

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MIM SOFTWARE INC.,
Petitioner,

v.

PROGENICS PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00630
U.S. Patent No. 10,665,346

PATENT OWNER'S PRELIMINARY RESPONSE

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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	PACER Docket, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS (as of June 11, 2025).
EX2003	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.
EX2004	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.
EX2005	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.
EX2006	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.
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EX2008	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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EX2012	<i>Cancer Control Month, 2025 – The White House</i> (Apr. 3, 2025).
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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	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).
EX2021	<i>FDA Approves First PSMA-Targeted PET Imaging Drug for Prostate Cancer</i> , Oncology Practice Management (2020).
EX2022	<i>FDA Approves Second PSMA-Targeted PET Imaging Drug for Men with Prostate Cancer</i> , Food and Drug Administration (2021).
EX2023	<i>Atlas-Based vs. AI Auto-Contouring in Clinical Practice</i> , MIM Software Inc. (2023).

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EX2027	Deng, et al., <i>ImageNet: A large-scale hierarchical image database</i> , IEEE Conference on Computer Vision and Pattern Recognition (2009).
EX2028	Bushberg, J.T., et al., <i>The Essential Physics of Medical Imaging</i> (2012), Ch. 1, Sec. 1.1, pp. 3-15.
EX2029	Bushberg, J.T., et al., <i>The Essential Physics of Medical Imaging</i> (2012), Ch. 3, Sec. 3.1, pp. 33-38.
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EX2031	Kelleher, <i>Deep Learning</i> (2019), Ch. 1, “The Key Ingredients of Machine Learning,” pp. 22-30.
EX2032	Kelleher, <i>Deep Learning</i> (2019), Ch. 3, “Neural Networks: The Building Blocks of Deep Learning,” pp. 65-67.
EX2033	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “The Era of Deep Learning,” pp. 143-145.
EX2034	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “Layer-Wise Pretraining Using Autoencoders,” pp. 145-148.
EX2035	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “Weight Initialization and ReLU Activation Functions,” pp. 148-153.
EX2036	Kelleher, <i>Deep Learning</i> (2019), Ch. 4, “The Virtuous Cycle: Better Algorithms, Faster Hardware, Bigger Data,” pp. 153-156.

I. INTRODUCTION

U.S. Patent No. 10,665,346 (the “’346 Patent”) discloses a novel solution to serious challenges faced by doctors when analyzing medical images for cancer diagnosis and treatment. Specifically, the ’346 Patent claims an inventive process for taking anatomical and/or functional images, automatically segmenting organs within those images using a machine learning algorithm, identifying regions of cancer within relevant organs, and generating a new 3D visualization that overlays a risk map demarcating cancer risk on the patient’s medical image(s).

Key advances of the ’346 Patent include the use of: (a) machine learning algorithms for medical imaging analysis, and (b) a network-based system involving databases. For example, the Patent Owner recognized that machine learning algorithms could be used to accurately and robustly identify the 3D boundaries of particular tissue regions in a way not previously possible. The Patent Owner also understood that it would be especially valuable for cloud-based systems of cancer diagnosis and treatment if one could take advantage of remote networking by uploading medical images to, and accessing them from, databases via network-based systems.

None of the Petition’s cited references discloses the particular manner in which the ’346 Patent utilizes new machine learning techniques to create a commercially viable risk map that displays regions of cancer risk overlaid on 3D

delineations of tissue region boundaries (such as organs and bones). Nor do the Petition's asserted references disclose the '346 Patent's combination of risk mapping with a network-based platform that enables the repeated imaging studies often necessary for monitoring patients throughout the arduous process of cancer diagnosis, treatment, and follow-up. These critical elements are absent from the Petitioner's cited materials.

Faced with this lack of express disclosure in its asserted references, the Petition strains to interpret vague and inapt disclosures in the references as purportedly teaching the claimed limitations. Based on a confounding constellation of 12 different grounds (some of which involve up to six separate sub-combinations), Petitioner's attempts are unavailing. For example, the Petition contends that its three primary references (Renisch, Sprencz, and Suehling) all disclose the use of a "machine learning algorithm," despite the fact that these references describe three fundamentally different techniques (neural networks, clustering, and marginal space learning, respectively). No person of ordinary skill in the art ("POSA") would understand that a single term ("machine learning algorithm") could encompass three such fundamentally different techniques. Similar issues arise with the Petition's attempts to misrepresent the primary references as disclosing the use of a "database" and "a network-based system."

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

II. TECHNOLOGY BACKGROUND

One major challenge in treating and managing cancer, as well as other serious diseases, has long been the difficulty of accurately and consistently interpreting the diagnostic images produced by medical imaging tools. *See* EX2014, ¶¶35, 58. Both anatomical scans (such as X-rays or CT scans) and functional scans (like PET or single-photon emission computed tomography (SPECT)) are valuable. EX2014, ¶¶26-28. However, before the inventions described in the Asserted Patents, 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, ¶¶27-30, 60. 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* EX2014, ¶¶60. 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.

More broadly, the traditional process of interpreting medical imaging—which involved a physician receiving one or more different scan images prepared by a computer—left room for human error. *See* EX2014, ¶35. Without automated integration, mapping, and assessment of those scan results, a physician might misinterpret a PET scan (or a combination of a CT scan and a PET scan) and miss a critical diagnostic insight that could save a patient’s life. *See* EX2014, ¶35.

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. To the extent Renisch describes image segmentation, his disclosure focuses on conventional atlas-based image segmentation. 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. Wu

Wu discloses “cloud-based medical image processing systems with tracking capability” that tracks user interactions with medical image data and analyses the tracked user interactions to determine overall trends, such as “overall trends in

software use, for example how long it takes a user to complete a certain type of case, or certain steps, billing trends etc.” EX1009, [0002], [0057]; EX2014, ¶53.

c. D’Souza

D’Souza discloses “compositions and methods of synthesis and uses” of fluorine isotope-labeled peptides or other targeting molecules comprising bifunctional chelating agent for imaging. EX1010, Abstract, 3:34-56; EX2014, ¶55. The F-labeled peptides or targeting molecules are antibodies or antibody fragments that target “a variety of cell surface or disease-associated antigens.” EX1010, 4:13-16, 4:54-64, 12:19-53; EX2014, ¶55. D’Souza’s antigen labelling technique is not tailored for any specific disease, but, rather, is presented as a generic antibody labeling method (e.g., are used for treating “a malignant disease, a cardiovascular disease, an infectious disease, an inflammatory disease, an autoimmune disease, a metabolic disease, or a neurological (e.g., neurodegenerative) disease.”). EX1010, 12:19-53; EX2014, ¶55.

d. Maier

Maier discloses a “computer implemented method for assessing and communicating a patient’s health status and risk,” primarily in relation to smoking-related diseases like “myocardial infarction, Chronic Obstructive Pulmonary Disease (COPD), emphysema, lung cancer, decreased lung function, COPD exacerbations, coronary artery disease, and stroke.” EX1008, [0007]; EX2014, ¶54.

