement that the claimed segmentation map is a **3D** segmentation map. *See* EX1001, 79:19-22; EX2014, ¶100. This is especially problematic for two reasons. First, the Petition does not provide a quote from Zhao that actually uses the term “3D” or any equivalent of 3D. *See* Pet., 25-26. Second, the passage of Zhao that the Petition contends discloses a “multi-value mask” (and, therefore, allegedly, a “segmentation map, as claimed”) indicates, on its face, that Zhao’s “multi-value mask” is *not* three-dimensional, but, rather, expressly two-dimensional by repeatedly and consistently referring to image *pixels*, which are 2D elements. Pet., 26 (citing EX1007, 5:30-42)

(“Each *pixel* of the mask may contain a value used to denote whether a particular corresponding *pixel* of the digital image is among any ROI... For a mask capable of representing multiple types of ROI, each *pixel* may be at one of a number of values each corresponding to one type of ROIs. A multi-value mask, however, may be decomposed into a combination [sic] the more fundamental binary masks each for one type of ROI.”) (“pixel” emphasis added; underline emphasis is Petition’s); *see also* EX2014, ¶¶97-100. Thus, it is unclear which part of Zhao the Petition contends discloses the element of a 3D segmentation map, as recited in claim 1.

Furthermore, the Petition argues that Zhao discloses 3D medical image segmentation and that “Zhao discloses segmentation masks representing particular volumes-of-interest within 3D medical images,” but requires Patent Owner to guess that the Petition is equating a CT image with a 3D medical image (which, as explained below, is incorrect and at odds with Zhao’s disclosure, which describes, expressly, only 2D image processing). Pet., 25; EX2014, ¶¶97-100. Namely, the Petition states the following:

Zhao implements 3D medical image segmentation, like that discussed in Renisch, using segmentation masks. Ex1007, 5:11-6:11 (“segmentation may be implemented in medical image processing”) (“Such medical images may include ... CT.”) (“[A]n ROI may be an entire organ.”). Zhao states: “ROIs, once determined, may be represented by a digital mask containing a same number of pixels as the digital image” and “[a] digital mask may be alternatively referred [to] as a mask or a segmentation mask.” Ex1007, 5:25-29. Thus, Zhao discloses segmentation masks representing particular volumes-of-

interest within 3D medical images, such as entire organs within CT images. Ex1002, ¶168.

Pet., 25. Moreover, this passage of the Petition still does not explain why Zhao discloses a 3D segmentation map (since a medical image is not a segmentation map). The Petition thus leaves Patent Owner (and the Board) to guess at the Petition’s actual argument, thereby failing to meet the particularity requirement.

Accordingly, the Petition fails to adequately map the references to claim elements of the claim elements with particularity. As the Board has repeatedly held, this failure warrants denying institution. *See C-Cation Techs., LLC*, IPR2014-00454, Paper 12, 10; *Shenzhen Jimuyida Tech. Co., Ltd. v. Artec Europe S.A.R.L.*, IPR2023-01148, Paper 6, 18 (PTAB Jan. 16, 2024).

The Petition creates further ambiguity by attempting to present multiple alternative grounds that cover overlapping sets of claims with different combinations of references. As a result, it impossible to understand which precise sub-combinations apply to which precise elements—let alone to understand “where” the Petition believes “each element of the claim is found in the prior art patents or printed publications relied upon.” 37 C.F.R. § 42.104(b)(4). *See also Corephotonics, Ltd.*, 84 F.4th at 1001-02.

For example, the Petition asserts that claims 8-9, 17-18, 22-25, and 29-32 are rendered obvious by Ground C (Renisch, or Renisch-Zhao, each in view of Baker), whereas claims 8-9, 17-18, 22, 24-25, 29, and 31-32 are rendered obvious by Ground

D (Renisch, or Renisch-Zhao, each in view of Eiber). Pet., 8, 43. The Petition addresses these grounds simultaneously for each claim, without an individualized treatment of how each reference of each ground applies to each claim element. This is especially confusing because the Petition does not contend that Grounds C and D cover exactly the same claims (e.g., Ground C covers claims 23 and 30, but Ground D does not), so the Board and Patent Owner are left to try to piece the puzzle together.

