

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 RESPONSE UNDER 37 C.F.R. § 42.120

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<i>In re Chudik</i> , 851 F.3d 1365 (Fed. Cir. 2017)	37, 42
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<i>Medichem, S.A. v. Rolabo, S.L.</i> , 437 F.3d 1157 (Fed. Cir. 2006)	52
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<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc)	12, 13, 17
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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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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, August 6, 2025.
EX2015	Curriculum Vitae of Dr. Milan Sonka, August 6, 2025.
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

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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.
EX2033	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “Layer-Wise Pretraining Using Autoencoders,” pp. 145-148.
EX2034	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “Weight Initialization and ReLU Activation Functions,” pp. 148-153.
EX2035	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “The Virtuous Cycle: Better Algorithms, Faster Hardware, Bigger Data,” pp. 153-156.
EX2036	Declaration of Anita M.C. Spieth in Support of Patent Owner’s Notice of Intent to Designate Anita M.C. Spieth, a Provisionally Recognized PTAB Attorney, as Back-Up Counsel Under 37 C.F.R. § 42.10(c)(2).

EXHIBIT	DESCRIPTION
EX2037	Declaration of Michael H. Bunis in Support of Patent Owner’s Motion for <i>Pro Hac Vice</i> Admission of Michael H. Bunis Under 37 C.F.R. § 42.10(c).
EX2038	Declaration of John C. Calhoun in Support of Patent Owner’s Notice of Intent to Designate John C. Calhoun, a Provisionally Recognized PTAB Attorney, as Back-Up Counsel Under 37 C.F.R. § 42.10(c)(2).
EX2039	Chang, K., et al., <i>Automatic assessment of glioma burden: a deep learning algorithm for fully automated volumetric and bidimensional measurement</i> , <i>Neuro-Oncology</i> , 21(11):1412-1422 (2019).
EX2040	Chang, K., et al., <i>Residual Convolutional Neural Network for the Determination of IDH Status in Low- and High-Grade Gliomas from MR Imaging</i> , <i>Clinical Cancer Research</i> , 24(5):1073-1081 (2018).
EX2041	Beers, A., et al., <i>DeepNeuro: an open-source deep learning toolbox for neuroimaging</i> , <i>Neuroinformatics</i> , 19(1):127-140 (2021).
EX2042	Deposition of Bruce Rosen, M.D., Ph.D., Transcript, January 6, 2026.
EX2043	Declaration of Dr. Milan Sonka, January 26, 2026

I. INTRODUCTION

U.S. Patent No. 11,941,817 (the “Patent”) addresses critical challenges in using medical imaging for cancer diagnosis and treatment. More specifically, the Patent claims a system and method that: (i) uses one or more supervised deep learning artificial neural networks to segment different tissue regions in a 3D anatomical image (*e.g.*, a CT scan), and then (ii) uses those segmented tissue regions to create a consolidated 3D segmentation map that helps physicians analyze the image for cancer detection and assessment. The result is a robust automated framework that improves accuracy, consistency, and clinical utility in identifying and tracking cancer throughout the body.

The Patent’s key innovations include: (a) the use of machine (supervised deep) learning modules that are tailored to identify specific tissue regions to perform detailed multi-organ segmentation of anatomical images; (b) the creation of a unified 3D segmentation map that combines multiple volumes of interest (VOIs) into a single, common volume, and accommodates the use of multiple machine learning modules; and (c) the integration of both 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 Patent’s priority date (January 7, 2019).

Petitioner's cited references do not disclose or render obvious these claimed innovations. In particular, the Petition fails to show that any reference—alone or in combination—teaches: (i) using one or more machine learning modules, each trained for particular tissue regions, to identify multiple 3D VOIs in an anatomical image, and/or (ii) determining the claimed 3D segmentation map that consolidates the outputs of those modules into a single labeled 3D volume for downstream use. To fill these gaps, the Petition relies on generalized, context-free statements (*e.g.*, isolated terms in boilerplate), waives away entire claim limitations, and ignores the distinction between 2D concepts and 3D claim elements.

Because Petitioner has not carried its burden to prove unpatentability by a preponderance of the evidence, and because the record demonstrates that the challenged claims are patentable, Patent Owner respectfully requests that Board confirm the claims.

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) and functional scans (like PET or SPECT) are valuable tools. EX2014, ¶¶26-28. However, before the inventions described in the 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. 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. The Patent aimed to address those (and other) challenges.

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; EX2043, ¶137.

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), clinicians, patients, and researchers faced 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. Existing approaches were often manual, organ-specific, two-dimensional, or insufficiently robust for full-body analysis and longitudinal assessment. *Id.*

The Patent addresses these limitations by disclosing and claiming 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; EX2043, ¶37. Among other things, the machine learning-based 3D image segmentation techniques described in the 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; EX2043, ¶39. For example, the Patent describes how convolutional neural network (CNN)-based 3D image segmentation methods can be used to identify a variety of specific target tissue volumes of interest (VOIs) within 3D anatomical images. EX1001, 31:60-32:21, 34:41-37:10, 42:5-48:41; EX2043, ¶37. The claimed methods support both early

detection and monitoring of disease progression or metastasis. EX1001, 4:66-5:11; EX2014, ¶56; EX2043, ¶37. These innovations provide tools for automated, image-based cancer detection and longitudinal tracking of disease evolution and treatment response. EX2014, ¶56.

A central advance of the Patent's claimed method and system is the ability to handle (i) multiple organs and (ii) 3D images. EX2043, ¶38. The Patent expressly emphasizes these advantages:

Notably, the image analysis approaches described herein are not limited to a single particular organ or portion of the body. Instead, they are robust and widely applicable, providing for consistent, efficient, and accurate detection of anatomical regions, including tissue and/or organs, in the entire body.

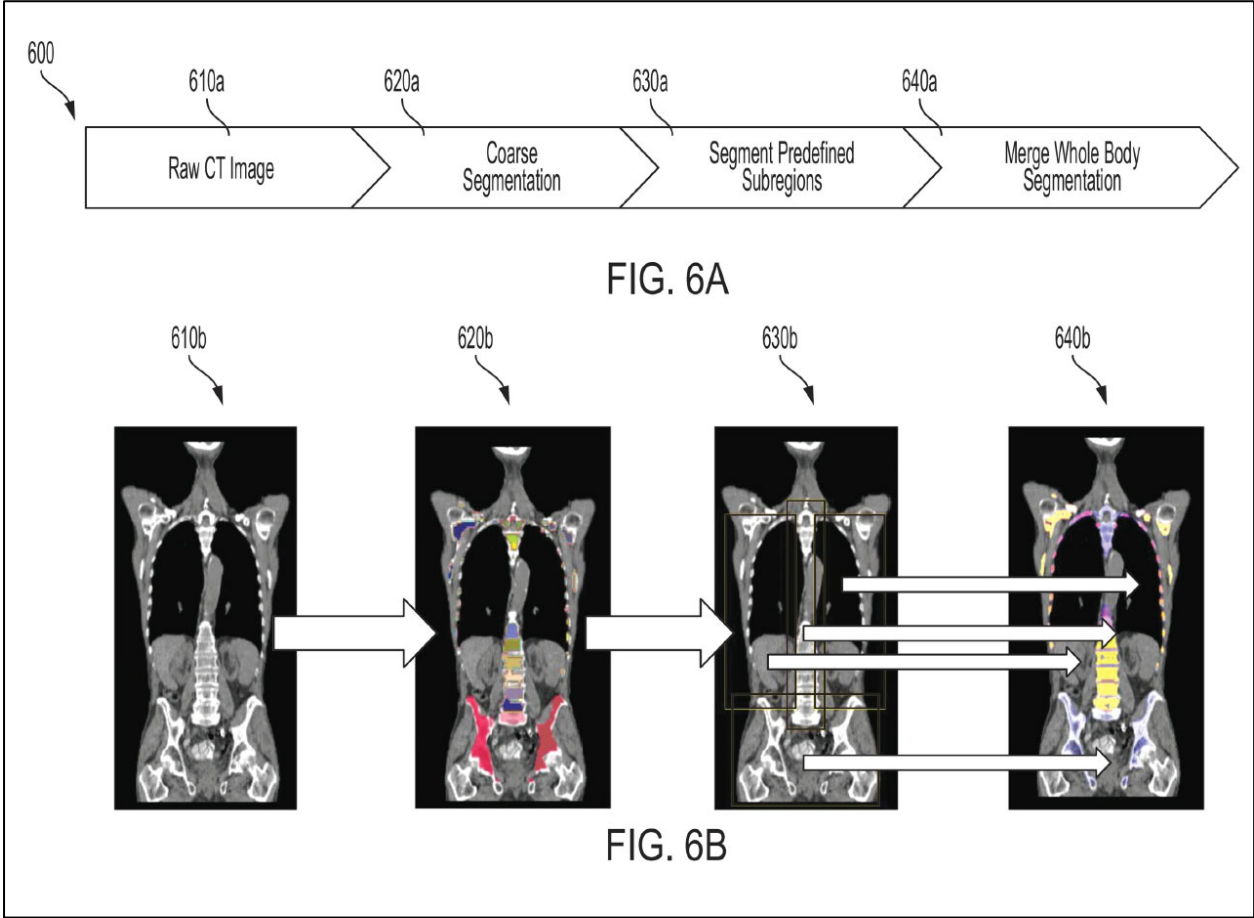
...