Maier's approach involves extracting values of features like numbers or percentages of voxels with intensities below or above a threshold intensity, mean image intensity within a region, etc., from CT images of a given patient and correlating these "imaging biomarkers" with values from historical patient populations having known clinical outcomes, analogous to how, for example, the BRCA1 and BRCA2 genes are genetic biomarkers for breast cancer risk and cholesterol levels are biomarkers for heart disease risk. EX1008, [0007]-[0008]; EX2014, ¶54.

e. Menon

Menon discloses systems and methods for "assisting in decision making for the treatment of stroke patient." EX1012, Abstract; EX2014, ¶56. Specifically, Menon provides a "triage decision support tool" for determining whether a stroke patient should be transferred to another hospital where endovascular therapy is available, based on factors such as "clot length, collateral blood flow, the presence of forward blood flow within and around the clot, and the clot permeability." EX1012, Abstract, [0010], [0103]; EX2014, ¶56.

f. Sprencz

Sprencz discloses "methods and systems for evaluating bone lesions." EX1006, [0001]; EX2014, ¶51. Sprencz's approach involves bone segmentation performed via a conventional "thresholding technique" that "define[s] image data

having attenuation values within a predetermined range as corresponding to skeletal or bone material.” EX1006, [0043], [0045]; EX2014, ¶51.

g. Suehling

Suehling discloses a method and system for detecting lesions in a 3D medical image with region-specific lesion detectors. EX1007, [0030]-[0031]; EX2014, ¶52. Suehling partitions a patient’s body into search regions based on detected landmarks, organs and bone structures, and detects lesions in each search region using a region-specific lesion detector; EX2014, ¶52.

IV. THE ’346 PATENT

a. The Invention

As of the priority date (October 27, 2016), there remained a critical need for innovative solutions to increase the accuracy, reliability, and consistency of medical imaging analysis, especially for (but not limited to) cancer diagnosis and treatment. EX2014, ¶¶57-58. The ’346 Patent addresses this need through an inventive process for taking anatomical and/or functional images, automatically segmenting organs within them, identifying regions of cancer within relevant organs, and then creating a new 3D visualization in which a risk map that demarcates cancer risk is overlaid on the patient’s medical image(s). EX2014, ¶59.

The ’346 Patent reflects multiple key innovations. One of those innovations was to leverage machine learning (“ML”) techniques, e.g., convolutional neural

networks (“CNNs”), to perform organ segmentation in 3D images (e.g., 3D CT scans). EX2014, ¶60; *see also id.*, ¶¶44-49. Patent Owner recognized that ML could be used to geographically identify 3D boundaries of particular tissue regions in a more accurate and robust manner than had been possible previously. *See* EX2014, ¶60; *see also id.*, ¶¶35-38, 44-49. By combining the ML-identified 3D tissue boundaries with demarcations of cancer risk into a single 3D overlay, the claimed invention greatly enhances the accuracy and reproducibility of tissue and organ segmentation. EX2014, ¶60.

The resulting overlay adds valuable anatomical context to demarcations of cancer risk, where it is often impossible to obtain, inaccurate, or subjective. EX2014, ¶60. This is especially significant because, as described in the ’346 Patent, cancer is often best detected via nuclear medicine imaging approaches, like 3D PET or 3D SPECT. EX2014, ¶60; *see also id.*, ¶¶29-34. However, these nuclear medicine approaches do not always capture the anatomy and structure of organs and tissues at a sufficiently high resolution, making it challenging to reliably differentiate between various organs or tissue regions. EX2014, ¶60; *see also id.*, ¶¶28-30.

Another key innovation of the ’346 Patent involves the integration of ML techniques with the capability of remote networking for uploading and accessing medical images via network-based systems. EX2014, ¶61. This claimed feature is

especially valuable in the context of cancer diagnosis, monitoring, and treatment. EX2014, ¶61.

As such, the claimed methods provide numerous advantages over prior art methods. EX2014, ¶62.

b. Prosecution History

The Application for the '346 Patent was filed on December 18, 2019, claiming priority to U.S. Provisional Application 62/413,936 filed on October 27, 2016. EX1004, 139; EX2014, ¶63. The '346 Patent issued on May 26, 2020. EX1004, 195. EX2014, ¶63. During prosecution, the Examiner identified seven references on his “Notice of References Cited,” including Wu and Maier. On February 07, 2020, as reflected in the Examiner’s interview summary, the Examiner conducted “a telephone interview . . . with applicant’s representative,” during which he “suggested ways to clarify the independent claim or amend the claim that may overcome the prior art of record . . .” EX1004, 169; EX2014, ¶63. The Examiner allowed the application after considering all the references and amending the independent claims to recite, *inter alia*:

creation of a 3D image of the one or more regions of risk of cancer or risk of recurrence of cancer overlaid on the one or more medical images, and wherein the 3D image comprises geographic identification of one or more specific tissue region(s) overlaid on the one or more medical images.

EX1004, 165-167; EX2014, ¶63. In the Notice of Allowance, the Examiner listed the key features that he found “neither taught nor suggested by (WU) prior art of record”:

perform an analysis of the one or more medical images associated with the particular patient using a “machine learning algorithm”, to generate the risk map, wherein the risk map comprises a visual representation of tissue overlaid with graphical denotations marking one or more regions of risk of cancer or risk of recurrence of cancer; and display of the risk map via a graphical user interface (GUI) for presentation or review of the risk map by a user, wherein the medical images comprises creation of a 3D image of the one or more regions of risk of cancer or risk of recurrence of cancer “overlaid” on the one or more medical images, and wherein the 3D image comprises geographic identification of one or more “specific tissue” region(s) overlaid on the one or more medical images.

EX1004, 167. Describing the ’346 Patent, the Examiner also stated, in the Notice of Allowance, that “the invention relates to a cloud-based platform and supported GUI decision-making tools for use by medical practitioners and/or their patients.”

EX1004, 167; EX2014, ¶63.

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, ¶¶13-15.

For purposes of this preliminary response, Patent Owner does not dispute Petitioner’s definition of a POSA.

VI. CLAIM CONSTRUCTION

Under 37 C.F.R. § 42.104(b), the Petitioner bears the burden to “set forth . . . [h]ow the challenged claim is to be construed” and “[h]ow the construed claim is unpatentable.” Therefore, when a petition relies on an incorrect claim construction (either expressly or impliedly), and fails to offer any evidence of unpatentability under the proper claim construction, institution should be denied. *See, e.g., Amazon Web Services, Inc. v. Saint Regis Mohawk Tribe*, No. IPR2019-00103, Paper 22, 14–15, 17, 19–20 (P.T.A.B. May 10, 2019) (denying institution); *Jiawei Technology Ltd. v. Richmond*, No. IPR2014-00937, Paper 22, 7-8 (P.T.A.B. Dec. 16, 2014) (denying institution where petition did not provide an express construction for the term and did not adequately explain how that term reads on the cited prior art). Here, the Petition relies on incorrect constructions of three important claim terms, and fails to offer evidence of unpatentability for any ground under the proper claim construction. Institution should thus be denied. Patent Owner addresses each term in turn.

a. The Petition relies on an incorrect implied construction of “a network-based system.”