Moreover, the Petition overly relies on internal cross referencing. This makes identifying the specific arguments and portions of the cited references that the Petition is presenting especially challenging.

For example, for claims 9 and 22-25, the Petitioner's argument consists exclusively of internal cross-references to other sections of the Petition: "Claims 9 and 22-25 depend from claim 8, which is obvious over Baker-Zhao. *See* Section VIII.D.4. Baker also discloses all the limitations of claim 9 (Section VIII.C.2), claim 22 (Section VIII.C.3), claim 23 (Section VIII.C.4), claim 24 (Section VIII.C.5), and claim 25 (Section VIII.C.6)." Pet., 56.

Furthermore, for claims 10-14, 16, and 26 under Ground A, the Petition exclusively relies on cross-referencing to the previous method claims. Here, the Petition's penchant for internal cross-referencing creates a clear substantive shortcoming, since the Petition entirely fails to address an element unique to the

system claim (as compared to the method claim) involving “a processor of a computing device; and *a memory having instructions stored thereon*, wherein the instructions, when executed by the processor, cause the processor to:” (emphasis added). *See id.*, 41-42. The same issue recurs in the Petition’s treatment of the system claims 10-11, 16-18, and 29-32 for Ground E. *See id.*, 56-57.

Petitioner’s excessive internal cross-referencing impermissibly forces the Board and Patent Owner to piece together scattered portions of the Petition (and exhibits). Therefore, as discussed above, the Petition fails to adequately map the references to the claim elements with particularity. As the Board has repeatedly held, this deficiency warrants denying institution. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363-64 (Fed. Cir. 2016); *Valeo N. Am., Inc. v. Magna Elecs., Inc.*, IPR2014-01206, Paper 13, 15 (PTAB Dec. 23, 2014); *Supercell OY v. Gree, Inc.*, IPR2021-00500, Paper 7, 12 (PTAB Aug. 16, 2021).

Institution should thus be denied.

C. The Petition does not establish a “reasonable likelihood” of unpatentability for any claim.

Under 35 U.S.C. § 314(a), the Board may not institute inter partes review unless the Petition demonstrates “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” This is a threshold requirement that the Petition must satisfy. *Harmonic Inc.*, 815 F.3d at 1363 (“the petitioner has the burden from the onset to show with particularity why

the patent it challenges is unpatentable”). Here, the Petition fails to establish a “reasonable likelihood” of unpatentability as to any challenged claim. Institution should thus be denied. Patent Owner addresses each ground below.

1. Ground A: Renisch does not anticipate claims 1-5, 7, 10-14, 16, 19, and 26.

The Petition fails to establish a reasonable likelihood that Renisch anticipates claims 1-5, 7, 10-14, 16, 19, and 26. EX2014, ¶69. Patent Owner specifically addresses claims 1 and 10 below since those are the only independent claims.

a. Renisch does not disclose a “3D segmentation map” as recited in claims 1 and 10.

The term “3D segmentation map” appears in claims 1 and 10. Representative limitation (c) of claim 1 recites: “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[.]” EX1001, 79:19-21 (emphasis added); EX2014, ¶78.

While the Petition concedes that Renisch does not mention a “3D segmentation map” or even a “3D segmentation mask,” it nonetheless contends that Renisch’s “suppression unit” implicitly involves the use of such masks. Pet., 24-25; *supra*, 20-21. That argument fails for at least two reasons.