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, 3:7-24. The Patent achieves its unique capabilities via (among other ways) a novel approach that uses multiple machine learning algorithms (such as CNNs) to analyze and segment multiple different target tissue regions in various anatomical subregions throughout a patient's body. EX2043, ¶39.

For example, as illustrated in FIGs. 6A and 6B, the Patent discloses a unique approach whereby the problem of multi-organ anatomical segmentation is simplified by subdividing the anatomy into multiple anatomical subregions (*e.g.*, pelvic region, left upper body, right upper body, abdomen, spine, etc.). EX2043, ¶40. Instead of

attempting to train and use a single machine learning module to segment every organ and bone throughout the patient's body, the Patent teaches how a different machine learning module can be used for each anatomical subregion. *Id.* This design allows each machine (supervised deep) learning module to focus on a simpler problem and yields segmentation that is both more accurate and more computationally efficient. EX1001, 6:40-42, 42:66-46:51, 34:27-29; EX2043, ¶40.



FIGs. 6A and 6B of the Patent

Critically, the Patent does not leave the segmentation results fragmented. After the individual machine learning modules segment their respective anatomical

subregions, the Patent describes recombining (or “stitching” together) the resulting segmentation outputs from the different machine learning modules to create a single, consolidated 3D segmentation map that represents the identified VOIs in a consolidated fashion. EX1001, 31:64-32:21; EX2043, ¶41. This 3D segmentation map is a specific and deliberate element of the disclosed invention. EX1001, 34:27-39. FIG. 8, reproduced below, shows an example of the 3D segmentation map:

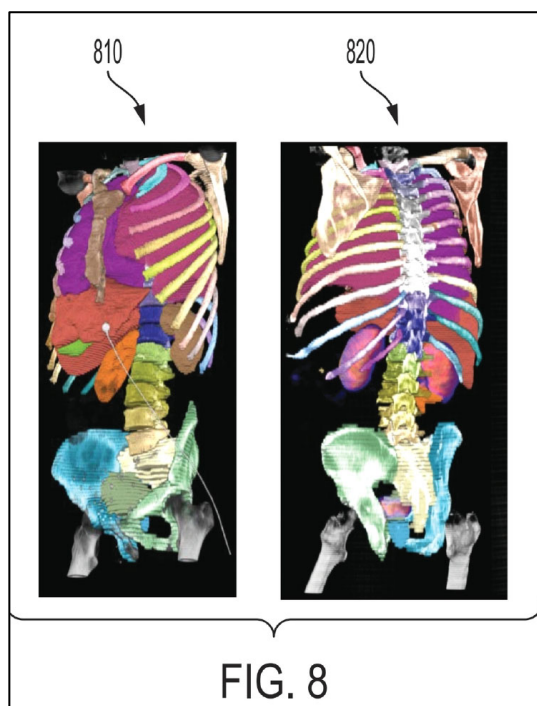
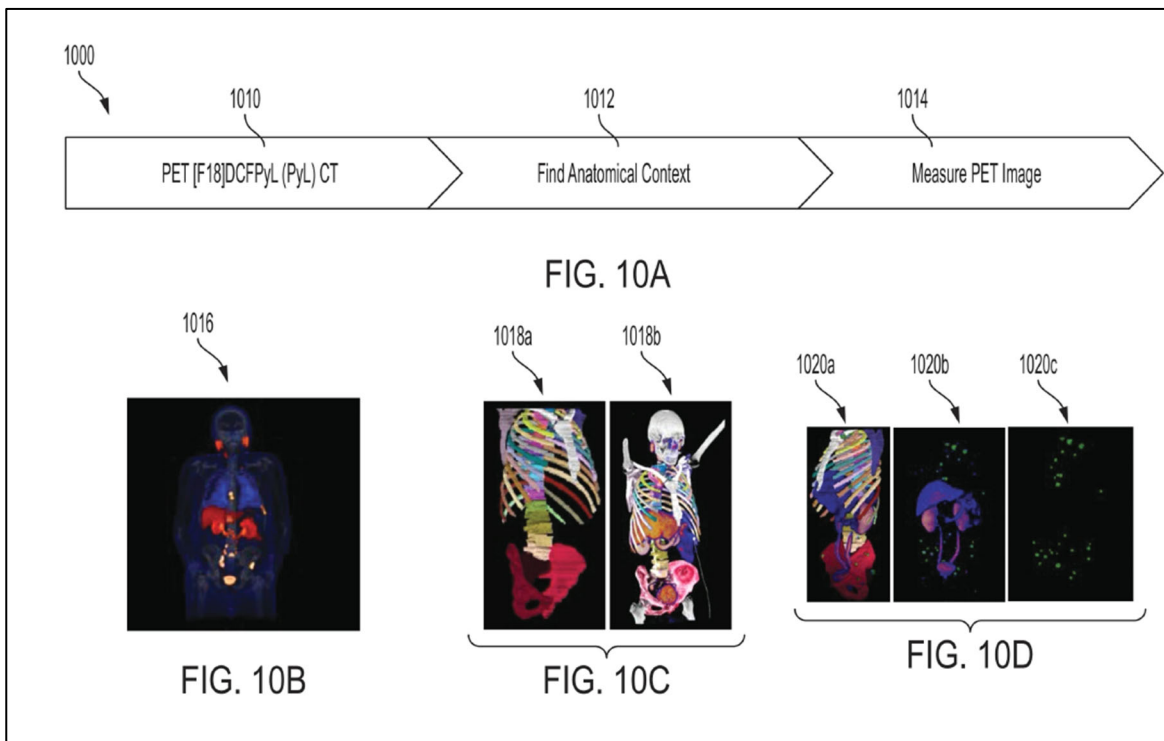


FIG. 8 of the Patent

The resulting 3D segmentation map then serves as a foundational element for subsequent medical image analysis techniques, particularly in connection with 3D functional images (*e.g.*, PET or SPECT images) acquired using a variety of radiopharmaceuticals. *See, e.g.*, EX1001, 31:65-33:40; EX2043, ¶42. The Patent

describes several clinically relevant applications of this invention, including using the 3D segmentation map to: isolate specific regions for the search for cancerous lesions, classify lesions (*e.g.*, as primary tumor, skeletal or lymph metastases), correct for physiological uptake in regions such as the bladder and kidneys; and quantify lesion severity in an improved fashion by virtue of the 3D nature of the segmented volumes. EX1001, 3:49-5:11; EX2043, ¶43. FIGs. 10A-D, reproduced below, illustrate how the detailed anatomical context provided by the 3D segmentation map can be leveraged to analyze PET images:



FIGs. 10A-D of the Patent

By providing for automated, accurate, and robust 3D segmentation and functional-anatomical integration, the Patent delivers significant advantages over the

prior art and supplies clinicians with powerful tools for image-based cancer detection, quantification, and longitudinal assessment. EX2014, ¶63; EX2043, ¶44.

B. Prosecution History

The application for the 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 Patent issued on March 26, 2024. EX1004, 464; EX2014, ¶64.

During prosecution of the 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, confirming that each of those references was considered during examination. EX1004, 280, 285; *see also* EX2014, ¶66.

On October 13, 2023, after considering the cited prior art, the Examiner issued a Notice of Allowance. In doing so, the Examiner stated 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; EX2043, ¶13. For purposes of this proceeding, Patent Owner does not dispute Petitioner’s definition of a POSA. *See, e.g.*, EX2014, ¶¶13-16; EX2043, ¶¶11-14.

VI. CLAIM CONSTRUCTION

Claim terms must be given their “ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc); 37 C.F.R. § 42.100(b). “Importantly, the person of ordinary skill in the art is

deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Phillips*, 415 F.3d at 1313.

The Board did not construe any terms in its Institution Decision. IPR2025-00827, Paper 13 (“Institution Decision”), 15 (PTAB Nov. 3, 2025). The Petition proposed (and relied on) an incorrect construction for “3D segmentation map.” Pet., 9-10. The Petition did not propose constructions for any other terms. Pet., 9.