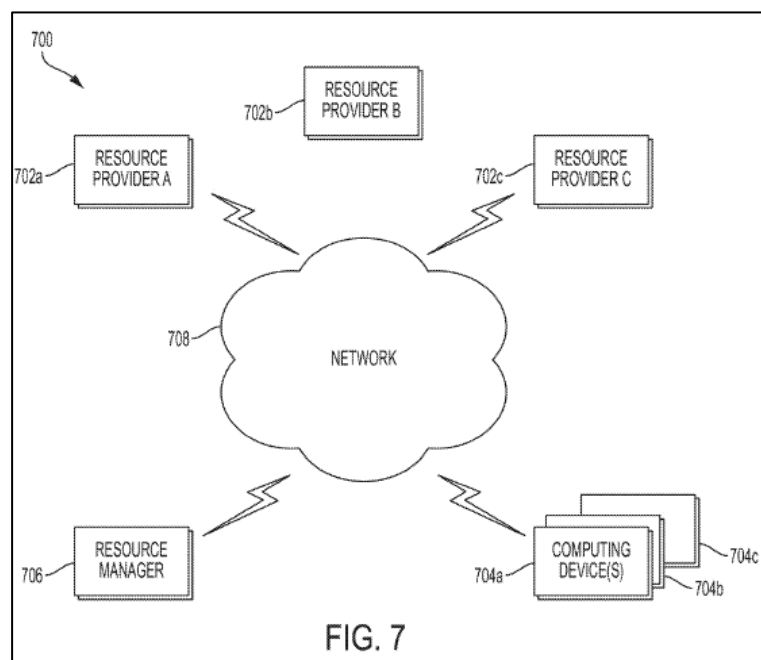
The term “a network-based system” is a key element in independent claim 1 of the ’346 Patent. In its limiting preamble, claim 1 recites “[a] **network-based**

system for generating a disease risk map for use as a decision-making support for evaluating risk of cancer or risk of recurrence of cancer, the system comprising:” EX1001, 35:46-49 (emphasis added); EX2014, ¶65.

The correct construction of the term “a network-based system” is “a system involving interaction across multiple interconnected and physically dispersed computing devices.” This construction comports with both the claim language and the specification. EX2014, ¶66.

First, the claim language makes clear that “a network-based system” is a system involving interaction across multiple interconnected and physically dispersed computing devices. The preamble begins: “**A network-based system . . . the system comprising: a processor; and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to**” perform functions that serve external computing devices, e.g., “access one or more medical images associated with a particular patient from a database” (step (i)) in order to then “cause display of the risk map via a graphical user interface (GUI) for presentation or review of the risk map by a user” (step (iii)). EX1001, 35:46-65 (emphasis added). EX2014, ¶67. The claim thus expressly uses language (“network-based”) that conveys the requirement that the system support interaction between multiple computing devices, such as a multi-patient/image database and a user computing device. EX2014, ¶¶67-68.

The specification affirms that “a network-based system” means a system involving interaction across multiple interconnected and physically dispersed computing devices. EX2014, ¶¶69. The specification repeatedly describes the invention as distributed platform (e.g., a cloud-based platform), rather than a standalone machine. EX2014, ¶¶69-70. For example, the “Summary of Invention” section begins: “Presented herein is a **cloud-based platform** and supported graphical user interface (GUI) decision-making tools for use by medical practitioners and their patients[.]” EX1001, 2:62-67 (emphasis added). The ’346 Patent introduces Figures 6-9 as illustrative examples of the invention, all of which are distributed platforms, including a “cloud-based platform,” “an exemplary cloud computing environment,” etc. *Id.*, 13:62-14:6. EX2014, ¶¶71-72. Figure 7, for example, shows the distributed network:



The specification's description of Figure 7 is instructive. It explains:

FIG. 7 shows an illustrative network environment **700** for use in the methods and systems described herein. . . . a block diagram of an exemplary cloud computing environment is shown . . . The cloud computing environment **700** may include **one or more resource providers 702a, 702b, 702c** (collectively, **702**). Each resource provider **702** may include computing resources. . . . Each resource provider **702** may be connected to any other resource provider **702** in the cloud computing environment **700**. . . Each resource provider **702** may be connected to one or more computer device **704a, 704b, 704c** (collectively, **704**), over the computer network.

Id., 30:57-31:11. The invention thus clearly contemplates a distributed network of different devices. EX2014, ¶73. So, too, does the description of FIG. 9, which describes “an example architecture 900 for implementing the cloud-based platform described herein,” which includes computer “services” that “can communicate with each other using standard protocols such as Hypertext Transfer Protocols (HTTP),” which “allows for parts of the platform to be scaled individually to meet high demand and to ensure minimal downtime.” *Id.*, 28: 30-51; EX2014, ¶¶73-74. FIG. 9 includes references to cloud-based services and shows client and servers interacting, which the specification describe as “generally remote from each other and typically interact[ing] through a communication network.” EX1001, 35:25-27; EX2014, ¶74.

Furthermore, the specification of the '346 Patent repeatedly emphasizes the ability of the network-based platform to provide access to multiple users and to

obtain, store, and analyze medical images that are obtained over the course of multiple visits to one or more doctors and/or clinical specialists. EX1001, 30:13-34; EX2014, ¶75. Altogether, then, a POSA would understand these various and repeated disclosures to require that “a network-based system” involves multiple physically distinct machines whose interaction occurs across a network. EX2014, ¶76.

In light of both the claim language and the specification, a POSA would understand that “a network-based system” thus refers to a system involving interaction across multiple interconnected and physically dispersed computing devices. *Id.*

The Petition, however, contends that the term “a network-based system” “do[es] not require an express construction” and thus should be given its plain and ordinary meaning. Pet., 9. However, as explained in greater detail below, the Petition relies on an incorrect construction of “a network-based system” that encompasses a standalone workstation rather than a distributed system. The Petition fails to offer any evidence or argument under the correct construction of “a network-based system.” Thus, the Petition fails to carry its burden at the institution phase and institution should be denied.

b. The Petition relies on an incorrect implied construction of “database.”

The term “database” is a key element in independent claims 1 and 13 of the ’346 Patent. Step (i) of claims 1 and 13 recites “access[ing] one or more medical images associated with a particular patient from a **database**.” EX1001, 35:54-55, 36:46-47 (emphasis added). EX2014, ¶77.

The correct construction of the term “database” is “a large structured set of data that contains multiple records that contain multiple fields.” This construction comports with both the claim language and the specification. EX2014, ¶78.

First, the claim language makes clear that a “database” is a persistent, structured repository that is distinct from a processor or memory. Step (i) of claim 1 teaches “access[ing] one or more medical images associated with a particular patient **from a database**.” EX1001, 35:54-55 (emphasis added). A “database” is thus a data set from which the recorded “medical images” can be “associated with a particular patient” and “access[ed].” EX2014, ¶79. The “database” thus is a structured repository, allowing medical images that are associated with a particular patient to be located and accessed.

The specification repeatedly affirms that “database” means a large structured set of data that contains multiple records that contain multiple fields. EX2014, ¶80. For example, when describing the cloud diagram in Figure 7 above, the specification

identifies “application servers and/or databases with storage and retrieval capabilities” as discrete network resources, separate from compute nodes. *Id.*, 31:2-10; EX2014, ¶80. That language mirrors Plaintiffs’ proposed definition of a database: a store built for structured retrieval.

The “Summary of Invention” section echoes this theme by describing the invention as “a network-based (e.g., cloud-based) support platform allowing multiple users to store, access, analyze, and/or provide feedback regarding a given set of image data for a patient” and stating that that the approach “allow[s] multiple users to store, access, analyze, and/or provide feedback regarding a given set of image data for a patient.” *Id.*, 3:1-14. Such language further affirms that “database” means a structured, multi-record repository. EX2014, ¶¶80, 81.

