

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

DECLARATION OF MILAN SONKA, PH.D.

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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	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.
EX2007	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.
EX2008	Scheduling Order, <i>Progenics Pharmaceuticals v. MIM Software Inc.</i> , Civil Action No. 1:24-cv-10437-PBS, Dkt. 85, Mar. 5, 2025.
EX2009	MIM's Invalidity and Noninfringement Contentions, Civil Action No. 1:24-cv-10437-PBS.
EX2010	U.S. District Courts, Judicial Caseload Profile 2024 (D. Mass. excerpted).
EX2011	MIM's Responses & Objections to Plaintiffs' First Set of Interrogatories (excerpted pp. 1, 13-14), Civil Action No. 1:24-cv-10437-PBS.

EXHIBIT	DESCRIPTION
EX2012	<i>Cancer Control Month, 2025 – The White House</i> (Apr. 3, 2025).
EX2013	<i>NIH Strategic Plan for Data Science FY 2025-2030</i> , Nat’l Institutes of Health.
EX2014	Declaration of Dr. Milan Sonka.
EX2015	Curriculum Vitae of Dr. Milan Sonka.
EX2016	RESERVED
EX2017	Crisan, et al., <i>Radiopharmaceuticals for PET and SPECT Imaging: A Literature Review over the Last Decade</i> , International Journal of Molecular Sciences 23(9):5023 (2022).
EX2018	<i>PET Scans</i> , CancerQuest, Emory Winship Cancer Institute (2025).
EX2019	Rowe, S.P., et al., <i>PSMA-Based [¹⁸F]DCFPyL PET/CT Is Superior to Conventional Imaging for Lesion Detection in Patients with Metastatic Prostate Cancer</i> , Molecular Imaging and Biology 18(3):411-419 (2016).
EX2020	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).
EX2024	Brown, <i>Machine Learning, Explained</i> , MIT Sloan (Apr. 21, 2021).
EX2025	RESERVED
EX2026	Krizhevsky, et al., <i>ImageNet Classification with Deep Convolutional Neural Networks</i> , Advances in Neural Information Processing Systems 25 (2012).
EX2027	Deng, et al., <i>ImageNet: A large-scale hierarchical image database</i> , IEEE Conference on Computer Vision and Pattern Recognition (2009).

EXHIBIT	DESCRIPTION
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.
EX2030	Kelleher, <i>Deep Learning</i> (2019), Ch. 1, “What Is Machine Learning?,” pp. 9-17.
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, Milan Sonka, hereby declare as follows:

I. INTRODUCTION

1. I have been retained by Progenics Pharmaceuticals, Inc. (“Progenics”) to provide expert opinions in this *Inter Partes* Review (IPR). I am being compensated for my time at my customary rate of \$715 per hour for my work on this matter. I am being paid for my time regardless of the outcome of this IPR. Beyond the compensation I received for my time in this matter, I will not be affected in any way, positively or negatively, by the outcome of this case.

II. QUALIFICATIONS

2. I am Professor of Electrical and Computer Engineering in the College of Engineering at the University of Iowa. I also hold the Lowell C. Battershell Chair in Biomedical Imaging, am the co-director of the Iowa Institute for Biomedical Imaging, and am the Director of the Iowa Initiative for Artificial Intelligence. I also hold secondary appointments at the University of Iowa in the Applied Mathematical and Computational Sciences, Ophthalmology and Visual Sciences, Radiation Oncology, and Biomedical Engineering departments.

3. I earned my Ph.D. in Technical Cybernetics-Digital Image Analysis from the Czech Technical University of Prague in 1983.

4. I was an Assistant Professor at the Czech Technical University of Prague from 1984-1990, before moving to the University of Iowa, where I have been a professor since 1990.

5. For the past 35 years, as the head of a research group at the University of Iowa, I have researched and developed techniques for semi-automated and automated analysis of medical images, including foundational research in quantitative medical image analysis and medical image segmentation, and development of artificial intelligence (AI) and machine learning (ML) techniques for prediction of disease outcomes and image analysis.

6. I was elected as a Fellow of the Institute of Electrical and Electronics Engineers (IEEE) in 2002 for my contributions to medical image analysis and computer vision. I am also a fellow of the American Institute for Medical and Biomedical Engineering, a fellow of the Medical Image Computing and Computer-Aided Intervention Society, and a Fellow of the National Academy of Inventors.

7. My curriculum vitae is provided herewith as EX2015.

III. MATERIALS CONSIDERED

8. In forming my opinions, I have read U.S. Patent No. 10,665,346 (the “346 Patent”) (EX1001) and reviewed relevant parts of its prosecution history. I have also reviewed the Petitioner’s Petition for *Inter-Partes* Review (IPR) dated February 21, 2025 (the “Petition”) along with the accompanying Declaration of Dr.

Rosen (EX1002). I have also reviewed the following references, which the Petitioner cited in their Petition against the '346 Patent:

- U.S. Patent Application Publication No. 2012/0123253 (“Renisch”) (EX1005);
- U.S. Patent Application Publication No. 2015/0063667 (“Sprenicz”) (EX1006);
- U.S. Patent Application Publication No. 2011/0007954 (“Suehling”) (EX1007);
- U.S. Patent Application Publication No. 2016/0203263 (“Maier”) (EX1008);
- U.S. Patent Application Publication No. 2016/0335395 (“Wu”) (EX1009);
- U.S. Patent No. 9,028,800 (“D’Souza”) (EX1010); and
- U.S. Patent Application Publication No. 2016/0180042 (“Menon”) (EX1012).

9. I have also reviewed other references that illuminate the state of the art as of October 27, 2016, which I have been instructed to use as the “priority date” of the '346 Patent. I have also called upon my extensive knowledge and experience in the field of medical imaging, medical image analysis, and artificial intelligence and machine learning.

10. I reserve the ability to review documents, deposition transcripts, or other information provided to me after the date of this Declaration and to supplement my opinions based upon such review.

IV. LEGAL PRINCIPLES

11. I have been informed of the following legal standards by Patent Owner's attorneys. I am not an attorney, but I have applied these understandings in my analysis herein.

A. Priority Date

12. I have been instructed to assume for purposes of my analysis that October 27, 2016 is the "priority date" for assessing the state of the art and for determining what is "prior art" when considering whether the claims of the '346 Patent would have been obvious.

B. A Person of Ordinary Skill in the Art

13. I have been asked to develop and offer opinions related to how a person of ordinary skill in the art ("POSA") would have understood the '346 Patent and the relevant references cited herein as of the priority date (October 27, 2016).

14. I have been informed and understand that certain factors may be considered in determining the level of ordinary skill in the art, for example, (1) the types of problems encountered in the art, (2) the prior art solutions to these problems, (3) the rapidity with which innovations are made, (4) the sophistication of the technology, and (5) the educational level of active workers in the field.

15. It is my opinion that a POSA for purposes of the '346 Patent 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.

16. I consider myself to be at least a POSA and to have been at least a POSA as of the priority date, October 27, 2016.

C. Claim Construction

17. I have been informed and understand that, in an IPR proceeding, the claims of a patent are to “be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b).

18. Specifically, I have been informed and understand that under the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), the claims of a patent are given their ordinary and customary meaning as would be understood by a POSA at the time of the invention. I have been informed that a *Phillips* construction of a claim is based on the entire record, including both intrinsic evidence (*i.e.*, the claims, specification, and prosecution history) as well as extrinsic evidence (*e.g.*, dictionary definitions and expert testimony). I have applied this standard in formulating my opinions in this matter.

19. I reserve the right to supplement my opinions in view of any additional information regarding the interpretation of the claims of the '346 Patent that becomes available to me and any matters raised by the parties, the Board, and/or other experts in this matter.

D. Novelty and Non-Obviousness

20. I have been informed that to be valid patent claims must be novel and nonobvious. 35 U.S.C. §§ 102 and 103.

21. I have been informed that a patent claim is not novel if it is anticipated by a prior art reference. I have been informed that in order for a prior art reference to anticipate a claim, that prior art reference must disclose each and every limitation as set forth in the claim.