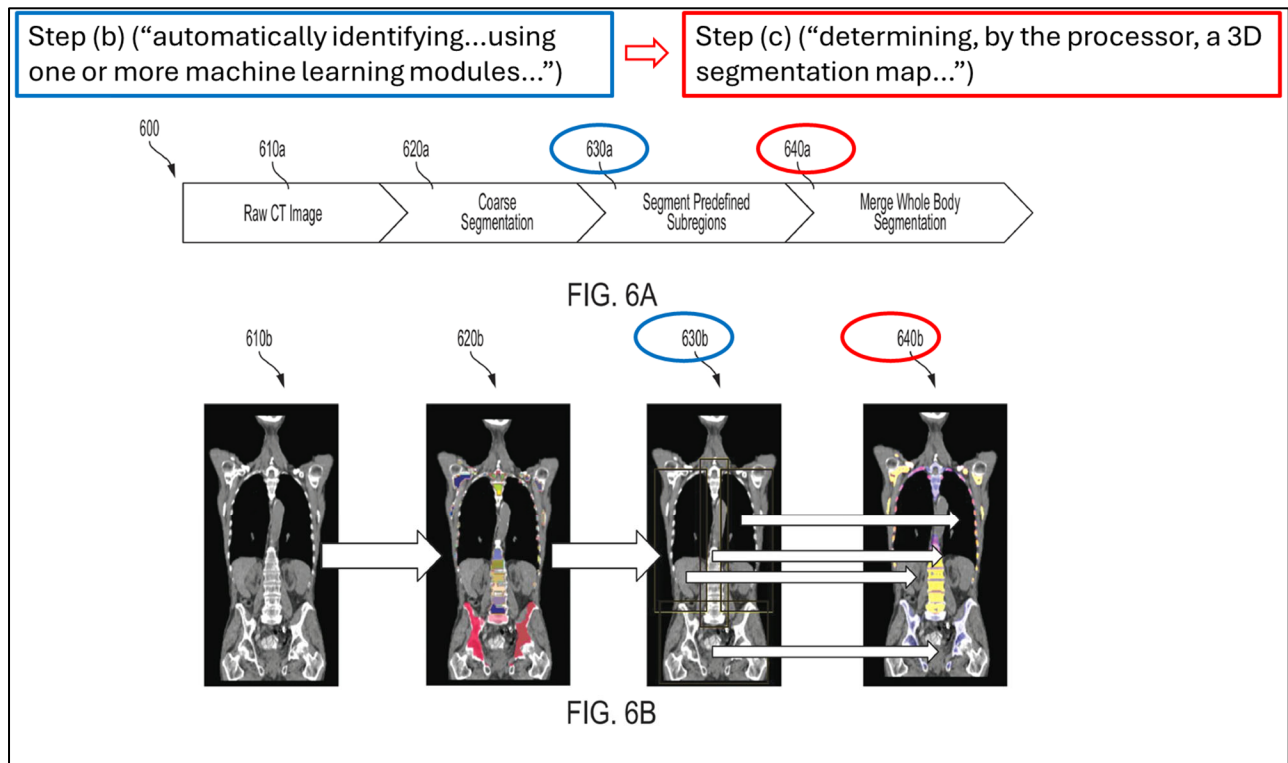
Consistent with the Board’s instruction that claim construction be addressed in the post-institution phase (Institution Decision, 15), Patent Owner now proposes the correct construction for two terms: (i) “3D segmentation map,” and (ii) “using one or more machine learning modules, for each of a plurality of target tissue regions,” which is another term recited in the independent claims of the Patent. Both terms appear in consecutive and related steps of independent claims 1 and 10 of the Patent. For example, independent 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;***

EX1001, 79:14-22 (emphasis added). These two claim steps are technologically and conceptually linked. As explained in the specification and illustrated in FIGs. 6A

and 6B below, the Patent: (i) uses supervised deep learning algorithms, like CNNs, to accurately segment multiple target tissue regions, like organs and bones, throughout a patient’s body, and (ii) leverages the resulting accurate anatomical segmentation to analyze 3D functional images, like PET or SPECT images, to assess cancer (*e.g.*, prostate cancer):



Annotated FIGS. 6A and 6B, with color boxes and circles illustrating corresponding claim steps for the circled reference numerals

In particular, as explained above and shown in FIGS. 6A and 6B, the Patent addresses the problem of multi-organ anatomical segmentation by subdividing the anatomy into multiple anatomical subregions (*e.g.*, pelvic region, a left and right upper body, an abdomen, a spine, etc.). EX2043, ¶¶39-40. Rather than relying on

a single machine learning module to segment every structure across the entire body, the Patent teaches using a different machine learning module for each anatomical subregion. EX2043, ¶40. Each individual machine (supervised deep) learning module is thus able to focus on a simpler problem, and is trained to segment a subset of organs and/or bones within the particular anatomical subregion that the module is associated with. EX1001, 6:40-42, 42:66-46:51, 34:27-29; EX2043, ¶40. Step (b) of independent claim 1 reflects this approach and recites “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.” EX1001, 79:14-18 (emphasis added).

After these individual segmentation results are generated, the Patent teaches recombining the different segmentation results from different machine learning modules to create a “3D segmentation map” that represents the identified VOIs in a consolidated fashion. EX1001, 31:64-32:21; EX2043, ¶41. This is the purpose of step (c) of claim 1, which expressly recites “determining ... a 3D segmentation map representing a plurality of 3D segmentation masks, each ... representing a particular identified target VOI.” EX1001, 79:19-22.

The resulting 3D segmentation map is then used to provide anatomical context for 3D functional images, like PET or SPECT images. *See, e.g.*, EX1001, 31:65-33:40; EX2043, ¶42. This downstream use is reflected in step (e) of claim 1, which

recites “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, 79:26-28 (emphasis added).

Accordingly, steps (b) and (c)—and their respective terms “machine learning modules” and “3D segmentation map”—are linked. Together, they capture the Patent’s claimed innovation whereby the target tissue regions identified via deep learning artificial neural networks (like CNNs) at step (b) are then consolidated (*i.e.*, ‘stitched’ together into a single volume) to form a specific map at step (c). In other words, steps (b) and (c) represent the particular way that the Patent uses multiple machine learning modules (like CNNs) to perform whole body segmentation, and how the results of those multiple machine learning modules (like CNNs) are merged to facilitate their use in providing anatomical context for the analysis of 3D functional images in later claim steps. Patent Owner’s two proposed claim constructions give effect to this disclosed and claimed architecture, and are set forth in detail below.

A. “using one or more machine learning modules, for each of a plurality of target tissue regions”

The term “machine learning modules” appears in independent claims 1 and 10 of the Patent. Petitioner does not propose a construction for this term.

Representative claim 1 of the Patent 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;

EX1001, 79:14-18 (emphasis added).

Under *Phillips*, claims must be construed in view of the intrinsic record, which is “the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315 (citation omitted). Here, the intrinsic record is unequivocal: a POSA would understand the term “using one or more machine learning modules, for each of a plurality of target tissue regions” to mean:

using one or more supervised deep learning artificial neural networks, such as convolutional neural networks (CNNs), each trained to identify one or more specific target three-dimensional volume(s) of interest (VOIs) within the 3D anatomical image.

See EX2043, ¶50.

Patent Owner will address each core element of its proposed construction in turn.

1. “Machine learning modules” means supervised deep learning artificial neural networks (e.g., CNNs).

The Patent consistently and exclusively uses “machine learning” to refer to deep learning artificial neural networks, including convolutional neural networks (CNNs). EX2043, ¶¶53-54; *see also* EX1001, 47:60-64, 48:47-50, 56:40-43, 60:47. The Patent never describes or suggests alternative forms of machine learning (e.g.,

rule-based systems, classical classifiers, or unsupervised statistical models) as part of the claimed invention. EX2043, ¶53.

The specification repeatedly and consistently refers to deep learning and/or CNNs when referring to machine learning. *Id.* For instance, Examples 2, 3, 6, and 9 in section C of the specification, “Example CNN-Based Whole Body Segmentation and Lesion Detection Approaches” (which are the only examples in the specification that describe the type of machine learning used), employ the term “deep learning” when referring to the technologies described in the Patent. EX1001, 47:60-64, 48:47-50, 56:40-43, 60:47; EX2043, ¶54. Example 2, for instance, states that “this example demonstrates automating the process of accurate bone segmentation in whole body CT images *using deep learning approaches in accordance with the whole body segmentation technology described herein.*” EX1001, 47:60-64 (emphasis added); EX2043, ¶54. Likewise, Example 3 states “[t]his example demonstrates automated segmentation of 49 bones and 27 soft-tissue regions in whole body CT images using *deep learning approaches in accordance with the whole body segmentation technology described herein.*” EX1001, 48:47-50 (emphasis added); EX2043, ¶54. Example 6 also states that it uses “deep learning” approaches in accordance with the description of the Patent. EX1001, 56:40-43 (“For each scan, a semantic segmentation of the CT image was performed using *the deep learning approaches described herein* in order to identify a set of

specific bone and soft-tissue regions (e.g., organs).”) (emphasis added); EX2043, ¶54. Example 9 describes “a cascaded deep learning pipeline.” EX1001, 60:47; EX2043, ¶54. No example suggests another approach.