First, Renisch does not disclose the creation of a “3D segmentation map” (or the component 3D segmentation masks) as recited in claim 1. EX2014, ¶¶79-83. As

discussed above, the '817 Patent teaches that the 3D segmentation map is a specific, structured element created by combining multiple 3D volumes, each corresponding to a target VOI identified via machine learning-based segmentation of anatomical images. EX1001, 35:10-26, 49:7-10, 50:20-21; *see also id.*, 5:37-48, 32:1-21, 34:27-29; EX2014, ¶¶80-81. For example, the Patent describes identifying multiple target volumes via machine learning-based image segmentation techniques and stitching them together to form a segmentation map, as shown in FIGs. 6A, 6B and FIG. 8:

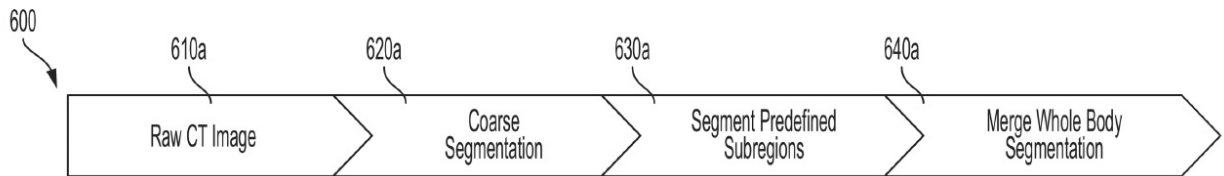


FIG. 6A

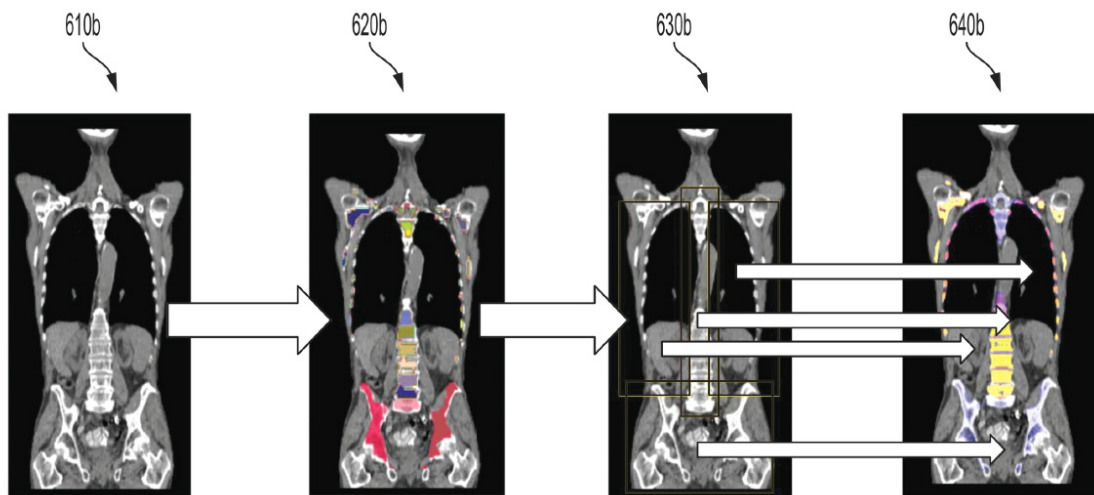


FIG. 6B

FIGs. 6A and 6B of the '817 Patent (above)

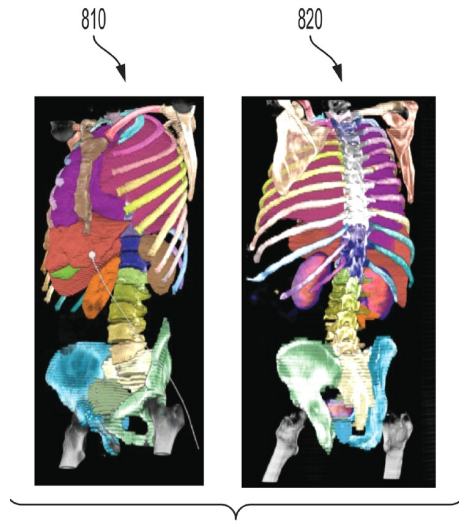


FIG. 8

FIG. 8 of the '817 Patent

EX1001, FIGs. 6A, 6B, FIG. 8, 34:27-39; EX2014, ¶81. Renisch, by contrast, does not describe any process or step in which one or more machine learning modules are used to segment multiple VOIs within a 3D anatomical image and their output combined into a unified 3D segmentation map. EX2014, ¶¶79-81.