22. I have been informed and understand that a patent claim is obvious if the differences between what is set forth in the claims and what is disclosed in the prior art are such that what is claimed would have been obvious to a POSA as of the patent's priority date (October 27, 2016 in the case of the '346 Patent). I have been informed and understand that a POSA is presumed to have knowledge of all of the relevant art as of the priority date. I have further been informed and understand that as part of the analysis of whether a patent claim is obvious, I should consider: (a) the scope and content of the prior art; (b) the level of ordinary skill in the art; (c) the

differences between what is claimed and the prior art; and (d) any secondary considerations that may indicate that the claim is not obvious.

23. I have been informed and understand that obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so; and that a reasonable expectation of success in achieving the subject matter of the claim at issue must also be shown. Further, I have been informed and understand that the teaching, suggestion, or motivation test is flexible and that an explicit suggestion to combine the prior art is not necessary – the motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, from the nature of the problem to be solved, market demand, or common sense. In undertaking an obviousness analysis, I have been informed and understand that I may take into account the inferences and creative steps that a person of ordinary skill would have employed in reviewing the prior art at the time of the invention. If the claimed invention combines elements known in the prior art and the combination yields results that would have been predictable to a person of ordinary skill at the time of the invention, then this evidence would make it more likely that the claim was obvious.

24. I have been informed and understand that an obviousness analysis must also take into account any “secondary considerations” or, as they are sometimes

called, objective indicia of non-obviousness. These secondary considerations can include: (i) a long-felt but unsolved need for the solution provided by the patent claim; (ii) unexpected results that arise from what is provided in the patent claim; (iii) unsuccessful attempts by others to find the solution provided by the patent claim; (iv) industry skepticism regarding what is provided in the patent claim; (v) praise from others in the field; (vi) commercial success of a product due to the merits of what is provided in the patent claim; and (vii) copying by others of what is claimed in the Patent. I further understand that a “nexus” must exist between the claimed invention and the evidence proffered on secondary considerations. Such secondary considerations, when present, offer objective information as to the state of the art at the time of the invention and provide a check to hindsight analysis.

V. TECHNOLOGY BACKGROUND

25. The '346 Patent is generally directed to computer-implemented methods and systems for analyzing medical images that facilitate decision making in the context of cancer diagnosis, monitoring, and treatment. As such, in order to frame my analysis and provide the proper context for my opinions, I provide the following overview of relevant technology at issue in this Petition.

A. Medical Imaging Techniques

26. Medical imaging (e.g., image acquisition) technologies provide a valuable way to detect and monitor disease in a non-invasive fashion. There are many

different medical imaging techniques (or “modalities”), each relying on different physical mechanisms to create images and having different benefits and shortcomings. EX2028, 3. Often images produced by different types of medical imaging modalities convey different information. Accordingly, multiple different types of images may be acquired and relied on, for example by physicians, to make decisions about patient diagnosis, treatment, and prognosis.

27. For example, anatomical imaging modalities are a class of imaging techniques that produce images showing detailed anatomical structures, like organs and bones, within a patient. More specifically, intensity variations (e.g., light and dark regions) within anatomical images typically reflect the differences in physical properties of various tissue regions within a patient’s body, which, in turn, impact the way tissue absorbs, reflects, or otherwise interacts with electromagnetic radiation (e.g., x-rays), magnetic fields, or pressure waves. Examples of anatomical imaging techniques are computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound (US).

28. Functional imaging techniques, on the other hand, reflect physiological properties and activity in a subject. They are often acquired using molecular probes administered to the subject and have intensity variations that reflect a spatial distribution of a probe within an imaged portion of the subject.

29. Nuclear medicine images are a type of functional image. EX2028, 11. Examples of nuclear medicine images include positron emission tomography (PET) images and single photon emission tomography (SPECT) images. EX2028, 14. PET and SPECT images are three-dimensional images.

30. Each of these nuclear medicine images is obtained by administering a specific type of probe – namely, a radiolabeled imaging agent, referred to as a radiopharmaceutical, containing a radioactive isotope, referred to as a radionuclide, to a patient. EX2028, 11. The radiopharmaceutical distributes throughout the patient’s body (as explained further, below, often selectively concentrating in regions associated with or exhibiting a particular molecular behavior, which, in turn, may be indicative of disease) and images are formed by detecting radiation emitted by the radionuclide as it decays, from within the patient. Accordingly, rather than conveying information that directly reflects the physical structures and properties of tissue within a patient, nuclear medicine images map the spatial distribution of radiopharmaceutical within the patient and thus relay information about tissue molecular properties or function.

31. The composition of a given radiopharmaceutical dictates (i) the type of nuclear medicine imaging modality that it is compatible with and (ii) the manner in which the radiopharmaceutical distributes throughout a patient’s body and, thus, the particular types and stages of disease for which it serves as a useful probe.

32. In particular, the radioactive decay properties of the radionuclide component of a radiopharmaceutical determine the specific imaging modality that it can be used with. PET imaging detects radioactive decay that results in positron emission¹, and thus relies on radionuclides that are short half-life positron-emitting isotopes, such as carbon-11 (¹¹C) and fluorine-18 (¹⁸F), as well as gallium-68 (⁶⁸Ga). EX2017, 2, 11. SPECT imaging, on the other hand, detects the direct emission of gamma radiation and use gamma-emitting radionuclides, such as ^{99m}Tc, ¹²³I, ¹³¹I, ¹¹¹In, ⁶⁷Ga, ²⁰¹Tl, ^{81m}Kr, ¹³³Xe. *Id.*, 4

33. The manner in which an administered radiopharmaceutical is distributed throughout a patient depends upon the particular radiopharmaceutical and the patient's physiological status. For example, the radiopharmaceutical fluorodeoxyglucose (FDG) is an ¹⁸F-labeled form of glucose and thus concentrates most heavily in tissue with high metabolic activity. EX2018, 3. Since cancer cells

¹ In a PET scanner, positron emission is detected by observing/measuring a characteristic byproduct of positron emission – specifically, simultaneously emitted and oppositely directed pairs of photons (gamma rays) that result from the annihilation of a positron-electron pair – as opposed to the positrons themselves. *See, e.g.*, EX2029, 37.

are typically characterized by higher metabolic activity than surrounding normal cells, PET images acquired with FDG can be used to detect cancer lesions, which typically appear as “hot spots” within images. *Id.* FDG, however, is not specific to cancer, and may also be absorbed by other cells with high metabolic activity, including areas of inflammation and infection. *Id.*, 4. FDG is also limited in its ability to detect slower growing cancers, which absorb less glucose. *Id.* Other radiopharmaceuticals, like F-18 sodium fluoride (^{18}F -NaF) and $^{99\text{m}}\text{Tc}$ -methyl diphosphonate ($^{99\text{m}}\text{Tc}$ -MDP) tend to accumulate within new bone and were used to detect bone metastases. Like FDG, however, these tracers target cancer cells indirectly, via the propensity of cancer cells to divide rapidly, and thus are also limited in their sensitivity and specificity.

34. Nevertheless, in 2016, men with known or suspected prostate cancer were typically evaluated and followed using conventional imaging modalities – namely, contrast-enhanced computed tomography in the chest, abdomen, and pelvis. EX2019, 412. New imaging agents, including PET imaging agents, were being researched and developed. *Id.* Among these new imaging agents, PSMA targeting radiopharmaceuticals had been developed, but were still being assessed for their clinical utility to detect and stage prostate cancer, with some of the first in-human

evaluations of the new small-molecule PSMA inhibitors² that would ultimately obtain approval from the Food and Drug Administration (FDA) for PET imaging just taking place in 2015. EX2019, 412. It would take another four years for the first PSMA-targeted PET imaging drug for prostate cancer to be approved by the FDA, in December of 2020. EX2021, 1.

B. Image Analysis

35. While radiologists and physicians have various medical imaging modalities and techniques at their disposal, the selection of exactly which types of images to obtain, and exactly how to interpret one or more of these images is not straightforward. 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

² The first molecular imaging agent targeting PSMA was an indium-111-labeled monoclonal antibody (ProstaScint®), which could be used for SPECT (not PET) imaging, but suffered from a number of intrinsic limitations that made it an ultimately unsuccessful agent. EX2020, 1. The two small-molecule PSMA inhibitors that have ultimately obtained FDA approval for PET - ⁶⁸Ga-PSMA-11 and [¹⁸F]DCFPyL – only obtained FDA approval in 2020 and 2021, respectively. EX2021, 1; EX2022, 1.

physician. In efforts to facilitate and standardize medical image analysis, researchers in the image processing and computer vision fields have sought to develop computer algorithms that automate various tasks associated with medical image analysis.