The Patent repeatedly refers to CNNs alongside, and in the same breath as, the phrase “machine learning.” EX2043, ¶55. For example, at column 17, line 14, the specification states:

In certain embodiments, the 3D anatomical image is a full body image and step (b) comprises: automatically determining, using one or more localization modules implementing machine learning technique(s) (e.g., wherein each localization module *is a CNN module that implements a CNN*), a plurality of initial VOIs within the 3D anatomical image, each initial VOI corresponding to a particular anatomical region (e.g., 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, etc.) and in which an associated subset of the target VOIs are located; and for each initial VOI, automatically identifying, using one or more segmentation modules implementing machine learning technique(s) (e.g., wherein each segmentation module *is a CNN module that implements a CNN*) the associated subset of target VOIs.

EX1001, 17:14-29 (emphasis added).

Analogous language appears elsewhere throughout the specification. *See, e.g.,* EX1001, 6:28-48, 12:17-32, 13:51-14:3, 15:21-56, 15:57-16:14, 23:1-17, 24:34-58, 26:5-42, 31:64-32:21, 34:4-26; EX2043, ¶56. The Patent devotes an entire section to “Image Segmentation Using Convolutional Neural Networks (CNNs),” further confirming that deep learning technologies, such as CNNs, are the machine

learning technology of the invention. EX1001, 34:44-37:10; EX2043, ¶57. The Patent’s lengthy first example provides extensive description of three different versions of CNN networks, spanning about six columns. EX1001, 42:17-47:50; *see* EX2043, ¶57.

Moreover, the specification makes clear that its “deep learning artificial neural networks, such as CNNs” are trained in a supervised manner and, thus, are “*supervised* deep learning artificial neural networks, such as CNNs.” EX2043, ¶59. The term “supervised” when utilized in reference to deep learning techniques refers to their manner of training—whether they are trained using expertly labeled “ground truth” examples, like manually annotated images and are thus “supervised,” or using unlabeled data in an “unsupervised” fashion. EX2043, ¶60; EX2014, ¶40; *see also* EX2023, 4; EX2030, 26. Here, the Patent describes that its machine learning modules are trained in a supervised fashion, using labeled data. *See, e.g.*, EX1001, 48:7-10 (describing training using “manually crafted segmentation maps”), 50:22-25 (stating that “numerous pre-labeled sample images...were used as a training dataset.”), 57:10-18 (“Training and validation was performed and evaluated for each particular region (bone or soft tissue region) using a manual identification of that region in a CT image.”); EX2043, ¶61. Therefore, a POSA would understand “machine learning modules” as recited in the claims to mean “supervised deep learning artificial neural networks, such as CNNs.” EX2043, ¶62.

2. “For each of a plurality of target tissue regions” requires training to identify specific 3D volumes of interest.

The second portion of the claim term—“for each of a plurality of target tissue regions”—further informs the scope of the claimed “machine learning modules.” Read in context by a POSA, the term “machine learning modules” requires that the claimed modules are “trained to identify one or more specific target three-dimensional volume(s) of interest (VOIs) within the 3D anatomical image.” EX2043, ¶63.

The Patent’s specification is again clear. It describes how to perform multi-organ segmentation, and provides several examples showing how multiple CNNs are trained to identify multiple target VOIs. EX2043, ¶64. Example 1 illustrates this architecture in detail:

In a first example version of a CNN network used for whole body segmentation, the first machine learning module (localization module) in this example is referred to as “coarse-seg”, and was trained to identify 49 bones in sub-sampled CT images (a sub-sampling factor of 4 along each dimension). The localization module was used to differentiate regions of the body in to a pelvic region, a spine, a left upper body, and a right upper body. *The four fine segmentation networks were as follows:*

“fine-seg-pelvic”: *Trained to identify* the left and right ilium and the sacrum and coccyx;

“fine-seg-spine”: *Trained to identify* 12 thoracic vertebrae, 5 lumbar vertebrae, and the sternum;

“fine-seg-left-upper-body”: *Trained to identify* 12 ribs on the left side of the body, the left scapula, and left clavicle; and

“fine-seg-right-upper-body”: *Trained to identify* 12 ribs on the right side of the body, the right scapula, and right clavicle.

EX1001, 42:61-43:12 (emphasis added). Example 1 also provides tables, highlighting the number of trainable parameters of each network, as in Table 3:

Number of parameters in five neural networks			
Network Name	Total params.	No. trainable params.	No. non- trainable params.
coarse-seg	5,881,978	5,878,678	3,300
fine-seg-pelvic	5,880,276	5,877,068	3,208
fine-seg-spine	1,472,815	1,471,177	1,638
fine-seg-left-upper- body	1,472,731	1,471,101	1,630
fine-seg-right-upper- body	1,472,731	1,471,101	1,630

EX1001, 44:20-35; EX2043, ¶65. Analogous multiple-CNN arrangements are also shown at EX1001, 46:32-51 and Table 10. EX2043, ¶¶66-67.

Accordingly, a POSA would understand that each machine learning module (specifically, each supervised deep learning artificial neural network) is trained to identify one or more specific target three-dimensional VOIs within the 3D anatomical image. EX2043, ¶68.

3. Patent Owner’s proposed construction of “machine learning modules” gives full effect to the claim language and reflects the intrinsic record.

In sum, when read in light of the claims and the specification as a whole, a POSA at the time of the invention would understand the phrase “using one or more machine learning modules, for each of a plurality of target tissue regions” to mean: “using one or more supervised deep learning artificial neural networks, such as convolutional neural networks (CNNs), each trained to identify one or more specific target three-dimensional volume(s) of interest (VOIs) within the 3D anatomical image.” EX2043, ¶69. This construction gives full effect to the claim language, is firmly rooted in the intrinsic record, and reflects the particular machine learning architecture that the Patent discloses and claims.

B. “3D segmentation map”

The term “3D segmentation map” appears in claims 1, 3, 10, 12, 19, and 26 of the Patent. Of those, claim 1 and claim 10 are independent claims. Representative claim 1 recites:

(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;*

EX1001, 79:19-21 (emphasis added).

The Petition proposes that “3D segmentation map” be construed as “a plurality of 3D segmentation masks distinguishing a plurality of regions within a 3D

image.” Pet., 9-10. Petitioner argues that the 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.’” *Id.*, 9 (citing claim 1 and claim 10). Essentially, Petitioner wants to define a “3D segmentation map” as any arbitrary assortment of segmentation masks. In fact, Petitioner’s own expert conceded that, under Petitioner’s construction, the 3D segmentation map is nothing more than the assortment of masks themselves. *See* EX2042, 54:2-4, 54:7-8 (Q: “[A]m I right that the 3D segmentation map itself is then no different than the plurality of 3D segmentation masks themselves?” A: “As I understand the claims, that’s how I would interpret it, yes.”).

The Board properly declined to adopt Petitioner’s construction in its institution decision. And for good reason: a POSA would not understand a “3D segmentation map” to be a disjointed assortment of masks. Rather, as the intrinsic record makes clear, a “3D segmentation map” is a single, unified representation of various masks purposefully stitched together in a way that makes them useful in downstream processes. EX2043, ¶73.

Patent Owner thus submits that the proper construction of “3D segmentation map” is “a consolidated representation of 3D objects in space that combines multiple 3D segmentation masks and accounts for their relative spatial relationships to each other within a common volume.” EX2043, ¶71. This construction flows directly

from the claim language and is confirmed repeatedly by the specification. EX2043, ¶73.

This construction is obvious from the claim language. *Id.* The surrounding claim language demonstrates that the “3D segmentation map” is a distinct construct, separate from the individual segmentation masks. *Id.* 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*;

(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

...

EX1001, 79:14-28 (emphasis added). That is, claim 1 discloses using machine learning modules used to identify, for each of a plurality of target tissue regions—like certain bones and organs—a corresponding target VOI within the 3D anatomical image. *See* EX1001, 79:14-18. Each of the identified target VOIs is represented via a 3D segmentation mask. *See id.*, 79:19-22 (“each 3D segmentation mask representing a particular identified target VOI”). The method “determin[es]” a 3D

segmentation map (*i.e.*, a single, consolidated representation) by combining multiple segmentation masks. *See id.* The 3D segmentation map is then used to identify corresponding volumes in a 3D functional image. *Id.*, 79:26-28. The disclosed system in claim 10 recites nearly identical steps.

Patent Owner’s proposed construction reflects these steps. It affirms that a separate, particular representation—a 3D segmentation map—is created by combining multiple 3D segmentation masks. The 3D segmentation map is more than a disjointed assortment of segmentation results or masks. It is a single object purposefully created by merging together multiple 3D segmentation masks (that were produced via machine learning-based segmentation) to create a consolidated representation that can be used for downstream processing. EX2043, ¶73.