The specification also describes how the claimed invention causes the processor to “repeatedly receive and store in a database over time, a plurality of medical images for each of the one or more patient(s) to obtain, a series of medical images taken over time (e.g., over the course of multiple visits to one or more doctors . . . thereby tracking determined values of the one or more risk indices over a course [of] prostate cancer progression and treatment for the patient[.]” *Id.*, 11:47-62; EX2014, ¶82. The database thus inherently carries multiple records (patients, series, images, etc.) and multiple fields (timestamps, modality, dose, metadata, etc.). EX2014, ¶81.

In light of both the claim language and the specification, a POSA would understand that a “database” thus refers to a large, structured set of data that contains multiple records that contain multiple fields. EX2014, ¶84.

The Petition, on the other hand, contends that “database” “do[es] not require an express construction” and thus should be given its plain and ordinary meaning. Pet., 9. However, the Petition relies on an incorrect construction of “database” because the Petition repeatedly argues that the asserted references’ disclosure of a “memory” satisfies the disclosure of a “database” in the ’346 Patent. Pet., 24. The Petition’s conflation of “memory” and “database” fails for at least three reasons.

First, the Petition’s equation of “memory” and “database” offends Claim 1’s express differentiation of those two terms. Claim 1 begins: “**A network-based system . . . the system comprising: a processor; and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to: (i) access one or more medical images associated with a particular patient from a database.**” EX1001, 35:46-55 (emphasis added); EX2014, ¶¶78-79. Claim 1 thus distinguishes three separate elements: the “processor,” “the memory having instructions,” and a “database” from which the processor accesses one or more medical images. Reading “database” to mean a simple memory would thus collapse the two expressly different claim terms. *Supra*, 16-17.

Second, the Petition ignores how the specification describes “memory” as a hardware element within the computing device, whereas “database” means a structured store of data. *See, e.g.*, EX1001, 32:12-17 (“The memory 804 stores information within the computing device 800. In some implementations, the memory 804 is a volatile memory unit or units. In some implementations, the memory 804 is a non-volatile memory unit or units. The memory 804 may also be another form of computer-readable medium, such as a magnetic or optical disk.”); 33:57-65 (“The memory may include, for example, flash memory and/or NVRAM memory . . . The instructions can also be stored by one or more storage devices, such as one or more computer- or machine-readable mediums (for example, the memory 864 . . .”); EX2014, ¶83.

The Petition fails to offer any evidence or argument under the correct construction of “database.” Thus, the Petition fails to carry its burden at the institution phase and institution should be denied.

c. The Petition relies on an implied construction of “machine learning algorithm” that is unclear and internally inconsistent.

The term “machine learning algorithm” is a key element of both independent claims of the ’346 Patent (claims 1 and 13). Both claims recite “using a machine learning algorithm” to perform the analysis required to create a risk map. EX1001, 35:56-58, 36:48-50. The Petition acknowledges the importance of the term. *See*,

e.g., Pet., 2 (beginning the Petition by noting that “[t]he Patent is generally directed to a system for automatically analyzing one or more medical images of a patient using ‘a machine learning algorithm’ . . . ”). Yet the Petition contends that the term “machine learning algorithm” “do[es] not require an express construction” and thus should be given its plain and ordinary meaning. Pet., 9; EX2014, ¶85.

Institution should be denied, however, because the Petition’s anticipation and obviousness arguments depend on “machine learning algorithm” having a facially implausible and internally inconsistent meaning. EX2014, ¶85. The Petition argues that all three primary references (Renisch, Sprencz, Suehling) disclose the use of a “machine learning algorithm” even though those references disclose the use of three fundamentally different techniques. *Id.* For example, the Petition argues that Renisch discloses a “machine learning algorithm” because Renisch mentions a “neural network,” Sprencz discloses a “machine learning algorithm” because Sprencz mentions “clustering,” and Suehling discloses a “machine learning algorithm” because Suehling mentions “marginal space learning” technique. Pet., 25, 48, 63; EX2014, ¶86. These are three completely different concepts across three completely different references. EX2014, ¶87. A neural network is a specific computational model that may be used (e.g., trained) in machine learning methods, but the two terms (i.e., “neural network” and “machine learning”) are not one and the same. EX2014, ¶¶41-43, 88. Clustering, on the other hand, refers to a general

class of statistical methods for grouping objects according to patterns in data. EX2014, ¶88. Clustering methods do not necessitate the use of machine learning. *Id.* Marginal space learning (MSL) is a segmentation technique that uses a sequence of weak classifiers that model parameters like organ position, orientation, and scale. *Id.*

The Petition never explains why these three different techniques all nonetheless qualify as a “machine learning algorithm” as a POSA would understand the term as of the priority date of the ‘346 patent.¹ EX2014, ¶¶89-91. Given the Petition’s reliance on a facially implausible and internally inconsistent construction of a key term, the Petition fails to offer any evidence of unpatentability under a proper claim construction per 37 C.F.R. § 42.104(b).²

¹ Furthermore, all three techniques are different than what the ’346 Patent refers to as “machine learning techniques” in the context of image segmentation and specific examples of deep-learning. EX1001, 25:33-35; EX2014, ¶¶90-91.

² Given that the Petition fails to carry its burden of proof because it relies on a facially implausible construction of “machine learning algorithm,” the Board can deny institution without considering a proposed alternative construction from Patent Owner. However, Patent Owner reserves the right to propose an alternative construction if the Board deems it necessary to deny institution.

Thus, institution should be denied because the Petition relies on an incorrect construction of the key term “machine learning algorithm.” *See also infra*, Section VII.

VII. THE PETITION DOES NOT ESTABLISH A “REASONABLE LIKELIHOOD” OF UNPATENTABILITY

Under 35 U.S.C. § 314(a), the Board may not institute inter partes review unless the Petition demonstrates “that there is a reasonable likelihood that the petition 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. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (“[T]he 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.

a. Ground A: Renisch does not anticipate claims 1-7, 9-10, or 13.

The Petition fails to establish a reasonable likelihood that Renisch anticipates claims 1-7, 9-10, and 13. Since claims 1 and 13 are the only independent claims, Patent Owner addresses each in turn. EX2014, ¶¶93-95, 106-08.

i. Renisch does not disclose a “network-based system” as recited in the preamble of claim 1.