36. Conventional image analysis techniques aim to craft a detailed series of step-by-step instructions for computers to follow in order to, for example, classify whether an image contains a particular object, like a lesion – referred to as “classification” or “object detection,” or to delineate complex boundaries of certain structures of interest within an image – referred to as “segmentation.”

37. For example, a simple conventional image segmentation technique is thresholding, whereby regions of an image are identified as part of one object or another based on whether their intensity values are above or below a particular threshold value or lie within a given range. EX1016, 7. This simple approach is best suited to segmenting objects that have uniquely high or low intensity values in an image, such as bones which tend to appear brighter in CT images than soft-tissue, and, even so, selection of proper threshold values may be challenging and performance may be impacted by image variability and presence of artifacts. EX1016, 7.

38. Another common conventional image segmentation technique is atlas-based segmentation. Atlas image segmentation relies on one or more templates, referred to as atlas images, in which various structures of interest, like organs or

bones, have been manually delineated. When a new image of a patient is received, one of the atlas images is registered with the new patient image, and the manually delineated contours from the atlas image are transferred to the new patient image. Atlas-based segmentation continues to be used in medical image analysis products today, even as newer techniques have been developed. *See* EX2023, 1.

C. Deep Learning and Convolutional Neural Networks

39. Machine learning techniques are different from conventional computer programs. Machine learning generally refers to the development and use of algorithms that allow computers to extract, or “learn,” desired functionality from datasets in an automated fashion. EX2024, 1; EX2030, 11. Thus, machine learning algorithms do not require a human programmer to explicitly create a detailed series of instructions for the computer to follow to perform a specific task. *Id.* Instead, machine learning algorithms involve a two-step process comprising a training phase and an inference phase. EX2030, 12. During training, examples from a training dataset are repeatedly provided to a computational model, the parameters of which are refined to optimize performance on a specified task (and on examples from the training dataset) according to desired behavior or output (like labeling an image as comprising a dog, cat, etc.). EX2030, 12. During inference, once trained, the (trained) computational model can be provided with new data, not previously

included in the training dataset and generate output reflecting the trained model's predictions based on information derived from the new input data. *Id.*, 14.

40. Machine learning algorithms can be trained (e.g., can “learn”). Supervised machine learning algorithms are trained using labeled datasets. EX2024, 4; EX2031, 26. In labeled datasets, each example is labeled with the desired output (e.g., “ground truth”) that the machine learning algorithm is intended to reproduce. EX2031, 26.

41. There are also different computational models that can be used in connection with, and optimized via, machine learning techniques. These include simpler statistical models, like models based on Bayes’ theorem (e.g., Naïve Bayes’ classifiers), and more complex models, like neural networks.

42. While the term “neural network,” is, today, closely associated with machine learning, machine learning and neural networks are distinct terms and convey different ideas. That is, as explained above, machine learning refers to the development and use of algorithms that allow computers to extract, or “learn,” functions from datasets in an automated fashion.

43. A neural network, however, is a particular computational model inspired by the structure of a human brain. EX2032, 65. In this model, the weights of each neuron’s excitations in a neural network can be used as adjustable parameters. While the weights can be determined using machine learning, the term “neural

network” is distinct from the term “machine learning.” A neural network is a type of model, whereas machine learning refers to algorithms that allow computers to extract, or “learn,” functions from datasets in an automated fashion. EX2024, 1.

44. Conventional artificial neural networks are shallow – they do not have many hidden layers. Before the confluence of multiple breakthroughs in the 2010’s, this was generally viewed as a requirement for any practical application, because multiple hidden layers were challenging and impractical to train. *See* EX2034, 143.

45. An important implication of the restriction to shallow neural networks is that conventional neural networks are not able to operate efficiently directly on raw, low-level data, like image pixels. EX2031, 23; EX1018, 1. Instead, they operated on limited and predefined sets of “handcrafted” features that could be extracted from raw low-level data. EX2031, 23-24; EX1018, 1. For example, a shallow neural network tasked with classifying an image would not operate directly on the image itself, but, instead, would require a pre-processing routine to extract features (things like a maximum intensity, variance in image intensity, a relative weight of different colors, etc.) from the image that, in turn, would be fed as input to the neural network. The task of designing sets of handcrafted features that would allow neural networks to effectively perform various desired tasks was a challenging, labor intensive, and highly subjective process that relied on human expertise.

EX2031, 23, 30. As a result, ultimately, traditional shallow neural networks failed to lead to commercially viable levels of performance and practical accuracy.

46. Deep-learning techniques (i) use neural networks with many hidden layers (hence, deep) and (ii) train them to learn complex patterns from data, including raw or low-level data (like image pixels or voxels). In doing so, deep-learning methods overcome key challenges that made conventional neural networks impractical.

47. Before 2012, deep learning algorithms were not considered viable for certain imaging applications. Limitations in learning algorithms, computational power, computer hardware, and the availability of sufficiently large datasets made training neural networks with multiple hidden layers impractical. EX2033, 143. Only in 2012, the confluence of (i) new algorithmic approaches, (ii) hardware improvements, and (iii) the creation of and access to large, labeled datasets that could be used paved the way for a breakthrough. In particular, on the algorithm side, new techniques like Glorot initialization, rectified linear units (ReLU's), and dropout techniques, greatly improved the ability to train deep neural networks. EX2035, 152. In terms of hardware, training was also dramatically improved via the discovery that graphical processing units (GPUs) could be used to train neural networks much more efficiently than conventional computer processing units (CPUs), which was made widely accessible via NVIDIA's release of its CUDA programming language in

2007. *Id.*, 153-154. Finally, the ImageNet database, created via a massive crowdsourcing effort, provided a huge hierarchical repository of millions of labeled images that could be used to train supervised image classifiers. EX2026, 1; EX2027, Abstract. By taking advantage of new algorithms, improved hardware capabilities, and the large ImageNet database, a convolutional neural network (CNN), referred to as AlexNet was able to achieve record performance on the ImageNet Large Scale Visual Recognition Challenge (ILSVRC). EX2026, Abstract, 7-8. This, December 2012 report is now considered a watershed moment that led to the use of deep learning for image analysis tasks. EX1018, 2.

48. While the performance of the AlexNet CNN spurred interest in deep learning techniques, the AlexNet report demonstrated performance of a CNN on an image classification task. EX2026, Abstract, 7. That is, given an example image, the AlexNet CNN was tasked with outputting a label for the image – i.e., “mite”, “container ship”, etc. (as shown in Fig. 1, below). EX2026, Figure 4. It would take several more years for deep learning techniques like CNNs to be developed for performance on the more challenging task of image segmentation – which requires delineating complex boundaries of objects within an image. EX1018, 5-6. Namely, neural network architectures that could adequately avoid degradations in resolution when performing segmentation would not appear until around 2015, when the U-net architecture was proposed. EX1018, 5-6.

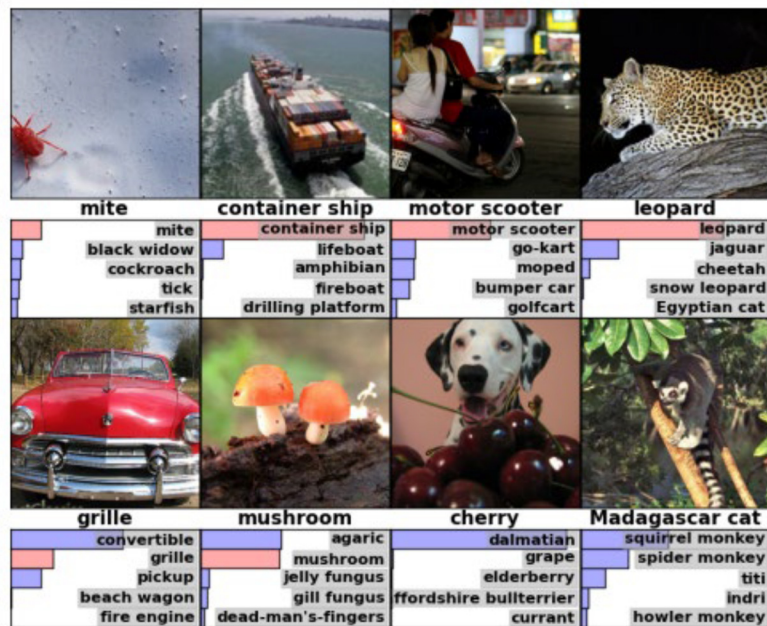


Fig. 1 Example test images and the five most probable labels for each predicted by the AlexNet CNN. EX2026, Figure 4.