The specification confirms what the claim language already makes clear. The specification repeatedly explains that individual per-structure segmentation masks are “stitched together” or “merged” to create the 3D segmentation map. *See, e.g.*, EX1001, FIG. 5A, FIG. 5B, FIG. 6A, FIG. 6B, 5:31-32, 5:38, 16:17-19, 31:66-32:13, 34:34-36; 41:2-7, 49:7-10; EX2043, ¶¶74-75. The Patent describes in close detail how to stitch the masks together in a way that accounts for the masks’ relative spatial relationships to each other within a common volume:

In certain embodiments, step (c) comprises digitally stitching together the plurality of 3D segmentation masks to form the 3D segmentation map {e.g., by creating an initially empty image volume (e.g.,

initializing all voxel values to zero) and then inserting labels from each segmentation mask into the image volume [e.g., by mapping labeled (e.g., as representing a particular target tissue region as determined by a machine learning module) voxels of input images to one or machine learning modules to voxels of the image volume (e.g., so as to match voxels of the image volume to voxels of the input images that represent a same physical location, thereby labeling voxels of the image volume correctly)]]}.

EX1001, 5:37-48; *see also id.*, 16:17-29; EX2043, ¶75. The process figures reinforce this: in FIGs. 5A and 5B, the system first identifies target VOIs, then “stitch[es] target volumes together” to yield the “3D segmentation map,” which is then stored and used downstream. EX1001, FIGs. 5A, 5B. Thus, in the Patent’s own words and figures, the “map” is a single consolidated volume that (i) combines per-structure masks and (ii) preserves where each structure sits relative to the others within the same 3D space. EX2043, ¶73. Petitioner’s expert agrees that the specification describes a “3D segmentation map” as “itself an image volume comprising a plurality of 3D voxels” and “a single labelled 3D” image. EX2042, 41:18-24, 42:1-4.

While Patent Owner’s proposed construction of “3D segmentation map” aligns with the intrinsic record, Petitioner’s construction cannot be reconciled with the claim language because it collapses step (c) into step (b). Petitioner construes “3D segmentation map” as “a plurality of 3D segmentation masks distinguishing a plurality of regions within a 3D image.” Pet., 9-10. But if a “3D segmentation map”

were merely the assortment of segmentation masks already produced in step (b), then there would be nothing left to “determine[e],” and the map would not “represent[.]” anything—it would simply *be* the masks. In practical effect, Petitioner’s erroneous construction would thus render the claim term “3D segmentation map”—and the entirety of step (c)—superfluous, as illustrated below:

(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 plurality of 3D masks segmentation map; and

EX1001, 79:14-28 (modified).

Petitioner’s construction would delete the independent function of step (c) and thus violate the fundamental rule that claim constructions must avoid rendering claim language “void, meaningless, or superfluous.” *See Wasica Fin. GmbH v. Continental Auto. Sys.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) (rejecting constructions that render claim language “void, meaningless, or superfluous”); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950-51 (Fed. Cir. 2006) (holding a

patent claim construction that reads limitations out of a claim is “contrary to the principle that claim language should not [be] treated as meaningless”). This distinction especially matters here because Petitioner’s anticipation and obviousness theories depend on collapsing claim step (c) into step (b), which is an approach that—if accepted—would erase the structural and functional architecture that the claims require.

Petitioner’s construction is thus at odds with the claim language, the intrinsic record, and the black-letter law of claim construction. Patent Owner’s proposed construction honors the claim text (“determining . . . representing”), gives full effect to step (c), and conforms to the patentee’s express teaching that the map is a single stitched, labeled volume used to drive the downstream PET/SPECT operations. EX2043, ¶73. Patent Owner thus respectfully submits that the Board should adopt Patent Owner’s construction of “3D segmentation map”: “a consolidated representation of 3D objects in space that combines multiple 3D segmentation masks and accounts for their relative spatial relationships to each other within a common volume.”

VII. ARGUMENT

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

Petitioner has not shown that Renisch anticipates any challenged claim—let alone both independent claims 1 and 10—by a preponderance of the evidence.

EX2014, ¶69; EX2043, ¶77. Anticipation requires a single reference to expressly or inherently disclose each and every claim limitation, arranged as in the claim. *See, e.g., Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Boilerplate or generic name-checking is not enough. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1084 (Fed. Cir. 2008). Petitioner has not met its burden here.

Patent Owner specifically addresses claims 1 and 10 below since those are the only independent claims.

1. Renisch does not disclose the supervised deep learning artificial neural networks, such as CNNs, required by limitation (b) of claim 1 (and its system analogue in claim 10)

Limitation (b) of claim 1 requires “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; EX2043, ¶78. Renisch does not disclose the use of “machine learning modules,” as recited in claim 1. EX2043, ¶78. The Petition’s attempt to argue otherwise is unpersuasive. *See* EX2014, ¶¶70-77; EX2043, ¶78.

As explained above, as properly construed, limitation 1(b) of claim 1 requires “using one or more supervised deep learning artificial neural networks, such as CNNs, each trained to identify one or more specific target three-dimensional VOIs within the 3D anatomical image.” EX2043, ¶79. This construction aligns with and

is grounded in the Patent's description of supervised deep learning technologies for performing multi-organ segmentation across a patient's body, including its repeated reference to CNNs and multiple pages describing how arrangements of multiple CNNs can be trained and used together to segment various organs and/or bones within a 3D anatomical image, like a CT image. EX2043, ¶80.

In contrast, the Petition's cited reference (Renisch) devotes a mere two short paragraphs to referencing previously-developed segmentation techniques in generic terms, as follows:

The segmentation unit 76 is capable of employing different types of segmentation methods. *For example, the segmentation unit 76 can employ a model-based segmentation in which the central assumption is that the anatomical structures of interest have, to some extent, relatively consistent forms of geometry and position across patients.* A library of three-dimensional anatomical structure models explaining the shape, geometrical location, size, and variations thereof are defined in an anatomical database 84 prior to the segmentation. During segmentation, the models act as templates to identify 86 and define the boundary of the structure of interest. 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.

The segmentation unit 76 can also employ an atlas of normal anatomical structures which is mapped to the actual anatomical image. In such an embodiment, the atlas includes the anatomical database 84.

EX1005, [0027]-[0028] (emphasis added); *see also* EX2043, ¶81.

These two short paragraphs only actually describe two segmentation techniques with more than passing reference. EX2043, ¶82. Renisch briefly describes “model-based segmentation” in paragraph [0027] and alludes to atlas-based segmentation in paragraph [0028]. *Id.* These two approaches (model-based and atlas-based segmentation) are both “template-based” approaches that rely on predefined models or atlases of anatomical structure geometry. *Id.; see also id.*, ¶¶26-29. Renisch provides no more than a quick name-check of other segmentation techniques, and does not disclose anything at all about how those other techniques would or could be used. EX2043, ¶82. Instead, the other techniques listed in paragraph [0027] of Renisch appear to be a boilerplate sentence and are at odds with the template-based approaches that Renisch describes. EX2043, ¶¶82-83.

a. Renisch’s template-based segmentation (model/atlas) is fundamentally distinct from the claimed supervised deep learning techniques.

The template-based approaches that Renisch describes are fundamentally distinct from—and incompatible with—the supervised deep learning techniques claimed in the Patent. EX2043, ¶83. Renisch’s core segmentation methods rely on a “central assumption”: that anatomical structures exhibit “relatively consistent forms of geometry and position across patients.” EX1005, [0027]; EX2043, ¶84. On the basis of that “central assumption,” Renisch employs model-based and atlas-

based techniques that rely on predefined anatomical templates mapped onto patient images. EX1005, [0027]-[0028]; EX2043, ¶¶82-84.

The Patent expressly rejects Renisch’s paradigm. EX2043, ¶85. The Patent’s supervised deep learning approaches do not assume fixed geometry or positioning. Instead, when properly trained, those machine learning techniques, like Convolutional Neural Networks (CNNs), learn patterns directly from images, and thus can, when presented with new images, identify individual voxels that make up either the contour or the interior of object(s) of interest within those new images. *See, e.g.*, EX1001, 48:1-18, 50:22-34, 57:6-26; EX2043, ¶30.

MIM’s expert, Dr. Bruce Rosen, M.D., Ph.D., acknowledged this distinction between Renisch and the Patent, testifying that paragraphs [0027]-[0028] of Renisch describe “a non-machine-learning based approach.” EX2042, 62:7-14 (“It does appear that they are describing a non-machine learning based approach in these two paragraphs.”).