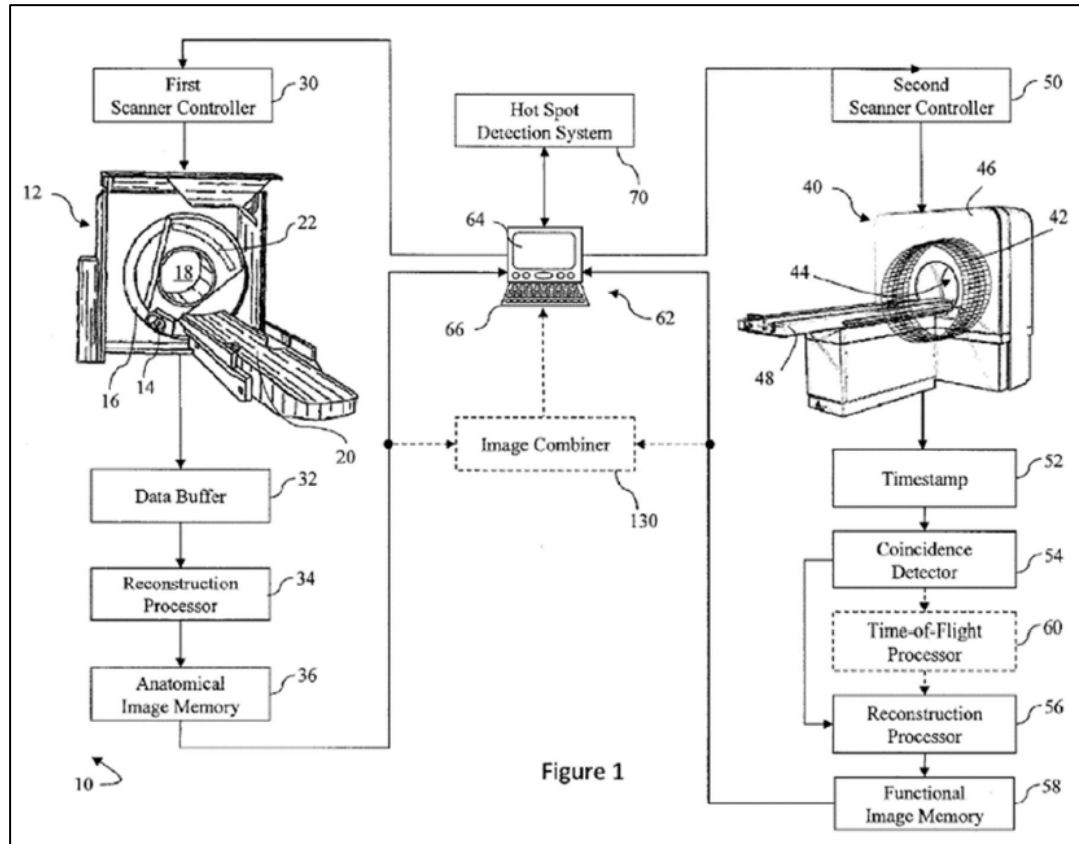
The preamble of Claim 1 recites “[a] **network-based system** for generating a disease risk map for use as a decision-making support for evaluating risk of cancer or risk of recurrence of cancer, the system comprising:” EX1001, 35:45-49; EX2014, ¶¶96. Renisch does not disclose the use of a “network-based system.”

As explained above, a POSA would understand that a “network-based system” comprises a system involving interaction across multiple interconnected and physically dispersed computing devices. *See supra*, Section VI(a); EX2014, ¶¶97. This is an important distinction, as it differentiates the technology described in the ’346 Patent from conventional computer workstations, which are dedicated computers tied to specific imaging devices and used solely to view images created on those devices. EX2014, ¶¶97.

In contrast to conventional workstations, the ’346 Patent’s specification emphasizes how the claimed “network-based system” utilizes cloud and internet-based services, enabling multiple users—including physicians, radiologists, and patients—to access and analyze medical images. EX1001, 3:1-14, 3:43-3:67, 27:1-10, 28:30-50. EX2014, ¶¶97. This feature is particularly significant for cancer diagnosis, monitoring, and treatment, which can span many years and require repeated visits to various healthcare providers. EX2014, ¶¶61, 97, 117.

Renisch does not disclose a “network-based system” because it only describes the use of a single computer workstation connected to a medical scanner. EX1005, [0020], Fig. 1; EX2014, ¶98. That setup does not involve interaction across multiple interconnected and physically dispersed computing devices. EX2014, ¶98. Thus, Renisch does not disclose a “network-based system.”

For instance, the Petition incorrectly asserts that Figure 1 of Renisch discloses a “network-based system”:



Petitioner argues that Figure 1 discloses a network-based system because “the automatic hotspot detection system 70 is interconnected for sharing data and resources with a workstation/GUI 62 as well as an anatomical imaging system 12

and a functional imaging system 40.” Pet., 21. Renisch itself, however, never describes Figure 1 as illustrating an “interconnected” system—that description is Petitioner’s own invention. EX2014, ¶99. Moreover, as Figure 1 reflects, the referenced “automatic hot spot detection system 70” is a software system, not a separate and interconnected computer device that is part of a “network-based system.” EX2014, ¶99.

Thus, Renisch does not anticipate claim 1 because it neither mentions a “network” nor describes anything that a POSA would consider to be “a network-based system.” EX2014, ¶100.

ii. Renisch does not disclose “access[ing] . . . one or more medical images . . . from a database,” as recited in claims 1 and 13.

The Petition also fails to show that Renisch discloses limitation (i) of claim 1, which recites “access[ing] . . . one or more medical images . . . from a database,” as required by independent claim 1. EX2014, ¶101.

As explained above, a POSA would understand that a “database” comprises a large, structured set of data that contains multiple records that contain multiple fields. *See supra*, Section VI(b); EX2014, ¶102.

Like for the “network-based system” limitation, the Petition relies on Figure 1 to argue that Renisch satisfies this limitation. EX2014, ¶103. Specifically, the Petition contends that Renisch discloses the use of a “database” because Renisch

teaches that an “automatic hotspot detection system 70 . . . accesses medical images from an anatomical image **memory** 36 of a first scanner 12 and a functional image **memory** 58 of a second scanner 40. The images . . . are both associated with a particular patient.” Pet., 24 (emphasis added). The Petition asserts that accessing scanner images from a “memory” is equivalent to using a “database.” *Id.*; EX2014, ¶103.

The Petition’s cursory argument is unavailing. The quoted passage from Renisch (and Figure 1 itself) does not even mention a “database.” *See* EX2014, ¶103. The referenced “first scanner 12” and “second scanner 40” are imaging devices, not a “database.” *Id.* Meanwhile, “anatomical image memory 26” and “functional image memory 58” are memories, not a “database.” *Id.* As discussed above, “memory” and “database” are clearly not equivalent as claimed in the ’346 Patent. *See supra*, Section VI(b); EX2014, ¶103. The Petition does not attempt to

justify its conflation of the two terms.³ Therefore, the Petition fails to show that Renisch discloses limitation (i) of claim 1.

Since the same limitation appears as limitation (i) of claim 13, this same shortcoming applies equally to independent claim 13. Renisch therefore does not anticipate independent claim 13. EX2014, ¶¶107-08.

iii. Renisch does not disclose “perform[ing] an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map,” as recited in claim 1.

Institution should also be denied because the Petition fails to show that Renisch discloses “perform[ing] an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map,” as recited in independent claim 1.

³ This is an especially glaring omission since the conventional definition of “a memory” differs from “a database.” A “memory” for computer engineering is “any device that holds computer data.” *See, e.g., Memory*, Basic Computer Terms, Portland State University (last accessed July 11, 2025), <https://web.pdx.edu/~stipakb/download/PA550/BasicComputerTerms.htm>. A “database” is “a large structured set of data; a file that contains numerous records that contain numerous fields.” *Id.*, *Database*.

The Petition argues that Renisch’s use of “segmentation unit 76” qualifies as “using a machine learning algorithm” per limitation (ii) of claim 1 because “segmentation unit 76 is capable of employing different types of segmentation methods including machine learning algorithms such as a ‘neural network’[.]” Pet., 25-26.