49. Accordingly, around 2016, deep learning approaches like CNNs were a nascent technology in computer vision and image analysis, and their adoption in the medical field in particular was gradual. Even years later (into the 2020s), challenges associated with machine learning techniques have made medical professionals skeptical of machine learning-based techniques, although they clearly provide advantages in terms of robustness and reliability, e.g., in comparison with more conventional atlas-based approaches. EX2023, 1 (“While some clinicians have embraced the technology, others remain skeptical about its ability to provide accurate results in clinical practice.”).

VI. THE PRIOR ART

A. Renisch

50. Renisch describes “diagnostic imaging systems and methods” for analyzing PET/CT images on a dedicated computer workstation. EX1005, [0001]. To the extent Renisch describes image segmentation, his disclosure focuses on conventional atlas-based image segmentation, as described above in the “Technology Background” section. EX1005, [0028] (“The segmentation unit 76 can also employ an atlas of normal anatomical structures which is mapped to the actual anatomical image.”).

B. Sprencz

51. Sprencz discloses “methods and systems for evaluating bone lesions.” EX1006, [0001]. 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].

C. Suehling

52. Suehling discloses a method and system for detecting lesions in a 3D medical image with region-specific lesion detectors. EX1007, [0030]-[0031]. 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.

D. Wu

53. Wu discloses “cloud-based medical image processing systems with tracking capability” that track user interactions with medical image data and analyze 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].

E. Maier

54. 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]. EX1008, [0007]. 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].

F. D’Souza

55. 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. 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. 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.

G. Menon

56. Menon discloses systems and methods for “assisting in decision making for the treatment of stroke patient.” EX1012, Abstract. 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].

VII. THE '346 PATENT AND ITS PROSECUTION HISTORY

A. The '346 Patent

57. The '346 Patent is generally directed to technologies for improving the ability of doctors and patient to detect and monitor cancer (particularly prostate cancer) progression and treatment over time. The specification, for example, begins by describing the disclosed technology as directed to “decision-making tools for use by medical practitioners and/or their patients, e.g., to aid in the process of making decisions about the course of cancer treatment and/or to track treatment and/or the progress of a disease.” EX1001, 2:63-67.

58. As of the priority date (October 27, 2016), there was a 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. The '346 Patent describes a technology for addressing this need via a combination of insight into the promise of deep-learning technologies, specific ways in which they could be applied to analyze specific types of medical images, and how providing these capabilities in the format of a network-based platform could be especially valuable in the context of cancer diagnosis and treatment.

59. To begin with, the '346 Patent describes inventive processes 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).

60. 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). Patentee recognized that ML could be used to geographically identify 3D boundaries of particular tissue regions in an overall in more accurate and more robust manner with desirable scan-to-scan reproducibility than had been possible previously. Patentee was thus able to combine the ML-identified 3D tissue region boundaries with demarcations of cancer risk in the form of a 3D overlay. This new and improved method dramatically increased the accuracy and reproducibility of tissue and organ segmentation. The resulting overlay adds valuable anatomical context to demarcations of cancer risk, where it is often impossible to obtain, inaccurate, or subjective. 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. Nuclear medicine techniques, however, do not capture features of anatomy and structure of organs and/or tissues at sufficiently high resolution. They thus cannot always reliably distinguish between different organs or tissue regions.

61. Another key innovation of the '346 Patent was combining the insight about ML techniques with the insight that taking advantage of remote networking by uploading medical images to, and accessing them from, databases via network-based systems would be especially valuable in the context of cancer diagnosis, monitoring, and treatment.

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

B. Prosecution History of the '346 Patent

63. 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. The '346 Patent issued on May 26, 2020. EX1004, 195. During prosecution, the Examiner identified 7 references on his “Notice of References Cited,” two of which were Wu and Maier, which are among the references asserted in the Grounds of the Petition. 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. The Examiner then allowed the application after considering all the references and amending the independent claims to include the following:

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. 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.

VIII. CONSTRUCTION OF TERMS OF THE ’346 PATENT

64. I have been asked to provide my opinion on how a POSA would understand several terms used in the claims of the ’346 Patent under the *Phillips* construction standard, of which I have been informed (as discussed in Section IV.C, above).

A. A “network-based system”

65. Claim 1 of the ’346 Patent begins “A *network-based system* for generating a disease risk map . . .” EX1001, 35:46-47 (emphasis added).

66. It is my opinion that a POSA, reading the term a “network-based system” in the context of the claims and specification, would understand the term to mean a system involving interaction across multiple interconnected and physically dispersed computing devices. This interpretation is consistent with both the claim language and the detailed description of the claimed subject matter laid out in the specification of the ’346 Patent.

67. To begin with, the claim does not simply state “a system,” but, rather, states a “network-based system.” EX1001, 35:46-49. The use of the term “network-based” would be given meaning by a POSA. In particular, it indicates that the claimed system is more than a single, isolated computer and, instead, is part of a network, which would be understood to mean multiple distinct computing devices.

68. The other elements of the claim further support, and make clear, that the system of claim 1 is connected with other computing devices. For example, the claim includes the steps of “access[ing] . . . one or more medical images associated with a particular patient from a database,” and “caus[ing] display of the risk map via a graphical user interface (GUI) for presentation or review of the risk map by a user.” EX1001, 35:54-55, 35:63-66. As explained below, in the context of the ’346 Patent,

both of these steps point to interaction with other computing devices as part of a network.

69. The specification further supports the reading that “a network-based system” means a system involving interaction across multiple interconnected and physically dispersed computing devices. The specification repeatedly describes the invention as distributed platform (e.g., a cloud-based platform) that provides for regular interaction by multiple users at potentially different locations and at different times, rather than a standalone machine. EX1001, 3:1-4.

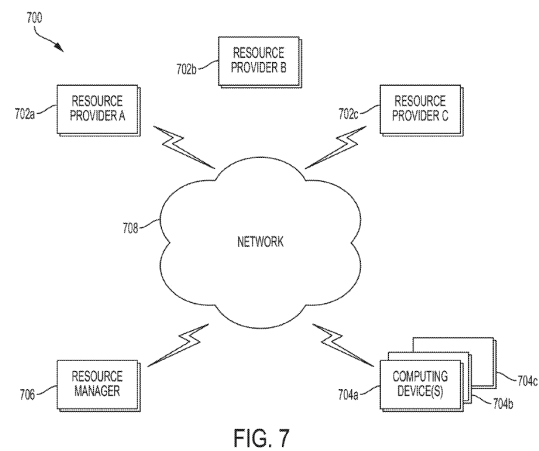
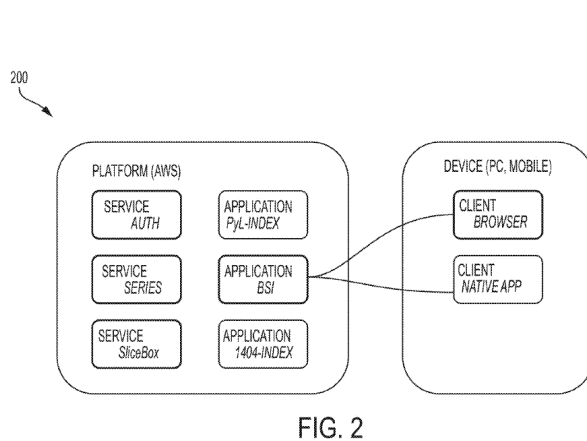
70. The specification states “For example, presented herein is a network-based (e.g., cloud-based) support platform allowing multiple users to store, access, analyze, and/or provide feedback regarding a given set of image data for a patient.” EX1001, 3:1-4.

71. Many figures in the Patent convey interactions between distinct computing devices, including between server and client devices, as well cases where a user computing device is a mobile application that interacts with a cloud-based service.

72. For example, FIG. 1 shows an example mobile app providing access to three cloud-based services. EX1001, 13:39-41 (“FIG. 1 is a screenshot of a graphical user interface (GUI) showing mobile app icons for three cloud-based services . . .”).