Bereft of any clear hook in Renisch, the Petition falls back on arguing that Renisch discloses 3D segmentation masks because Renisch refers to suppressing certain volumes within a 3D functional image. Pet., 24 (“Each segmented VOI is represented by its own segmentation mask because, as explained below, each can be used separately to selectively suppress (or mask) uptake within corresponding volumes of a 3D functional image. Ex1005, [0030]-[0031].”); EX2014, ¶¶82-83. This gambit fails, however, for two reasons.

First, contrary to the Petition’s assertion, Renisch does not selectively suppress VOIs that are identified as representing specific organs in a 3D anatomical image as recited in claim 1. Instead, the regions that Renisch suppresses are “regions in the functional second image representation that indicate high metabolic activity”. EX1005, [0029] (“The regions of high intensity 92, generally referred to as hot spots, are regions in the functional second image representation that indicate high metabolic activity, which potentially can be caused by tumor growth or by other malignant processes.”); *id.*, [0031] (“[a] suppression unit, processor, or algorithm 102 uses the results of the classification unit to **suppress the regions of high intensity 92** in the functional second image representation 74.” (emphasis added)); EX2014, ¶¶82, 86-87. Unlike the VOIs that are represented by the 3D segmentation map recited in claim 1, Renisch’s regions of high intensity are (i) identified as having high metabolic activity - not particular tissue regions like specific organs and bones), (ii) detected in a “functional second image representation” – not a 3D anatomical image, and (iii) are detected using a conventional watershed algorithm – not a machine learning algorithm or technique of any kind. EX2014, ¶87.

Second, the Petition cannot plug the hole in Renisch by contending that Renisch *inherently* discloses the creation of a 3D segmentation map. EX2014, ¶85. In order for a claim limitation to be inherently disclosed, evidence “must make clear that the missing descriptive matter is **necessarily** present in the thing described in

the reference, and that it would be so recognized by persons of ordinary skill.” *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (emphasis added). It is not sufficient if a material element or limitation is “merely probably or possibly present” in the prior art. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002); *Pers. Web Techs., LLC v. Apple, Inc.*, 917 F.3d 1376, 1382 (Fed. Cir. 2019) (“The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.”) (emphasis in original) (citation and internal quotation marks omitted).

Here, the Petition fails to show that Renisch “necessarily” creates a 3D segmentation map. *Cont’l Can Co.*, 948 F.2d at 1268; EX2014, ¶85. The Petition contends that “[e]ach segmented VOI” in Renisch “is represented by its own segmentation mask because, as explained below, each can be used separately to selectively suppress (or mask) uptake within corresponding volumes of a 3D functional image.” Pet., 24 (citing EX1005, [0030]-[0031]); EX2014, ¶¶85-87. However, neither cited passage in Renisch even uses the phrase “mask” or describes anything akin to creation of a 3D segmentation map, as recited in claim 1. EX2014, ¶¶87-88. The suppression of high-intensity regions in functional images is not equivalent to anatomical segmentation—and certainly not to the creation of a structured 3D *map*. EX2014, ¶¶87-89. Accordingly, Renisch does not disclose—

either expressly or inherently—the creation of a “3D segmentation map” as required by claims 1 and 10. EX2014, ¶¶90-91.

Since this limitation appears as limitation (c) of independent claim 10, this same shortcoming applies equally to independent claim 10. Renisch therefore does not anticipate independent claim 10. EX2014, ¶¶92-93.