But, as discussed above, the Petition relies on an implausible and inconsistent construction of “machine learning algorithm.” *See supra*, Section VI(b); EX2014, ¶104. The Petition cannot—and does even attempt to—square its argument that Renisch’s one-off allusion to a “neural network” qualifies as disclosing a “machine learning algorithm” alongside Sprencz’s allusion to “clustering” and Suehling’s discussion of “marginal space learning.” Since the Petition’s construction of “machine learning algorithm” is implausible, the Petition necessarily fails to create a reasonable likelihood that limitation (ii) of claim 1 is unpatentable over Renisch. EX2014, ¶104.

b. Ground B: Renisch and Wu do not render claims 1-7 or 9-10 obvious.

For Ground B, the Petition only alleges that Wu discloses “a network-based system”, but otherwise relies on Renisch for every other element of claim 1. Pet., 22-23; EX2014, ¶109. The Petition does not contend that Wu discloses any other

limitations of claim 1. EX2014, ¶109. Accordingly, for at least the reasons above, Renisch and Wu fail to render claim 1 obvious. EX2014, ¶109.

c. Ground C: Renisch, Wu, AAPA, and D’Souza do not render claim 5 obvious.

For Ground C, the Petition adds AAPA and D’Souza to Renisch and Wu. Pet., 8, 31-33. Neither addition changes the obviousness analysis discussed above for claim 1 (from which claim 5 depends). Ground C should thus be denied.

First, the Petition improperly relies on alleged AAPA. The Federal Circuit recently clarified that IPR petitions cannot rely on AAPA “in combination” with prior art patents or printed publications. *Qualcomm Inc. v. Apple Inc.*, 134 F.4th 1355, 1365 (Fed. Cir. 2025). In that case, the Federal Circuit concluded that the petition impermissibly relied on AAPA for Ground 2 because the “petition opened with a table that prominently labeled the ‘Basis’ of Ground 2 as ‘**AAPA in view of [other reference].**’” *Id.*, 1366 (emphasis added).

That is exactly how the Petition relies on alleged AAPA. The Petition’s Ground C is based on “Renisch, or Renisch in view of Wu, each in view of **the Applicant’s Admitted Prior Art (AAPA)** or D’Souza.” Pet., 8 (emphasis added). Ground H is based on “Sprenecz in view of **AAPA** or D’Souza.” *Id.* (emphasis added). Therefore, Grounds C (and H) fail to the extent they rely on alleged AAPA in combination with other prior art.

Second, D’Souza does not render claim 5 obvious. EX2014, ¶111. The Petition only relies on D’Souza for the alleged disclosure of prostate cancer-specific radiotracers. Pet., 32-33; EX2014, ¶111. The Petition does not contend that D’Souza discloses the other limitations of claim 1 discussed above that do not appear in Renisch or Wu. EX2014, ¶111. Therefore, for at least the reasons above, Renisch, Wu, and D’Souza fail to render claim 5 obvious. EX2014, ¶111.

d. Ground D: Renisch, Wu, and Sprencz do not render claim 8 obvious.

For Ground D, the Petition alleges that Sprencz discloses 3D image analysis for bones, but otherwise relies on Renisch (and Wu) for every other element of claim 8. Pet., 34-36; EX2014, ¶112. The Petition does not contend that Sprencz (or Wu) discloses any other limitations of claim 1, from which claim 8 depends. EX2014, ¶112. Accordingly, for at least the reasons above, Renisch, Wu, and Sprencz fail to render claim 8 obvious. EX2014, ¶112.

e. Ground E: Renisch, Wu, and Maier do not render claims 9-11 obvious.

For Ground E, the Petition alleges that Maier discloses the generation and use of a radiologist report as recited in claims 9-11, but otherwise relies on Renisch (and Wu) for every other element of claims 9-11. Pet., 37-39, 40; EX2014, ¶113. The Petition does not contend that Maier (or Wu) discloses any other limitations of claim

1, from which claims 9-11 depend. EX2014, ¶113. Accordingly, for at least the reasons above, Renisch, Wu, and Maier fail to render claims 9-11 obvious. *Id.*

f. Ground F: Renisch, Wu, and Menon do not render claim 12 obvious.

For Ground F, the Petition alleges that Menon discloses “an automated triaging decision support tool that utilizes machine learning to continuously refine the tool,” but otherwise relies on Renisch (and Wu) for every other element of claim 12. Pet., 41-42; EX2014, ¶114.. The Petition does not contend that Menon (or Wu) discloses any other limitations of claim 1, from which claim 12 depends. EX2014, ¶114. Accordingly, for at least the reasons above, Renisch, Wu, and Menon fail to render claim 12 obvious. EX2014, ¶114.

g. Ground G: Sprencz does not anticipate claims 1-10 or 13.

The Petition fails to establish a reasonable likelihood that Sprencz anticipates claims 1-10 and 13. EX2014, ¶115. Since claims 1 and 13 are the only independent claims, Patent Owner addresses each in turn.

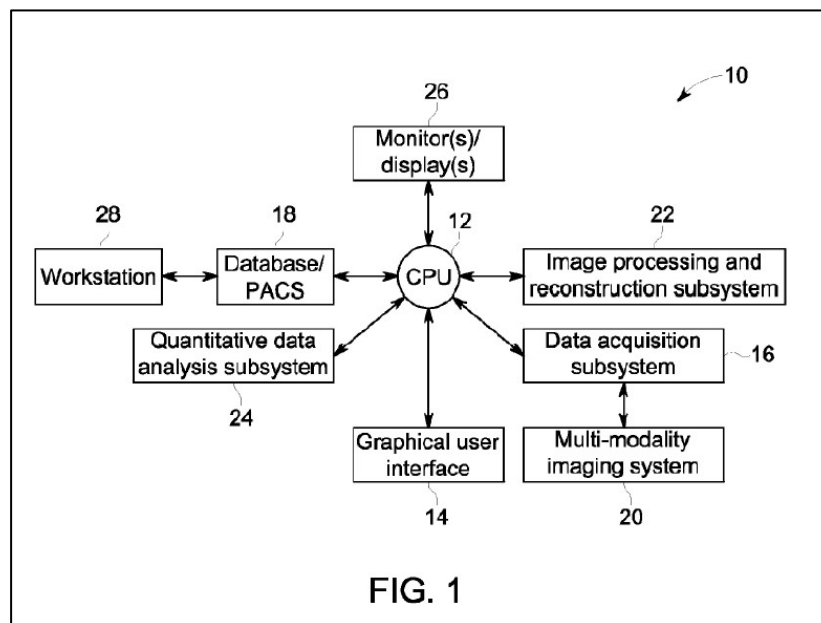
i. Sprencz does not disclose a “network-based system” as recited in claim 1.

Claim 1 recites “[a] network-based system for generating a disease risk map for use as a decision-making support for evaluating risk of cancer or risk of recurrence of cancer, the system comprising:”. EX1001, 35:46-49; EX2014, ¶116. Sprencz does not disclose such a “network-based system.” EX2014, ¶116.

As discussed above, a POSA would understand that a “network-based system” comprises a system involving interaction across multiple interconnected and physically dispersed computing devices. *See supra*, Section VI(a); EX2014, ¶117. The ’346 Patent’s specification repeatedly explains how the claimed network-based system uses cloud- and/or internet-based services by which multiple users (e.g., physicians, radiologists, patients) access and analyze patients’ medical images. EX1001, 3:1-14, 3:43-3:67, 27:1-10, 28:30-50; EX2014, ¶117.