FIGs. 3-6 all are described as relating to features of exemplary cloud-based embodiments. EX1001, 13:48-65.

73. FIGs. 2, 7, and 9 (reproduced below) show schematics relating to network-based platforms, where platform services are provided via distinct computing devices that serve a user, client, computing device, like a personal computer, mobile device, smart phone. EX1001, 13:39-46 (“FIG. 2 is a schematic showing the relationship between a platform and a computing device (e.g., personal computer or mobile computing device, e.g., smart phone . . .”); 13:66-67 (“FIG. 7 is a block diagram of an exemplary cloud computing environment . . .”); 14:4-6 (“FIG. 9 is a block diagram of an example architecture for implementing the cloud based platform described herein, according to an illustrative embodiment.”).



FIGs. 2 and 7, reproduced from the '346 Patent.

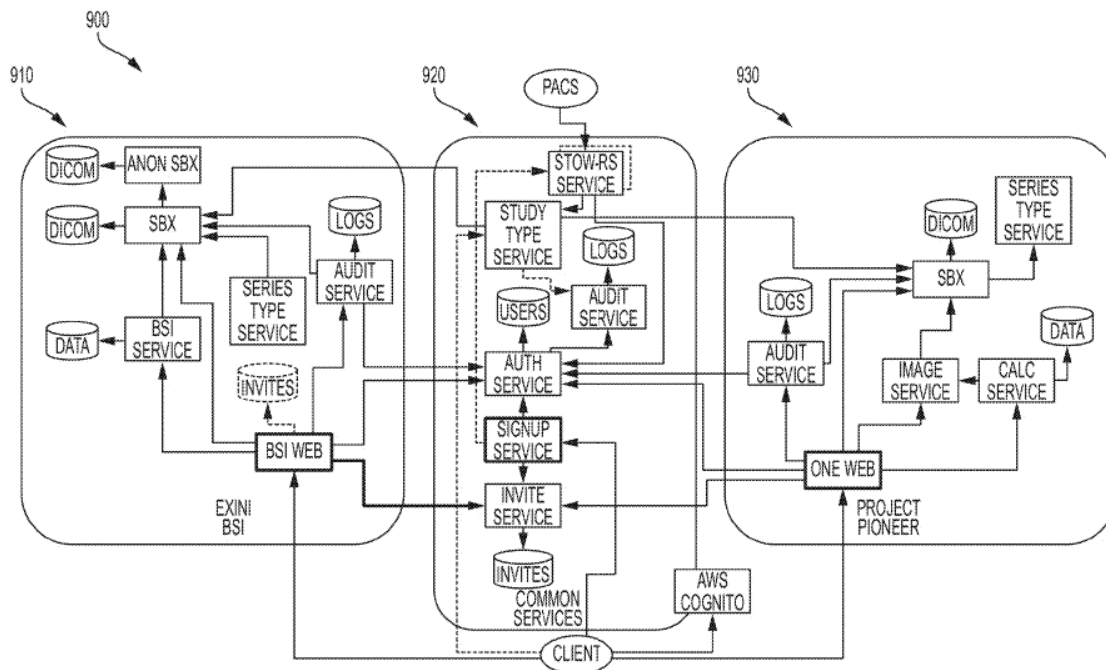


FIG. 9

FIG. 9, reproduced from the '346 Patent.

74. For example, FIG. 9 provides a detailed architecture for a cloud-based system involving multiple dispersed computing devices, including client and server devices. EX1001, FIG. 9 (among other things, including reference to “AWS COGNITO,” which is a cloud-based service provided by Amazon Web Services); FIG. 2 (referring also to “Platform (AWS)”). The specification of the '346 Patent describes, in detail, how the platform approach of the claimed technology can be implemented in a way that allows it to be dispersed across multiple datacenters, allowing parts of the platform to be scaled individually e.g., to meet high demand and ensure minimal downtime. EX1001, 28:19-67. The specification further explains

that “[t]he computing system can include clients and servers. A client and server are generally remote from each other and typically interact through a communication network.” EX1001, 35:25-27.

75. Moreover, the specification of the ’346 Patent explains that the choice to structure the claimed technology as a network-based platform is linked with a key challenge that the technology of the ’346 Patent aims to address, namely, improving the ability of doctors and patient to detect and monitor cancer – particularly prostate cancer - progression and treatment over time. The specification, for example, begins by describing the disclosed technology as directed to “decision-making tools for use by medical practitioners and/or their patients, e.g., to aid in the process of making decisions about the course of cancer treatment and/or to track treatment and/or the progress of a disease.” EX1001, 2:63-67. Throughout, the specification repeatedly emphasizes the ability 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. For example, the specification describes the following example practical/clinical benefits of the claimed network-based implementation:

In certain embodiments, the cloud-based platform facilitates evaluating prostate cancer progression and treatment efficacy over time. For example, as shown in the example process 1100 of the block flow diagram of FIG. 11, in certain embodiments medical images of a particular patient are repeatedly received and stored over time 1110,

over the course of multiple visits to one or more doctors and/or clinical specialists (e.g., radiologists) by the patient.

...

Notably, by virtue of the capability of the cloud-based platform described herein to receive, store, and analyze a variety of different medical image types, such as composite SPECT-CT images, whole-body scans, and composite PET-CT images, the medical images need not be of the same type.

76. Thus, reading the claim language in the context of 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.

B. A “database”

77. Claim 1 recites “access one or more medical images associated with a particular patient from a *database*,” and, similarly, claim 13 recites “access one or more medical images associated with a particular patient from a *database*.” EX1001, 35:54-55; 36:46-47 (emphasis added).

78. It is my opinion that a POSA, reading the term a “database,” in the context of the claims and specification, would understand the term to mean a large, structured, set of data that contains multiple records that contain multiple fields (e.g., along with data-associated attributes thereof). They would, moreover, understand that this definition is not synonymous with computer “memory.” This interpretation

is consistent with both the claim language and the detailed description of the claimed subject matter laid out in the specification of the '346 Patent.

79. To begin with, claim 1 uses both terms, “database,” and “memory,” and, true to their different meanings, uses them differently. Claim 1 states “the system comprising...a *memory* having instructions stored thereon, wherein the instructions, when executed cause the processor to:...*access one or more medical images* associated with a particular patient *from a database*.” EX1001, 35:51-55 (emphasis added). Thus, a POSA would understand that the element “a database” is different from computer “memory” and that, as stated in claim 1, the recited database is a set of data that contains multiple patient images (i.e., records). Moreover, the fact that the claim specifies accessing medical images *associated with a particular patient* from the database would indicate to a POSA the presence of a structured store of data, such that medical images that are associated with not just any patient, but a *particular* (i.e., sought) *patient*, can be located and accessed.

80. The specification repeatedly confirms that “database” means a large, structured, set of data that contains multiple records that contain multiple fields. For example, when describing the cloud diagram in FIG. 7 above, the specification identifies “application servers and/or databases with storage and retrieval capabilities” as discrete network resources, separate from compute nodes. EX1001, 31:2-10. In the “Summary of Invention” section, the specification describes the

claimed technology 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 states that “[i]n certain embodiments, multiple (accredited) users can access the information, e.g., to weigh in on data interpretation.” EX1001, 3:1-14. A POSA would understand that this functionality would involve a large, structured, set of data that contains multiple records that contain multiple fields (e.g., medical image data, with records including not just image data, but also patient identifiers, dates, and the like).

81. Indeed, FIG. 3 of the '346 Patent, reproduced below, illustrates exactly this, showing an example of a GUI window that “allows a user to enter information about a patient and upload and/or access medical images for the patient, e.g., series of images obtained over a period of time.” EX1001, 13:47-52.