- b. Renisch does not disclose “automatically identifying, . . . 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” as recited in claim 1.**

Limitation (b) of claim 1 recites “automatically identifying, . . . 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.” EX1001, 79:14-18; Pet., 22; EX2014, ¶70. Renisch does not disclose the use of “machine learning modules,” as recited in claim 1. The Petition’s attempt to argue otherwise is unpersuasive. *See* EX2014, ¶¶70-77.

First, the Petition points to paragraph [0027] of Renisch, which generically lists various segmentation methods, including “clustering” and “neural network.” Pet., 22-23 (“It is to be appreciated, however, that other segmentation methods such as clustering, edge detection, region growing, principle [sic] components analysis, neural network, and the like are also contemplated.”) (citing EX1005, [0027]); EX2014, ¶71. Based on this quote, the Petition argues that Renisch discloses the use

of “machine learning modules” because “clustering and artificial neural networks are machine learning algorithms used for medical image segmentation tasks.” Pet., 23; EX2014, ¶71.

The Petition overreaches by suggesting that isolated mentions of “neural network” and “clustering” qualify as disclosing the use of a “machine learning module” in the ’817 Patent. EX2014, ¶72. A POSA would not interpret such references as disclosing the use of a “machine learning module” in the context of the ’817 Patent because “neural network[ing]” and “clustering” do not require the use of machine learning, and both terms (as used in Renisch) are too remote and generalized to map to the ’817 Patent’s specific claimed architecture. EX2014, ¶¶72-73. “Neural network” and “clustering” do not even refer to the same type of analytical technique. EX2014, ¶¶73-74. A “neural network” is a specific computational model that uses variable weights and interconnected neurons to capture a wide variety of behavior. EX2014, ¶73. “Clustering” refers to a general class of statistical methods for grouping similar objects into different groups, or more precisely, for partitioning a data set into subsets (e.g., according to some defined distance measure in the (multi-dimensional) space of features (descriptors)). EX2014, ¶73. Therefore, a POSA would not interpret Renisch’s generic list of segmentation methods as disclosing the use of “machine learning modules” as

claimed in the specific context of the '817 Patent. EX2014, ¶¶77; *see also* EX2014, ¶¶73-76.

2. Ground B: Renisch, in view of Zhao, does not render obvious claims 1-5, 7, 10-14, 16, 19, and 26.

a. Renisch and Zhao do not disclose a 3D segmentation map as recited in claims 1 and 10.

For Ground B, the Petition argues that Zhao discloses “segmentation masks,” but relies on Renisch for all other limitations. Pet., 25-26. EX2014, ¶¶96-97. The proposed combination of Renisch and Zhao, however, fails to disclose the creation of a “3D segmentation map” as required by claims 1 and 10. EX2014, ¶95. This is true for at least two reasons. EX2014, ¶95

First, Zhao’s disclosure is confined to **2D**—not 3D—image segmentation. *See* EX1007; EX2014, ¶¶98-99. Zhao does not mention 3D image processing *of any kind*, let alone 3D segmentation. *See* EX1007; EX2014, ¶¶98-99. Zhao repeatedly uses the term “pixel,” which is the smallest unit of a *2D* image, rather than the term “voxel,” which is the smallest unit of a *3D* image. *See, e.g.*, EX1007, 5:25-42; *id.*, 7:56-64. Zhao describes a “100-pixel by 100-pixel input.” EX1007, 7:56-64; EX2014, ¶¶98-99. Zhao refers to “two spatial dimensions” when describing the disclosed image processing techniques. EX1007, 7:65-8:7; EX2014, ¶¶98-99. Thus, Zhao does not disclose the *3D* image processing of any kind, let alone 3D image segmentation.

This is a critical omission. The '817 Patent's claimed invention centers on the ability to perform 3D segmentation using machine learning modules and to construct a 3D segmentation map that spans multiple anatomical regions. *See* EX2014, ¶¶99; *see also id.*, ¶¶58-62. The '817 Patent notes that “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.” EX1001, 3:21-29. The '817 Patent also describes additional benefits of the invention:

Notably, a significant advantage of the approach described in this example over previous approaches is the ability to compute reference intensity values (as well as hotspot intensity values) from automatically identified 3D volumes In contrast to such small 2D regions, the 3D volume that are identified via the approaches used herein capture intensities throughout entire organs, and thereby offer increased accuracy and repeatability.