Sprencz does not disclose such a “network-based system.” The Petition’s two arguments to the contrary rely on a conclusory and incorrect mischaracterization of Sprencz. Neither is persuasive. EX2014, ¶118.

First, the Petition argues that Figure 1 of Sprencz discloses a “network-based system”:



Specifically, the Petition argues that Figure 1 discloses a “network-based system” by “disclos[ing] a **distributed system** 10 controlled by a CPU 12 and including one or more **remotely located imaging system** 20, workstation 28, and image database 18.” Pet., 44-45 (emphasis added). EX2014, ¶¶119-20. However, the terms “distributed system” and “remotely located imaging system” do not appear in Sprencz; they are inventions of the Petitioner. EX2014, ¶121. Instead, Sprencz describes system 10 simply as an “imaging system” and system 20 as a “multi-modality imaging subsystem.” EX1006, [0023]-[0027]; EX2014, ¶121. Sprencz does not disclose a “network-based system” as understood by a POSA. EX2014, ¶121.

Second, the Petition argues that Sprencz discloses a “network-based system” because Sprencz states that “database 18” in Figure 1 above “may be . . . remotely located from the site of data acquisition,” i.e., workstation 28. Pet., 45 (“it is contemplated that a dedicated workstation 28 having a computer, monitor(s), and operably connected to the one or more databases may be used such that a physician may analyze the image and quantitative data remote from the scanner.”); EX2014, ¶122. Based on this passage, the Petition conclusorily asserts that “Sprencz’s system for obtaining, analyzing, and displaying images is carried out on a network of remotely located components.” *Id.*; EX2014, ¶123. However, the Petition never explains why a “remotely located” database means that the overall disclosed system

is necessarily a “network-based system.” EX2014, ¶123. Nor does the Petition address Patent Owner’s discussion above about how a single workstation attached to a scanner cannot qualify as a “network-based system.” *See supra*, Section VI(a); EX2014, ¶123. Therefore, the Petition fails to show that Sprencz discloses this limitation. EX2014, ¶123.

- ii. **Sprencz does not disclose “perform[ing] an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map” as recited in claim 1.**

Limitation (ii) of claim 1 recites “perform[ing] an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map.” EX1001, 35:56-58.

Sprencz does not disclose this limitation as correctly construed. Sprencz never refers to “machine learning,” “artificial intelligence,” “train,” or “learn.” Nor does Sprencz describe any kind of data-driven supervised learning system.

Unable to point to any straightforward disclosure of a machine learning algorithm, the Petition argues that Sprencz’s disclosure of clustering for bone segmentation qualifies as a “machine learning algorithm.” Pet., 46-48 (“Although bone segmentation can be accomplished by something as simple as thresholding, Sprencz also states that ‘one having skill in the art will recognize that embodiments of the invention may segment different anatomical region bone structures using

alternative techniques, such as, for example, clustering.’ Clustering is a machine learning technique for image segmentation.”) (citation omitted). EX2014, ¶124.

But, as discussed above, the Petition relies on an implausible and inconsistent construction of “machine learning algorithm.” *See supra*, Section VI(c); EX2014, ¶124. The Petition cannot—and does even attempt to—square its argument that “machine learning algorithm” encompasses: (a) Renisch’s one-off allusion to a “neural network,” (b) Sprencz’s allusion to “clustering,” and (c) Suehling’s discussion of “marginal space learning.” EX2014, ¶124. Since the Petition’s construction of “machine learning algorithm” is implausible, the Petition necessarily fails to create a reasonable likelihood that limitation (ii) of claim 1 is unpatentable over Sprencz. EX2014, ¶124.

h. Ground H: Sprencz, AAPA, and D’Souza do not render claim 5 obvious.

Ground H fails for the same reasons as Ground C. *See supra*, Section VII(c); EX2014, ¶125. Ground H impermissibly relies on AAPA in a way that the Federal Circuit has expressly rejected. *Id.* And Ground H’s reliance on D’Souza for prostate cancer radiotracers does not plug the shortcomings in Spencz vis-à-vis claim 5. *Id.* Ground H thus fails for the same reasons as Ground C.

i. Ground I: Sprencz and Maier do not render claim 11 obvious.

For Ground I, the Petition alleges that Maier discloses the use of reference images, but otherwise relies on Sprencz for every other element of claim 11. Pet.,

57-59; EX2014, ¶126. The Petition does not contend that Maier discloses any other limitations of claim 1, from which claim 11 depends. EX2014, ¶126. Accordingly, for at least the reasons above, Sprencz and Maier fail to render claim 11 obvious. EX2014, ¶126.

j. Ground J: Suehling does not anticipate the challenged claims.

The Petition fails to establish a reasonable likelihood that Suehling anticipates claims 1-10 and 13. EX2014, ¶127. Since claims 1 and 13 are the only independent claims, Patent Owner addresses each in turn.

i. Suehling does not disclose “access[ing]...one or more medical images...from a database” as recited in claims 1 and 13.

Limitation (i) of claim 1 recites “access[ing] one or more medical images associated with a particular patient from a database.” EX1001, 35:54-55; EX2014, ¶128.

As explained above, a POSA would understand that a “database” comprises a large, structured set of data that contains multiple records that contain multiple fields. *See supra*, Section VI(b); EX2014, ¶129. Suehling does not disclose this limitation. EX2014, ¶130.

The Petition argues that Suehling teaches this limitation because it discloses that a 3D medical image “can be received by loading a medical image that was previously stored, for example **on a memory** or storage of a computer system or a computer readable medium.” Pet., 62 (emphasis added); EX2014, ¶130. As with

Renisch, however, the Petition never attempts to explain how accessing an image from “a memory” is tantamount to accessing the image from “a database”—especially given that POSAs recognize a clear distinction between those two terms. *See supra*, Section VI(b); EX2014, ¶¶78-79, 130.

Therefore, Suehling does not disclose limitation (i) of claim 1. EX2014, ¶131. Since the same limitation appears as limitation (i) of claim 13, this same shortcoming applies equally to independent claim 13. EX2014, ¶131. Suehling therefore does not anticipate independent claim 13. EX2014, ¶131.

ii. Suehling does not disclose “perform[ing] an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map” as recited in claim 1.

Limitation (ii) of claim 1 recites “perform[ing] an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map.” EX1001, 35:56-58.