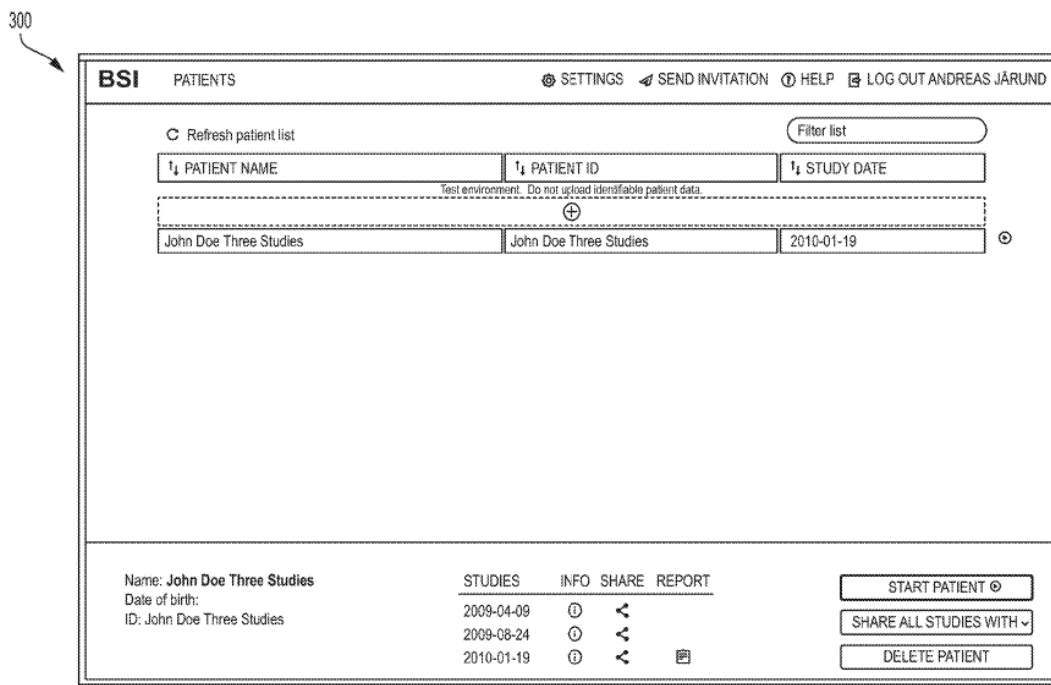


FIG. 3

FIG. 3 reproduced from the '346 Patent.

82. Finally, the specification makes clear that the element “database,” as used in the '346 Patent is a large, structured, set of data that contains multiple records that contain multiple fields, so as to allow the storage, retrieval, and analysis of multiple images taken over the course of a patient’s cancer diagnosis, any monitoring period, and treatment, as is often relevant for, e.g., prostate cancer. For example, the specification describes functionality like “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 doctor . . . thereby tracking determined values of the one or more

risk indices over a course of prostate cancer progression and treatment for the patient[.]” EX1001, 11:41-49.

83. A POSA would understand that this is different from how the specification describes computer “memory,” which, in contrast, is described as a hardware storage element. 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 . . .”).

84. Therefore, it is my opinion that, having read the claim language and the specification of the ’346 Patent, a POSA would understand that a “database” refers to a large, structured, set of data that contains multiple records that contain multiple fields and that “database,” as used in the claims of the ’346 Patent, is different from computer “memory,” which is a hardware element.

C. The Petition Relies on an Implied Construction of “Machine Learning Algorithm,” that is Unclear and Internally Inconsistent, and Fails to Reflect the Understanding of a POSA as of the Priority Date

85. I have also been asked to provide my opinion on the way the term “machine learning algorithm” is used in the specification and claims of the ’346 Patent and, by comparison, in the three primary references (Renisch, Sprencz, and Suehling), which the Petition alleges each anticipate claims 1 and 13. As explained in further detail below, in my opinion, while the Petition does not propose an express construction of the term “machine learning algorithm,” its arguments that each of Renisch, Sprencz, and Suehling individually discloses “analyz[ing] the one or more medical images using a machine learning algorithm, to generate the risk map . . .” require the term to be read differently in each case, i.e., three different ways, in an inconsistent fashion.

86. To begin with, the Petition argues that Renisch discloses machine learning algorithms, referencing what appears to be an isolated and off-hand mention of the term “neural network,” in paragraph [0027] of Renisch. Pet., 25. The phrase ‘neural network’ appears in Renisch just once, as one member of a list of miscellaneous segmentation techniques. EX1005, [0027] (“It is to be appreciated, however, that other segmentation methods such as clustering, edge detection, region growing, principle components analysis, neural network, and the like are also contemplated.”). In regard to Sprencz, the Petition argues that the mention of the

term “clustering,” also discloses machine learning. Pet., 48. Here again, the Petition relies on the presence of a single off-hand mention of a particular word – “clustering” – in what appears to be an arbitrary list of segmentation techniques. EX1006, [0045] (“While various segmenting techniques are described herein, 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, level set, and region growing.”). Finally, in regard to Suehling, the Petition argues that a third, different technique, “marginal space learning (MSL)” discloses use of a machine learning algorithm as recited in claims 1 and 13 of the ’346 Patent. Pet., 63.

87. Thus, the Petition appears to attempt to read three different phrases in three different references – “neural network” in Renisch, “clustering” in Sprencz, and “marginal space learning (MSL)” in Suehling – onto the machine learning step recited in claims 1 and 13. These are three very different techniques and they each would imply a unique interpretation of “machine learning,” inconsistent with each other and at odds with the way machine learning is described in the ’346 Patent.

88. For example, as explained above, a neural network is a specific computational model that uses variable weights and interconnected neurons to capture a wide variety of behavior. As discussed above, a neural network is not the same thing as, and does not necessitate the use of, a machine learning algorithm.

Clustering refers to a general class of statistical methods for grouping similar objects into different groups, or more precisely, for partitioning a data set into subsets (e.g., according to some defined distance measure in the (multi-dimensional) space of features (descriptors)). Clustering methods do not necessitate the use of machine learning. MSL is a segmentation technique that uses a sequence of weak classifiers that model parameters like organ position, orientation, and scale.

89. Thus, the three techniques – neural network, clustering, and MSL – which the Petition tries to read on the claim elements in different grounds are all different algorithms or classes of algorithms that work in different ways. Each of the Petition’s anticipation arguments therefore requires a different interpretation of machine learning. The Petition does not articulate an interpretation that encompasses these examples, and provides no explicit construction at all.

90. Not only are the different ways that the Petition requires machine learning to be interpreted inconsistent with each other, they are also at odds with the way the ’346 Patent describes machine learning. For example, Section A.iv (“Positron Emission Tomography (PET) Scans”) of the specification describes how machine learning-based segmentation, such as performed by a CNN, can be used to segment organs in a CT image and thereby provide anatomical context that can be transferred to a PET image in order to compute a risk map and/or determine risk indices. EX1001, 26:24-27:37. For example, the specification states the following:

Automated segmentation of CT scans can be accomplished via a variety of approaches, include machine learning techniques [e.g., ANN-based approaches (including, e.g., convolutional neural networks (CNNs))],...

EX1001, 26:50-54.

91. Here and elsewhere in the specification, the '346 Patent expressly references a specific type of machine learning technique, namely, convolutional neural networks (CNNs). EX1001, 25:32-35, 26:50-55. As explained above in Section V.C, machine learning techniques evolved significantly, especially after 2010, with breakthroughs leading to new understandings about the viability of deep-learning CNNs. Thus, the understanding of what terms like machine learning and neural network meant was in flux and, at the time of the priority date (October 27, 2016), the use of the term machine learning in connection with specific algorithms, like CNNs, as appears in the '346 Patent would mean something very different from Renisch's off-hand mention of "neural network" (in 2009, when deep-learning CNN techniques were not used) or Sprencz's mention of clustering (a general algorithm for sorting data) or Suehling's MSL (also in 2009, before the breakthroughs in the 2010s).

92. Accordingly, the Petition does not set out any explicit construction for the term "machine learning algorithm," as it is used in the claims of the '346 Patent, and any interpretation implied from the Petition's arguments relies on three different

and inconsistent constructions. Moreover, any such implied interpretation is also at odds with the way one would understand the term “machine learning algorithm” as recited in the claims of the ’346 Patent.

IX. ANALYSES OF THE PETITION GROUNDS

A. Ground A: Renisch fails to anticipate claims 1-7, 9-10, and 13

93. It is my opinion that the Petition does not establish that Renisch anticipates claims 1-7, 9-10, and 13.

1. Claim 1

94. Claim 1 is directed to “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.” EX1001, 35:46-36:7. Claim 1 states the following:

1. 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:

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;

(ii) 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

(iii) cause display of the risk map via a graphical user interface (GUI) for presentation or review of the risk map by a user,

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.