Id., 55:63-56:9; *see also* EX2014, ¶¶58-62. Zhao's 2D segmentation methods cannot achieve these benefits and are fundamentally incompatible with the claimed architecture.

Although the Petition does not make this argument clear, Petitioner appears to presume that Zhao discloses 3D medical imaging analysis because Zhao mentions the use of CT scans. *Supra*, Section VII.B; EX2014, ¶100. But a CT image is not necessarily a 3D image, and (as discussed above) Zhao exclusively refers to the use of 2D images. EX2014, ¶100.

Accordingly, for at least the reasons above, Renisch in view of Zhao does not render obvious claims 1-5, 7, 10-14, 16, 19, and 26. EX2014, ¶¶101, 111-12.

- b. The Petition fails to show that a POSA would have been motivated to combine Renisch and Zhao to perform limitations (b)-(e) of claims 1 and 10 with a reasonable expectation of success.**

The Petition fails to establish that a POSA would have been motivated to combine Renisch and Zhao to perform the process recited in limitations (b) through (e) of claims 1 and 10. Representative claim 1 recites:

(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*;

...

(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*; . . .

EX1001, 79:14-28 (emphasis added). As reflected in the claim language, the '817 Patent recites more than just a "3D segmentation map" in isolation. *See id.*; EX2014, ¶102. Instead, claim 1 recites "determining . . . a 3D segmentation map" that combines multiple "3D segmentation masks" to represent multiple target VOIs that are identified via segmentation of a 3D anatomical image using one or more machine learning modules. EX2014, ¶¶102-04.

A POSA would not have been motivated to combine Renisch and Zhao with a reasonable expectation that they would succeed in achieving the particular process claimed in limitations (b)-(e). EX2014, ¶105. To the extent Renisch describes anatomical image segmentation, it focuses primarily on conventional, atlas-based image segmentation. EX2014, ¶¶106-07. Zhao, meanwhile, is limited to 2D (not 3D) image segmentation and does not disclose any method for processing 3D anatomical images or integrating anatomical and functional data. *Supra*, Section VII.C.2.a; EX2014, ¶¶106-07. Nor does Renisch or Zhao contemplate the particular challenges associated with performing detailed 3D image segmentation with deep learning-techniques that are described in the '817 Patent, and which, among other things, motivated the particular step of creating a 3D segmentation map as recited in claim 1. EX2014, ¶¶105-07. Therefore, a POSA would not have had the motivation to combine Renisch and Zhao with a reasonable expectation of success to, for example, create and use 3D segmentation maps. EX2014, ¶107.

The Petition argues that “improving Renisch with the teachings of Zhao would merely have amounted to applying a known technique (segmentation masks) to a known device (Renisch) ready for improvement to yield predictable results.” Pet., 27; EX2014, ¶108. But, as discussed above, Zhao’s segmentation masks involved exclusively 2D images. *Supra*, Section VII.C.2.a; EX2014, ¶108. And Renisch’s disclosure of suppressing high-intensity regions is not akin to the 3D segmentation

masks recited in claim 1 (let alone a 3D segmentation map) because Renisch's high-intensity regions are regions of high-metabolic activity identified in a functional image representation—not VOIs that are identified, within a 3D anatomical image, as representing specific organs via one or more machine-learning modules. *Supra*, Section VII.C.1.a; EX2014, ¶108. Thus, a POSA would not have had a motivation to combine Zhao's 2D analysis with Renisch to achieve the claimed 3D segmentation map with a reasonable expectation of success. EX2014, ¶¶109-12.

3. Ground C: Renisch, or Renisch-Zhao, each in view of Baker, does not render obvious claims 8-9, 17-18, 22-25, and 29-32.