This technical gulf between Renisch and the Patent is not merely theoretical. Even Petitioner acknowledges that it has material, real-world consequences. In 2023—several years after the Patent’s January 2019 priority date—Petitioner published EX2022, which is a document titled “Atlas-Based vs. AI Auto-Contouring in Clinical Practice.” EX2022. The document compares atlas-based contouring with AI-based auto-contouring in actual patient cases. *Id.* It concedes that although atlas-

based contouring may produce “reasonably accurate” results in simple, high-quality cases, it fails or requires extensive manual correction as cases become more complex, *precisely because* “there isn’t a close-match atlas subject to use,” and thus “the atlas-based results are inaccurate or unusable.” *Id.* at 4; *see also* EX2043, ¶84. By contrast, Petitioner writes that its AI auto-contouring software successfully delineates anatomical structures even in difficult cases. *Id.* at 5 (concluding that its AI-based contouring “delivered better results than the atlas-based contouring method”).

Petitioner’s admissions are directly relevant here. They confirm that what the Patent teaches is fundamentally different than what Renisch teaches. Renisch’s template-based segmentation is inherently limited by its reliance on assumed anatomical similarity. The Patent’s supervised deep learning technique, on the other hand, can robustly and accurately handle anatomical variety—which is one of the very problems that the Patent set out to solve.

Accordingly, Renisch’s model- and atlas-based segmentation techniques do not disclose—and indeed operate on a fundamentally different principle from—the supervised deep learning segmentation claimed in the Patent. EX2043, ¶85. Far from anticipating those claims, Renisch exemplifies the shortcomings that the Patent overcame—shortcomings that Petitioner itself publicly acknowledged years later in EX2022.

b. Renisch’s mere mention of “clustering” and “neural network” does not disclose the Patent’s supervised deep learning approach.

The Petition does not (and cannot) argue that Renisch’s template-based segmentation techniques anticipate or disclose limitation 1(b) of claim 1. Instead, the Petition points to a single sentence in Renisch that states the following: “It is to be appreciated, however, that other segmentation methods such as clustering, edge detection, region growing, principle components [sic] analysis, neural network, and the like are also contemplated.” Pet., 23; *see* EX1005, [0027]; EX2043, ¶86.

Renisch’s boilerplate list of various unrelated segmentation techniques does not disclose limitation (b) of claim 1. EX2043, ¶86. The Parties agree that edge detection, region growing, and principal components analysis are not supervised deep learning approaches as described in the Patent. Instead, the Petition argues that Renisch’s references to “clustering” and “neural network” qualify as disclosure of the detailed supervised deep learning technologies for multi-organ image segmentation described in the Patent and recited in claim 1. Pet., 23. Not so.

“Clustering” refers to a general class of 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; EX2043, ¶90. Clustering is an *unsupervised* technique. EX2043, ¶90. It expressly avoids use of labeled data—directly

contrasting with the extensive use of labeled data described in the Patent. *See, e.g.*, EX1001, 48:7-10, 50:22-25, 57:10-18; EX2043, ¶90. Accordingly, an isolated mention of “clustering” does not disclose the use of supervised deep learning as described in the Patent (if anything, in fact, it teaches away from it). EX2043, ¶¶88-90.

Likewise, a “neural network” is a specific computational model that uses variable weights and interconnected neurons to capture a wide variety of behavior. EX2014, ¶73; EX2043, ¶91. A neural network is not the same thing as, and does not necessitate the use of, supervised deep learning approaches as described in the Patent. EX2043, ¶91. The term “neural network” alone would not suggest to a POSA a supervised deep learning approach as described in the Patent. *Id.*

Petitioner cites to the declaration of its expert, Dr. Rosen, to argue that clustering and neural networks are well-known machine learning techniques akin to what is claimed in the Patent. Pet., 23 (citing EX1002, ¶157). Petitioner’s reliance on Dr. Rosen for this point is unavailing because Dr. Rosen testified at his deposition that he could not recall ever seeing or reading the article that his declaration cites in support of this point. EX2042, 72:14-23 (“Q. Dr. Rosen, do you recognize this document?;” “A: I don’t have a clear recollection of it at this moment;” “Q: Do you recall whether you read this document before?;” “A: I honestly don’t recall.”). He also testified that Petitioner’s counsel supplied him with all the background

references that he cited for his discussion of machine learning (and its history). *See* EX2042, 26:5-10. In any event, Dr. Rosen testified that Renish describes “a non-machine learning-based approach.” EX2042, 62:7-14, and anticipation requires disclosure in the reference itself, not in a later expert declaration. *See Net MoneyIN, Inc.*, 545 F.3d at 1369.

Because Renisch describes “a non-machine learning template approach” per Dr. Rosen, and does not disclose the claimed supervised deep learning modules trained for each target tissue region, it cannot anticipate the “machine learning modules” requirement of claim 1(b) (or the corresponding system elements in claim 10). *See In re Chudik*, 851 F.3d 1365, 1372 (Fed. Cir. 2017) (“a prior art reference that must be distorted from its obvious design does not anticipate a patent claim.”) (citation and internal quotation marks omitted).

c. Renisch does not disclose using one or more supervised deep learning modules, where each is trained to identify a specific target three-dimensional VOI within the 3D anatomical image.

Limitation 1(b) also requires that each of the one or more supervised deep learning artificial neural networks (such as CNNs) “is trained to identify one or more target three-dimensional VOIs within the 3D anatomical image.” EX2043, ¶92. Renisch does not disclose any particular training, arrangement, or related detail pertaining to how one or more machine learning modules are trained. EX2043, ¶94.

The Petition does not, and cannot, point to any such description in Renisch. *Id.* All that the Petition points to are two terms amounting to a total of three words: “clustering” and “neural network.” EX2043, ¶93.

Renisch thus fails to disclose the use of one or more supervised deep learning artificial neural networks, each trained to identify one or more specific target 3D VOIs, as described in the Patent. EX2043, ¶95. Petitioner therefore fails to show disclosure of limitation 1(b). EX2043, ¶96. Claims 1 and 10 are therefore not anticipated by Renisch, and the dependent claims necessarily survive for at least this reason.

2. Renisch does not disclose “determining . . . a 3D segmentation map representing a plurality of 3D segmentation masks, each 3D segmentation mask representing a particular identified target VOI” as required by claims 1 and 10.

The Petition’s anticipation theory fails for another reason: Renisch does not disclose limitation (c) of claims 1 and 10—*i.e.*, “determining . . . a 3D segmentation map representing a plurality of 3D segmentation masks”—under the proper construction of “3D segmentation map” as “a consolidated representation of 3D objects in space that combines multiple 3D segmentation masks and accounts for their relative spatial relationships to each other within a common volume.” *See supra* § VI.B; EX2014, ¶¶79–91; EX2043, ¶97.

- a. **Renisch does not disclose “determining” a “3D segmentation map” that combines multiple 3D segmentation masks and accounts for their relative spatial relationships to each other within a common volume.**

The Petition contends that “Renisch discloses [1(c)] to a POSITA even though Renisch does not use the same terminology.” Pet., 24. But the difference between Renisch and the claims is substantive, not semantic. EX2014, ¶¶79; EX2043, ¶¶101.

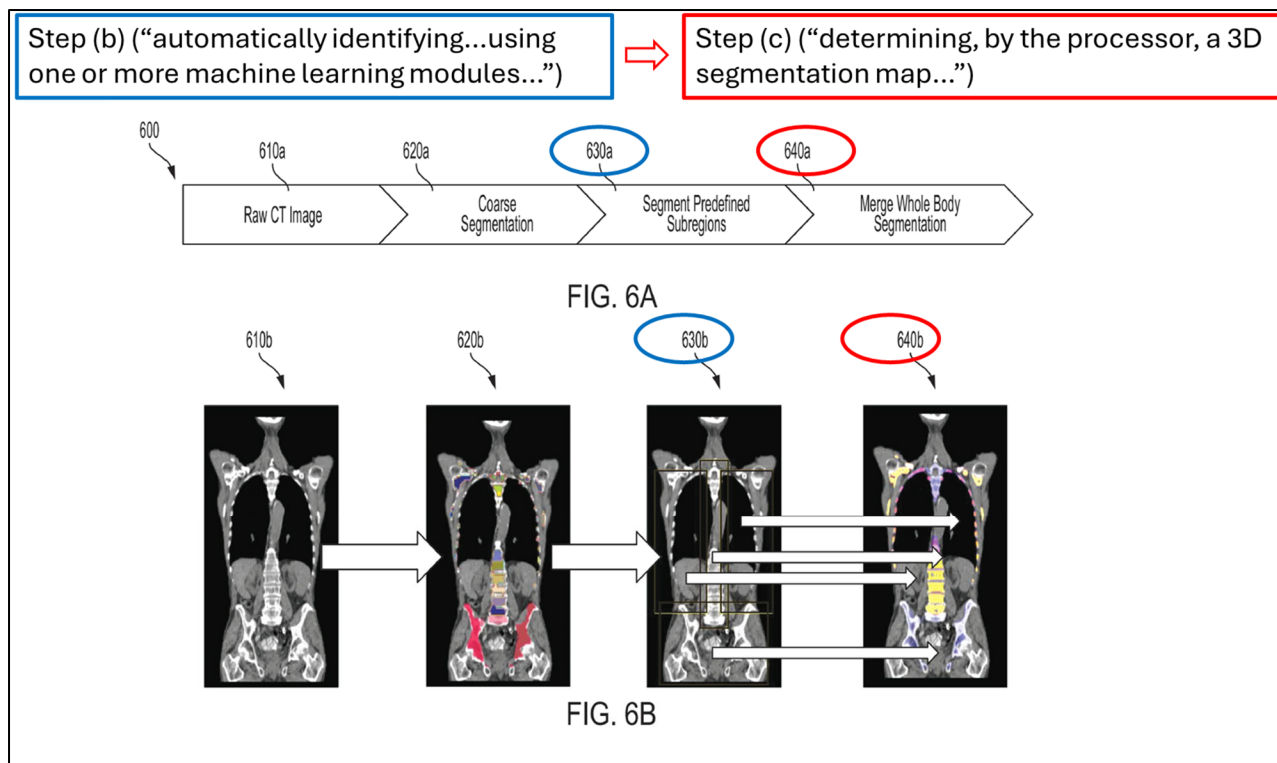
As discussed above, the Petition proposes and relies on a construction of “3D segmentation map” as just any arbitrary assortment of masks, rendering step (c) of claim 1 meaningless or irrelevant. But as properly construed, limitation 1(c) is a distinct, active step that requires combining multiple 3D segmentation masks that represent VOIs identified via one or more machine learning modules to create a new structure—a 3D segmentation map. EX2043, ¶¶99, 102-104. That step does not merely acknowledge the existence of segmentation results. *Id.* Instead, it requires “determining” a consolidated representation that “represent[s]” those results. *See* EX1001, 79:18-21; 49:7-10, 31:66-32:13, 34:27-39; *see also* EX2043, ¶¶99, 102-104.