95. As I explain below, based on my review of the Petition, Renisch, and the '346 Patent, in my opinion Renisch does not disclose a “network-based system,” or the step of “access[ing] one or more medical images associated with a particular patient from a database” as recited in claim 1, above.

a. Renisch fails to disclose a “network-based system” as recited in claim 1.

96. Claim 1 begins with the language “A *network-based system* for generating a disease risk map.” EX1001, 35:46-47 (emphasis added). In my opinion, Renisch does not disclose a “network-based system.”

97. As I explained above, a POSA reading the claims and the specification of the '346 Patent would understand that a “network-based system,” as the term is used in claim 1, means a system with interaction across multiple interconnected and physically dispersed computing devices. This is not a trivial element, and it (among other features) differentiates the technology described in the '346 Patent from conventional computer workstations, which were dedicated computers associated

with specific imaging devices and used to view images created on those devices. Contrasting with conventional dedicated computer workstations, the specification of the '346 Patent 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 medical images from patients, for example over the course of multiple visits, over time. EX1001, 3:1-14, 3:43-3:67, 27:1-10, 28:30-50. As I explain above, this is particularly relevant to cancer diagnosis, monitoring, and treatment, which can be a many years' long process, requiring repeated visits to multiple doctors.

98. Renisch does not disclose such a “network-based system.” Renisch does not appear to mention computer networking, the internet, or cloud-based services. Instead, the sole computer that Renisch appears to illustrate and discuss is described as “[a] workstation or graphic user interface 62 includes a display device 64 and a user input device 66 which a clinician can use to select scanning sequences and protocols, display image data, and the like.” EX1005, [0023]. Taking this description together with FIG. 1 of Renisch, in my opinion, Renisch is describing a single computer workstation (“*workstation* or graphic user interface 62 (emphasis added)”) with a monitor (“display device 64”) and keyboard (“input device 66”) that clinicians use to control instrumentation (“a clinician can use to select scanning sequences and protocols”) to acquire images, and then view them (“...display image

data...”). That is not a system that involves interaction across multiple interconnected and physically dispersed computing devices and Renisch, therefore, does not disclose a “network-based” system, within the meaning of claim 1 and the ’346 Patent.

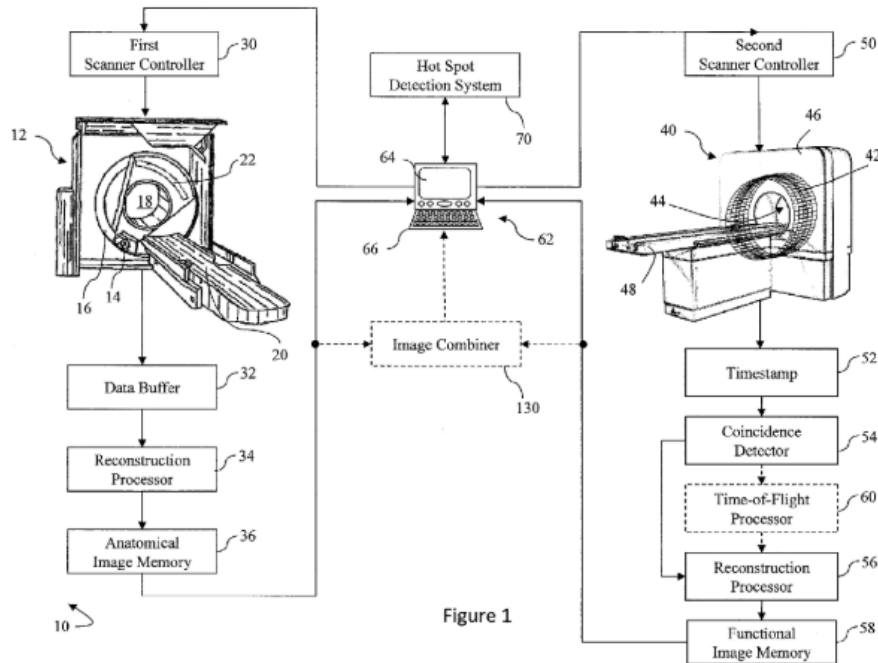


Figure 1 reproduced from Renisch (EX1005).

99. The 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 and a functional imaging system 40.” Pet., 21. As explained above, however, Renisch’s description indicates that the computer (element 62) in Figure 1 is a dedicated workstation that clinicians use to control, and view images from, specific

scanners, and not a network-based system. Though the Petition alleges that “hotspot detection system 70 is interconnected for sharing data and resources with a workstation/GUI,” that description is not present in Renisch. Instead, Renisch states only that “the diagnostic system 10 includes a hot spot detection system 70 for automatic detection of a region of interest (ROI) pertaining to a lesion and automatic quantification of metabolic activity in detected lesions based on anatomical images 72 from the anatomical image memory 36 and functional images 74 from the functional image memory 58.” EX1005, [0025]. Renisch then proceeds to describe his hot spot detection system and the functions it performs in a way that conveys a software system or unit that may be invoked by his workstation and not a separate networked computer system. *See, e.g.*, EX1005, FIG. 1 (expressly illustrating element 62 as the sole computer system and using simple boxes to refer to individual inputs, outputs, and steps in what appear to be computer implemented methods).

100. Thus, it is my opinion that Renisch does not anticipate claim 1 since, at least, he neither mentions a “network” nor describes anything that a POSA would consider to be “a network-based system,” within the meaning of claim 1 and the specification of the ’346 Patent.

b. Renisch fails to disclose “access[ing] one or more medical images associated with a particular patient from a database,” as recited in claim 1.

101. The Petition also fails to show that Renisch discloses step (i) of claim 1 (which the Petition refers to as limitation “1(b)”), which recites “access[ing] one or more medical images associated with a particular patient from a database,” as required by independent claim 1.

102. As explained above, a POSA would understand that the term “database,” as used in the ’346 Patent, means a large, structured, set of data that contains multiple records that contain multiple fields. A POSA would take note of the fact that the ’346 Patent repeatedly uses “database” to refer to collections of medical images of potentially different types, for different patients, and acquired at different times. In contrast, the ’346 Patent uses the term “memory,” to refer to a hardware storage element. A POSA would, therefore, not conflate these two terms, especially given that they both appear and are used differently (in a way that is consistent with the specification) in claim 1.

103. The Petition, however, points to Figure 1 of Renisch and argues that “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. The passage that the Petition quotes, however, does not mention

a “database.” To the extent that the Petition refers to a “first scanner 12” and a “second scanner 40,” those are imaging devices, not a “database.” To the extent that the Petition refers to “anatomical image memory 26” and “functional image memory 58,” those are memories, not a “database.” As explained above, “memory” and “database” are not equivalent as claimed in the ’346 Patent. Therefore, the Petition fails to show that Renisch discloses this limitation (b) of claim 1.

c. The Petition fails to establish 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 claim 1.

104. As explained above in Section VIII.C, it is my opinion that the Petition fails to establish a construction for the term “machine learning algorithm,” as it is used in the ’346 Patent and in the context of the understanding of a POSA. Instead, the Petition’s arguments appear to rely on three different and inconsistent implied constructions, depending on the particular reference at hand. Moreover, in each case, any such implied interpretation is also at odds with the way one would understand the term “machine learning algorithm” as recited in the claims of the ’346 Patent. Accordingly, in my opinion, the Petition thus fails to establish that the limitation “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 stated in claim 1 is taught by Renisch.

d. Conclusion

105. Based at least on the foregoing reasons, it is my opinion that Renisch fails to teach each and every element recited in claim 1 and, therefore, Renisch fails to anticipate claim 1.

2. Claims 2-7 and 9-10

106. Claims 2-7 and 9-10 are dependent claims, each depending from claim 1. As I understand it, each of these claims necessarily includes the limitations of claim 1, from which each depends. Therefore, at least because, as explained above, Renisch does not anticipate claim 1, Renisch also cannot anticipate any of these dependent claims.

3. Claim 13

107. Claim 13 is the second independent claim in the '346 Patent and states the following:

13. A method 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 method comprising:

(i) accessing, by a processor, one or more medical images associated with a particular patient from a database;

(ii) automatically analyzing, by the processor, using a machine learning algorithm, the one or more medical images 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

(iii) causing, by the processor, display of the risk map via a graphical user interface (GUI) for presentation or review of the risk map by a user,

wherein step (ii) 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.