For Ground C, the Petition only alleges that Baker discloses the use of certain radiopharmaceuticals, “including PSMAAs for prostate cancer.” Pet., 43. The Petition otherwise relies on Renisch and Zhao for every other element of claims 8-9, 17-18, 22-25, and 29-32 for Ground C. Pet., 60-63; EX2014, ¶¶113-14. Accordingly, for at least the reasons above, Renisch, or Renisch-Zhao, each in view of Baker, fail to render obvious claims 8-9, 17-18, 22-25, and 29-32. *See id.*

4. Ground D: Renisch, or Renisch-Zhao, each in view of Eiber, does not render obvious claims 8-9, 17-18, 22, 24-25, 29, and 31-32.

For Ground D, the Petition only alleges that Eiber discloses the use of certain radiopharmaceuticals, “including PSMAAs for prostate cancer.” Pet., 43-44. The Petition otherwise relies on Renisch and Zhao for every other element of claims 8-

9, 17-18, 22, 24-25, 29, and 31-32 for Ground D. Pet., 60-63; EX2014, ¶¶115-16. The Petition does not contend that Eiber discloses any other limitations of those claims. EX2014, ¶¶115-16. Accordingly, for at least the reasons above, Renisch, or Renisch-Zhao, each in view of Eiber, fail to render obvious claims 8-9, 17-18, 22, 24-25, 29, and 31-32. *See id.*

5. Ground E: Baker, in view of Zhao, does not render obvious claims 1-2, 7-11, 16-18, 22-25, and 29-32.

For Ground E, the Petition argues that Baker in view of Zhao renders the claims obvious because Zhao teaches the use of 3D segmentation masks. EX2014, ¶117. However, as discussed above, Zhao does not discuss 3D image analysis at all, let alone 3D segmentation masks. *Supra*, Section VII.C.2; EX2014, ¶118. Thus, a POSA would not have been motivated to combine Baker and Zhao with a reasonable expectation of success to teach the creation of “3D segmentation maps” as claimed in limitation (c) of independent claims 1 and 10 (or, as a result, any of the other dependent claims that depend from claims 1 and 10). EX2014, ¶¶118-20.

6. Ground F: Baker-Zhao, in view of Eiber, do not render obvious claims 3-5 and 12-14.

For Ground F, the Petition only alleges that Eiber adds elements relating to reference and hotspot intensities, but otherwise relies on Baker and Zhao for every other element of claims 3-5 and 12-14. Pet., 60-63; EX2014, ¶121. The Petition does not contend that Eiber discloses any other limitations of those claims. EX2014,

¶121. Accordingly, for at least the reasons above, Baker-Zhao in view of Eiber fail to render claims 3-5 and 12-14 obvious. *See id.*

7. Ground G: Baker-Zhao, in view of Suehling, do not render obvious claims 19, 26, and 28.

For Ground G, the Petition only alleges that Suehling discloses certain elements related to hotspot detection, but otherwise relies on Baker and Zhao for every other element of claims 19, 26, and 28. Pet., 60-63; EX2014, ¶122. The Petition does not contend that Suehling disclose any other limitations of those claims. *See* EX2014, ¶122. Accordingly, for at least the reasons above, Baker-Zhao in view of Suehling fail to render claims 19, 26, and 28 obvious. *See id.*

VIII. CONCLUSION

For all the foregoing reasons, the Board should deny institution of the Petition.

Date: August 6, 2025

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

I hereby certify that the foregoing complies with the type-volume limitation of 37 C.F.R. § 42.24 and contains 8,354 words based on the word count indicated by the word-processing system used to prepare the paper, excluding the table of contents, table of authorities, mandatory notices under 37 C.F.R. § 42.8, certificate of service, certificate of word count, appendix of exhibits, and claim listing.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing **PATENT OWNER'S PRELIMINARY RESPONSE** was served electronically in its entirety on August 6, 2025 via electronic mail to the following attorneys of record:

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