The Petition identifies no passage in Renisch that discloses—or could reasonably be understood by a POSA to disclose—such a consolidated representation. EX2043, ¶¶105. Instead, Petitioner’s argument depends entirely on its incorrect claim construction that collapses the “3D segmentation map” into the

assorted masks themselves. EX2043, ¶106. Because that construction reads step (c) out of the claims, it should be rejected and thus cannot support anticipation. EX2014, ¶90; EX2043, ¶107.

b. Renisch does not combine outputs of a supervised deep learning multi-organ segmentation process into a 3D segmentation map.

Limitation 1(c) of claim 1 is an active step of a method claim that requires “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, 79:18-21. Thus, claim 1 specifies that a 3D segmentation map is “*determin[ed]*.” The Patent teaches this explicitly: the 3D segmentation map is created by *merging or digitally stitching together* a plurality of 3D segmentation masks, each representing a particular target VOI identified (using the one or more machine learning modules) within the 3D anatomical image. EX1001, 49:7-10 (“Segmentation masks representing the identified target volumes can be created, and merged 640a, for example to create a 3D whole body segmentation map.”), 32:11-13 (“The multiple segmentation masks, identifying multiple target tissue regions across a patient’s body, can be stitched together to form a segmentation map.”). The annotated version of FIGs. 6A and 6B shown below summarizes this point:



Annotated FIGS. 6A and 6B, with color boxes and circles illustrating corresponding claim steps for the circled reference numerals

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 then their output combined into a unified 3D segmentation map. EX2043, ¶109. Relying on a construction of “3D segmentation map” that renders it meaningless, *see supra* Section VI.B, Petitioner insists that Renisch’s undescribed “segmentation results” are masks and, while never merged or combined in Renisch, are nonetheless collectively a “3D segmentation map.” Pet., 23-25. The Petition waives away step (c) of claim 1 as “merely an explicit statement of a routine implementation detail in digital image segmentation.” Pet., 23. Even if that were

true (it is not), it would not relieve Petitioner of its burden to establish that Renisch discloses “all the elements in the same form and order as in the claim.” *See In re Chudik*, 851 F.3d at 1372 (citation and internal quotation marks omitted). Renisch simply does not.

The Board’s preliminary interpretation of Renisch in its institution decision is incorrect for similar reasons. The Board noted:

[O]n 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.

Institution Decision, 21.

Patent Owner respectfully submits that the Board’s preliminary view rests on three errors.

First, the Board relied on Petitioner’s untenable construction of “3D segmentation map,” without the benefit of considering Patent Owner’s alternative proposed construction.

Second, Renisch nowhere discloses “a scanned 3D image of a fuller anatomy” as a segmentation map. *See* Institution Decision, 21; EX2043, ¶113. A scanned

anatomical image is an input, not the claimed output created by step (c). EX2043, ¶113.

Third, the Board reversed the claimed order of operations. The Patent is clear that the 3D segmentation map is created based on, and represents the output of, multiple machine learning modules. It is not an input to, or operated on, by a segmentation technique. Respectfully, the Board had it backwards when it stated that “it appears that Renisch 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.” See Institution Decision, 21 (emphasis added); EX2043, ¶113.

Under the claims and specification, the “3D segmentation map” is the *result* of segmentation and consolidation—it is not the raw image being segmented. Accordingly, Renisch does not disclose limitation 1(c). EX2043, ¶113.

c. Renisch does not inherently disclose a 3D segmentation map.

Unable to identify any express disclosure, the Petition implicitly argues inherency, contending that Renisch must use “3D segmentation masks” because it 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. That argument fails for two reasons.

First, it simply mischaracterizes Renisch. Petitioner’s description of how Renisch’s suppression unit works is different from what Renisch actually describes. In particular, Petitioner contends that Renisch selectively suppresses VOIs that are identified as representing specific organs in a 3D anatomical image and must do so using a collection of 3D segmentation masks representing those specific organs in the 3D anatomical image (even this argument fails to identify an actual 3D segmentation map). Pet., 24-25. Renisch, however, does not do this. *See* EX2043, ¶119. Instead, Renisch identifies *hotspots* (regions of high tracer uptake) within a *functional (not anatomical) image* and suppresses those identified hotspots. 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); *see also* EX2014, ¶¶82, 86-87; EX2043, ¶119. These hotspots are not anatomical tissue regions (*e.g.*, organs or bones), and they are not identified within a 3D anatomical image. EX2043, ¶¶119-120. Thus, contrary to the Petition’s argument, Renisch’s

suppression of hotspots does not disclose the use of “3D segmentation masks ... representing a particular identified target VOI,” let alone a “3D segmentation map” that combines multiple 3D segmentation masks into a common volume, as required by claim 1(c). EX2014 ¶¶82, 86–87; EX2043, ¶121.

Second, for inherency to apply, the 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 enough that something 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 does not—and cannot—establish that Renisch “necessarily” creates 3D segmentation masks or a 3D segmentation map. *Cont’l Can Co.*, 948 F.2d at 1268; EX2014, ¶85, EX2043, ¶115. Segmentation masks are not required to represent segmentation results. Nor is there any requirement in Renisch to merge multiple masks into a single labeled 3D volume. The creation and use of a 3D segmentation map is a particular way that Patent Owner chose to represent results of 3D machine learning-based image analysis, driven, among other things, by the desire

for flexibility and applicability to a variety of downstream image applications. EX2014, ¶¶57-62, EX2043, ¶¶116-18. Renisch does not disclose that choice—expressly or inherently.

Because Renisch does not disclose—either expressly or inherently—determining a 3D segmentation map representing a plurality of 3D segmentation masks, it fails to anticipate independent claims 1 and 10. EX2014, ¶¶90–93; EX2043, ¶¶121-124. The dependent claims necessarily fall with them. *See* EX2014, ¶94; EX2043, ¶125.

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

1. Renisch and Zhao do not disclose a “3D segmentation map” as required by claims 1 and 10.

For Ground B, the Petition argues that Zhao discloses “segmentation masks,” while Renisch purportedly supplies all remaining limitations. Pet., 25-26. EX2014, ¶¶96-97; EX2043, ¶128. The combined theory fails, however, because neither Renisch nor Zhao—alone or together—discloses the claimed creation of a “3D segmentation map.” EX2014, ¶¶95, 98-101; EX2043, ¶¶129-132.

For the reasons explained above, Renisch does not disclose a “3D segmentation map.”

Nor does Zhao disclose a “3D segmentation map,” as Zhao’s disclosure is confined to *2D*—not 3D—image segmentation. *See* EX1007; EX2014, ¶¶98-99;

EX2043, ¶¶129-130. Zhao never mentions 3D image processing of any kind, let alone 3D segmentation. *See* EX1007; EX2014, ¶¶98-99; EX2043, ¶¶129-130. Zhao repeatedly refers to “pixels,” 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, 5:25-42,7:56-64; EX2043, ¶129. Zhao describes a “100-pixel by 100-pixel input.” EX1007, 7:56-64; EX2014, ¶98; EX2043, ¶129. Zhao refers to “two spatial dimensions” when describing the disclosed image processing techniques. EX1007, 7:65-8:7; EX2014, ¶98; EX2043, ¶129. Zhao therefore cannot disclose the 3D processing necessary to create a consolidated 3D segmentation map. EX2043, ¶129.