Suehling does not disclose this limitation as properly construed. The Petition argues that Suehling uses a “machine learning algorithm” because Suehling discloses the use of “marginal space learning (MSL).” Pet., 62-63; EX2014, ¶132. But, as discussed above, the Petition relies on an implausible and inconsistent construction of “machine learning algorithm.” *See supra*, Section VI(c); EX2014, ¶132. The Petition cannot—and does even attempt to—square its argument that

“machine learning algorithm” encompasses: (a) Renisch’s one-off allusion to a “neural network,” (b) Sprencz’s allusion to “clustering,” and (c) Suehling’s discussion of “marginal space learning.” EX2014, ¶132. Since the Petition’s construction of “machine learning algorithm” is implausible, the Petition necessarily fails to create a reasonable likelihood that limitation (ii) of claim 1 is unpatentable over Suehling. *Id.*

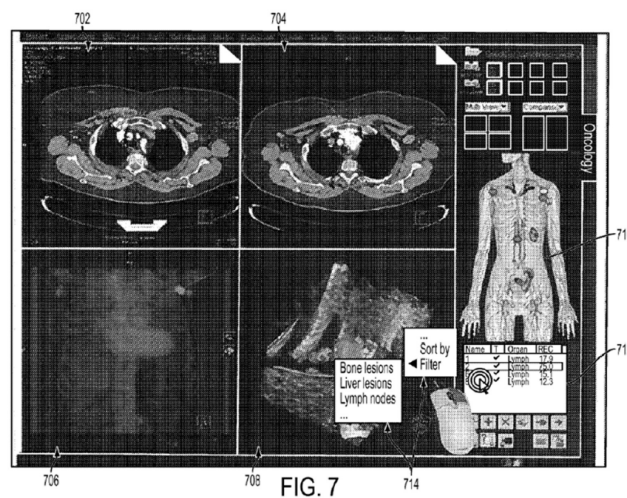
- iii. **Suehling fails to disclose “wherein the analysis of the one or more medical images comprise creation of a 3D image...wherein the 3D image comprises geographic identification of one or more specific tissue region(s) overlaid on the one or more medical images,” as recited in claim 1.**

Limitation (e) (as referred to by the Petition) of claim 1 recites: “wherein *the analysis* of the one or more medical images comprises creation of a 3D image of the one or more regions of risk of cancer or risk of recurrence of cancer overlaid on the one or more medical images, *and* wherein *the 3D image* comprises geographic identification of one or more specific tissue region(s) overlaid on the one or more medical images.” EX1001, 36:1-7 (emphasis added); EX2014, ¶133. The limitation thus specifies that “the analysis of the one or more medical images,” i.e., the analysis recited earlier, at step (ii), of claim 1, “comprises creation of a 3D image,” and that **the 3D image: (1) comprises “the one or more regions of risk of cancer ... overlaid on the one or more medical images” and (2) “geographic identification of one or**

more specific tissue region(s) overlaid on the one or more medical images.” *Id.* (emphasis added).

The Petition fails to show that Suehling discloses all elements of this limitation, for at least two reasons.

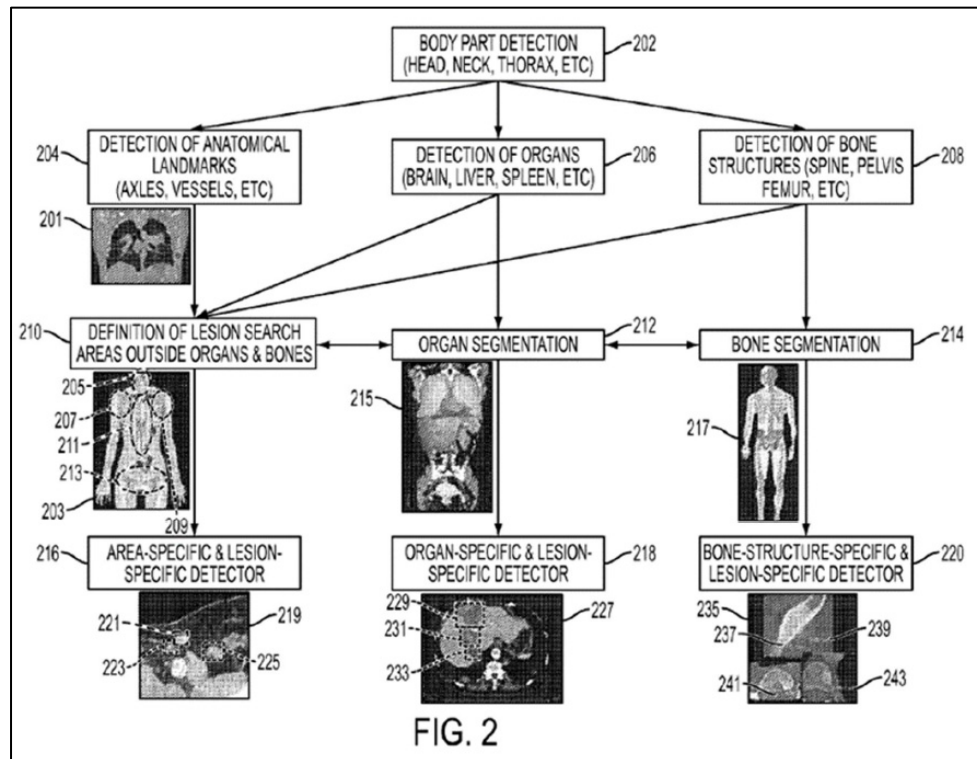
First, Suehling never discloses a graphical overlay of segmented lesions on segmented anatomical structures. EX2014, ¶135. The Petition points to Figure 7 of Suehling, but Figure 7 does not show a “graphical overlay of segmented lesions on segmented anatomical structures”:



Pet., 64-65. Nothing in Figure 7 shows a “segmented anatomical structure,” let alone a “graphical overlay of segmented lesions on segmented anatomical structures.” EX2014, ¶136.

Second, the Petition does not—and cannot—identify a single 3D image in Suehling that comprises both of the key claimed features in limitation (e) of claim 1: (1) “regions of risk of cancer . . . overlaid on medical images;” and (2) “geographic

identification of specific tissue region(s) overlaid on the medical images.” EX2014, ¶137. The Petition suggests that Figure 2 may reflect this disclosure, but the Petition misrepresents Figure 2:



Pet., 64-66. The Petition points to images 215 and 217 as allegedly showing “segmented tissue regions overlaid on the medical image,” and then points to images 227 and 235, which show lesions. Pet., 64-65; EX2014, ¶138. But images 215 and 217 are two separate sets of images. EX2014, ¶138. Claim 1 is clear: the 3D image that comprises the overlay of regions of risk of cancer is the same 3D image that also comprises geographic identification of regions of risk of cancer. *Id.* Thus, the Petition fails to show how Suehling discloses the relevant claim limitations. *See id.*

Accordingly, Suehling fails to disclose an image with the features recited in claim 1.

k. Ground K: Suehling and Maier do not render claim 11 obvious.

For Ground K, the Petition only alleges that Maier discloses elements specific to claim 11 that are not disclosed by Suehling, but otherwise relies on Suehling for every other element of claim 11. Pet., 70-72; EX2014, ¶139. The Petition does not contend that Maier discloses the limitations absent from Suehling, which Patent Owner identified above. *See supra*, Section VII(i); EX2014, ¶139. Accordingly, for at least the reasons above, Suehling and Maier fail to render claim 11 obvious. EX2014, ¶139.

l. Ground L: Suehling and Menon do not render claim 12 obvious.

For Ground L, the Petition only alleges that Menon discloses elements specific to claim 12 that are not disclosed by Suehling, but otherwise relies on Suehling for every other element of claim 12. Pet., 73; EX2014, ¶140. The Petition does not contend that Menon discloses the other limitations absent from Suehling, which Patent Owner identified above. *See supra*, Section VII(j); EX2014, ¶140. Accordingly, for at least the reasons above, Suehling and Menon fail to render claim 12 obvious. EX2014, ¶140.

VIII. CONCLUSION

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

Date: July 12, 2025

Respectfully submitted,

By: /William R. Haulbrook/

William R. Haulbrook (Reg. No. 53,002)

Stephanie L. Schonewald (Reg. No. 72,452)

Michael H. Bunis (*pro hac vice* to be filed)

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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 8,160 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 July 12, 2025 via electronic mail to the following attorneys of record:

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