This omission is critical. The 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 Patent expressly contrasts its 3D approach with prior 2D techniques, noting that “[t]he 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 Patent further explains that 3D segmentation enables more accurate and repeatable quantification from entire organs than 2D methods could provide:

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; EX2043, ¶130. 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 assume that Zhao discloses 3D medical imaging analysis because Zhao mentions the use of CT scans. *Infra*, Section VII.B.1; EX2014, ¶100; EX2043, ¶131. But a CT image is not necessarily a 3D image—indeed, as Dr. Rosen testified, CT images are always “acquired as 2D data.” EX2042, 107:5-6; *see also* EX2043, ¶¶32-35, 131. And Zhao exclusively refers to the use of 2D images. EX2014, ¶100; EX2043, ¶131.

Accordingly, Zhao does not disclose determining a 3D segmentation mask, let alone a 3D segmentation map. EX2043, ¶132. 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; EX2043, ¶132.

2. A POSA would not have been motivated to combine Renisch and Zhao with a reasonable expectation of success.

Even if Renisch and Zhao disclosed the necessary limitations (they do not), the Petition fails to establish that a POSA would have been motivated to combine

Renisch and Zhao to perform limitations (b) through (e) of claims 1 and 10 with a reasonable expectation of success.

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). 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), for at least three reasons. *See* EX2014, ¶105; EX2043, ¶135.

a. Combining Renisch and Zhao would require non-obvious modification of both references.

To arrive at the claimed inventions, a POSA would need to: (i) fundamentally alter Renisch, (ii) fundamentally alter Zhao, and then (iii) combine the two fundamentally altered systems. That tall task is incompatible with proving obviousness. *See* EX2043, ¶136.

Renisch emphasizes template-based (*e.g.*, model-based or atlas-based) segmentation, grounded in a “central assumption” of consistent anatomy across patients. EX1005, [0027]; EX2043, ¶¶137-138. Supervised deep learning techniques like those described in the Patent operate based on a fundamentally different paradigm. EX2043, ¶138. It would therefore not have been obvious to substitute Renisch’s model- and atlas-based segmentation with supervised deep learning as described in the Patent. *Id.*

Zhao, meanwhile, is limited to 2D image analysis and does not contemplate multi-organ 3D segmentation, anatomical-functional integration, or the need for a consolidated 3D segmentation map. EX2043, ¶139. Substantial, non-obvious redesign would be required before Zhao could be adapted to the claims. EX2043, ¶140.

Because both references would require non-obvious modification before any combination, the proposed combination is itself non-obvious. *In re Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959); EX2043, ¶140.

b. Neither Renisch nor Zhao address the problems solved by the Patent.

Neither Renisch nor Zhao contemplate the particular challenges that motivated the Patent—namely, achieving robust, accurate 3D multi-organ segmentation via deep learning techniques and using a stitched 3D segmentation map to enable downstream 3D functional image analysis. EX2014, ¶¶105-07;

EX2043, ¶141. 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; *see* EX2043, ¶146.

The Petition’s stated rationale to combine—that both references “are directed to segmentation of 3D medical images, such as CT images, using neural networks”—is incorrect. Pet., 26. Renisch mentions a “neural network” once in passing, and proposes no implementation at all. Moreover, Renisch does not contemplate the kind of deep learning-based 3D image segmentation that the Patent describes. EX2043, ¶141. And Zhao does not disclose 3D segmentation at all—it only describes 2D. EX2043, ¶141.

The Petition also 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; EX2043, ¶142. That rationale does not fit these facts. As discussed above, Zhao’s “segmentation masks” are 2D, and Renisch’s suppression of high-intensity regions pertains to hotspots in functional images, not machine-learned anatomical VOIs derived from a 3D anatomical image. *See supra*, Section VII.A.2.c, VII.B.1; EX2014, ¶108; EX2043, ¶142.

c. A POSA would not have a reasonable expectation of success in combining Renisch and Zhao.

Obviousness requires more than simply a motivation to combine—it further requires that a POSA would have had a reasonable expectation of success in achieving the claimed invention. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). The Petition also fails because a POSA would not have had a reasonable expectation of success in combining Renisch and Zhao to arrive at the claimed invention. EX2043, ¶147. The Patent’s achievement—accurate and robust 3D segmentation, capable of identifying multiple organs within a patient body via a unique approach that uses multiple machine (supervised deep) learning algorithms (such as CNNs) to analyze and segment multiple different target tissue regions (like organs and bones) and stitch them together into a 3D segmentation map—was non-trivial. EX2043, ¶¶148-149.

Neither Renisch nor Zhao provide any insight about how to achieve accurate and robust 3D multi-organ segmentation across a patient’s body. EX2043, ¶150. Instead, Renisch is primarily directed to template-based approaches that do not provide adequate accuracy in performing image segmentation, and Zhao is limited to 2D image analysis, primarily of a single organ (the lungs). *Id.* Neither teaches how to generalize deep learning segmentation across scanners, imaging protocols, and anatomical regions—challenges well recognized in the art, including by Petitioner’s own expert (Dr. Rosen). As Dr. Rosen has explained in a 2021 paper,

“[m]edical images require numerous highly specialized preprocessing techniques to account for differences between scanners and imaging sequences, each of which can unpredictably affect the performance of deep learning algorithms” and “**slight differences** in preprocessing methods **can lead to catastrophic prediction failures.**” EX2042, 145:3-7, 145:22-24 (quoting EX2041, 3-4) (emphasis added). Along these lines, Dr. Rosen confirmed at his deposition that neither Renisch nor Zhao “describe in detail [the] preprocessing pipelines” that a POSA would have needed as of the Patent’s priority date in order to perform multi-organ 3D segmentation. EX2042, 146:6-11. Dr. Rosen further testified that concerns “that deep learning segmentation could fail to generalize across sites and machines” were “fully applicable” to the “concepts of Renisch and the concepts in Zhao.” EX2042, 110:21-111:13.

Indeed, years after the Patent’s January 2019 priority date, clinicians and researchers remained skeptical about the clinical reliability of 3D deep learning segmentation. *See, e.g.*, EX1017, 1115; *see also* EX2022 (referring to an “auto-contouring driven by artificial intelligence (AI)” approach and stating, even in 2023, that “[w]hile some clinicians have embraced the technology, others remain skeptical about its ability to provide accurate results in clinical practice”); EX2043, ¶148. This context—including EX2022 authored by Petitioner—confirms that applying

deep learning to 3D medical image segmentation was not obvious as of the Patent's January 2019 priority date. EX2043, ¶¶147-152.

Accordingly, a POSA would not have been motivated to combine Renisch and Zhao with a reasonable expectation of success. EX2014, ¶¶109-12; EX2043, ¶¶152-155.

C. Ground C: Renisch, or Renisch-Zhao, each in view of Baker, do 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; EX2043, ¶¶156-57. Because Renisch and Zhao fail to disclose the core segmentation and mapping limitations, adding Baker does not cure those defects. Therefore, Ground C fails. EX2014, ¶114; EX2043, ¶157.

D. Ground D: Renisch, or Renisch-Zhao, each in view of Eiber, do 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; EX2043, ¶¶158-59. The Petition does not contend that Eiber discloses any other

limitations of those claims. EX2014, ¶¶115-16; EX2043, ¶¶158-59. 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. EX2014, ¶¶116; EX2043, ¶159.

E. 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; EX2043, ¶160. However, as discussed above, Zhao does not discuss 3D image analysis at all, let alone 3D segmentation masks. *Supra*, Section VII.B.1; EX2014, ¶118; EX2043, ¶161. 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; EX2043, ¶¶160-63.

F. Ground F: Baker-Zhao, in view of Eiber, does 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; EX2043, ¶164. The Petition does not contend that Eiber discloses any other limitations of those

claims. EX2014, ¶121; EX2043, ¶164. Accordingly, for at least the reasons above, Baker-Zhao in view of Eiber fails to render claims 3-5 and 12-14 obvious. *See id.*; EX2043, ¶164.

G. Ground G: Baker-Zhao, in view of Suehling, does 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; EX2043, ¶165. The Petition does not contend that Suehling disclose any other limitations of those claims. *See* EX2014, ¶122; EX2043, ¶165. Accordingly, for at least the reasons above, Baker-Zhao in view of Suehling fails to render claims 19, 26, and 28 obvious. *See id.*; EX2043, ¶165.

VIII. CONCLUSION

For all the foregoing reasons, the Petition fails to establish by a preponderance of the evidence that the challenged claims are unpatentable. Accordingly, the claims should be confirmed under 35 U.S.C. § 316.

Date: January 26, 2026

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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 11,570 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 RESPONSE** was served electronically in its entirety on January 26, 2026, via electronic mail to the following attorneys of record:

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