108. Therefore, similar to claim 1, claim 13 includes the element “accessing, by a processor, one or more medical images associated with a particular patient from a database.” As I explained above (in Section IX.A.1.b) with regard to claim 1, Renisch does not disclose this element. Therefore, for at least this reason, Renisch does not disclose each and every element of claim 13 and, accordingly, fails to anticipate claim 13.

B. Ground B: Renisch in view of Wu fails to render any of claims 1-7 and 9-10 obvious

109. The Petition also challenges claims 1-7 and 9-10 as allegedly obvious based on Renisch in view of Wu. In its arguments in support of 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. The Petition does not contend that Wu discloses any other limitations of claim 1. Accordingly, at least because, as explained above, Renisch does not disclose the step in claim 1 of “access[ing] one or more medical images associated with a particular patient from a

database,” and the Petition does not make any argument that Wu discloses this feature, the Petition does not show that Renisch and Wu render claim 1 obvious.

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

110. Ground C of the Petition challenges claim 5 as allegedly “obvious over Renisch (or Renisch with Wu) in view of the Applicant’s admitted prior art (‘AAPA’) or D’Souza.” Pet., 8, 31-33. I have been informed by Patent Owner’s counsel that IPR petitions cannot rely on AAPA as the basis of a ground, and therefore limit my analysis to D’Souza.

111. In my opinion, D’Souza does not render claim 5 obvious. Among other things, the Petition only alleges that D’Souza discloses prostate cancer-specific radiotracers (which I do not necessarily agree with). Pet., 32-33. The Petition does not contend that D’Souza discloses any of the other limitations of claim 1 that, as I have explained above, are not disclosed in Renisch or Wu. Therefore, for at least the reasons above, Renisch, Wu, and D’Souza fail to render claim 5 obvious.

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

112. Ground D of 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. The Petition does not contend that Sprencz (or Wu) discloses

any other limitations of claim 1, from which claim 8 depends. Accordingly, for at least the reasons above, Renisch, Wu, and Sprencz fail to render claim 8 obvious.

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

113. 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. The Petition does not contend that Maier (or Wu) discloses any other limitations of claim 1, from which claims 9-11 depend. Accordingly, for at least the reasons above, Renisch, Wu, and Maier fail to render claims 9-11 obvious.

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

114. 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. The Petition does not contend that Menon (or Wu) discloses any other limitations of claim 1, from which claim 12 depends. Accordingly, for at least the reasons above, Renisch, Wu, and Menon fail to render claim 12 obvious.

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

115. Ground G of the Petition challenges independent claims 1 and 13, along with several dependent claims (claims 2-10, which depend from claim 1) as allegedly

anticipated by Sprencz. I disagree. In my opinion, the Petition fails to establish that Sprencz anticipates claims 1-10 and 13.

1. Claim 1

a. Sprencz does not disclose a “network-based system.”

116. Claim 1 recites “[a] network-based system for generating a disease risk map . . .” EX1001, 35:45-46. Sprencz does not disclose such a “network-based system.”

117. As discussed above, a POSA reading the claims and the specification of the ’346 Patent would understand that a “network-based system,” as used in claim 1, means a system involving interaction across multiple interconnected and physically dispersed computing devices. This feature, among other things, sets the claimed network-based platform technology in the ’346 Patent apart from conventional computer workstations, with the ’346 Patent repeatedly explaining how the “network-based” approach allows multiple users (e.g., physicians, radiologists, patients) to access and analyze medical images, for example over the course of multiple visits, over time. EX1001, 3:1-14, 3:43-3:67, 27:1-10, 28:30-50. This is particularly relevant to cancer diagnosis, monitoring, and treatment, which can be a many years’ long process, requiring repeated visits to multiple doctors.

118. It is my opinion that Sprencz does not disclose such a “network-based system.”

119. First, the Petition argues that FIG. 1 of Sprencz (reproduced below) discloses a “network-based system.”

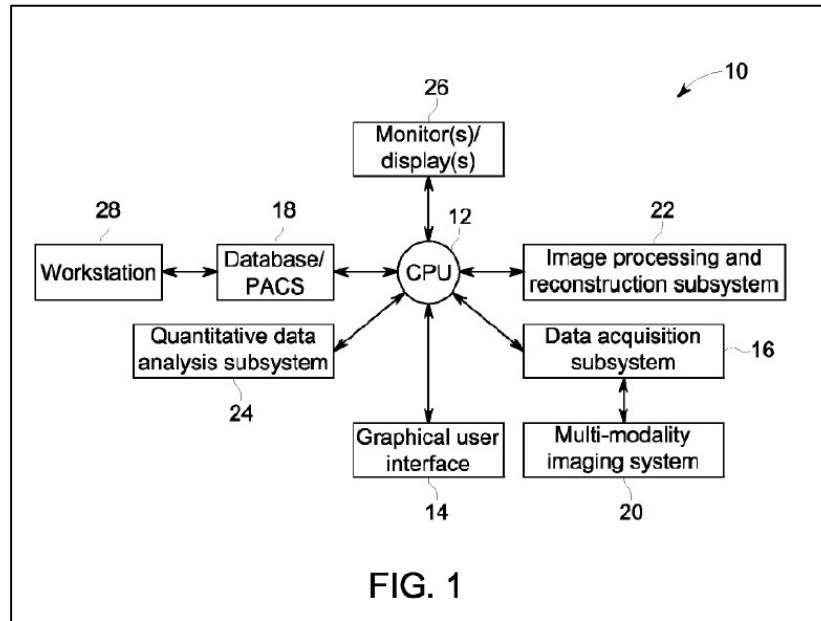


FIG. 1, reproduced from Sprencz

120. Specifically, the Petition states the following:

Additionally, the system disclosed by Sprencz is network-based. Referring to Fig. 1, which is reproduced below, Sprencz discloses *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. Ex1006, [0023]-[0027].

(emphasis added)

Pet., 43-45.

121. Respectfully, I disagree. Sprencz does not use the term “distributed system” with regard to element 10. The term “distributed” never actually appears in Sprencz and paragraphs [0023]-[0027] refer only to either “imaging system 10” or just “system 10.” EX1006, [0023]-[0026] (system 10 is not referenced in paragraph

[0027] of Sprencz). Likewise, the term “remotely located imaging system 20” is not a phrase that Sprencz uses. Instead, Sprencz refers to element 20 as a “multi-modality imaging subsystem.” EX1006, [0023]-[0027]. Thus, the description in Sprencz itself does not appear to disclose a “network-based system,” as a POSA would understand the term as used in claim 1 and the ’346 Patent.

122. Second, the Petition also argues that Sprencz discloses a “network-based system” stating the following:

Sprencz states: “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.” Ex1006, [0026], [0024] (“database 18 may be ... remotely located from the site of data acquisition.”). Thus, Sprencz’s system for obtaining, analyzing, and displaying images is carried out on a network of remotely located components.

123. It is not exactly clear what configuration Sprencz is describing in the referenced passages, but his merely stating that a workstation or database can be remote from a scanner does not disclose a network. As I explained above, a single workstation attached to a scanner cannot qualify as a “network-based system” on its own and the Petition never explains why a “remotely located” database means that the overall disclosed system is necessarily a “network-based system.” Therefore, the Petition fails to show that Sprencz discloses this limitation.

- b. The Petition fails to establish that Sprenecz 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 claim 1.**

124. As explained above in Section VIII.C, it is my opinion that the Petition fails to establish a construction for the term “machine learning algorithm,” as it is used in the ’346 Patent and in the context of the understanding of a POSA. Instead, the Petition’s arguments appear to rely on three different and inconsistent implied constructions, depending on the particular reference at hand. Moreover, in each case, any such implied interpretation is also at odds with the way one would understand the term “machine learning algorithm” as recited in the claims of the ’346 Patent. Accordingly, in my opinion, the Petition thus fails to establish that the limitation “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 stated in claim 1 is taught by Sprenecz.

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

125. As with Ground C, I have limited my analysis to D’Souza. As with Ground C, Ground H relies on D’Souza solely for its disclosure of prostate cancer radiotracers. The Petition does not argue (and D’Souza does not) overcome the above-explained shortcomings of Spencz with regard to claim 1, from which claim 5 depends.

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

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

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

127. Ground J of the Petition challenges claims 1-10 and 13 as allegedly anticipated by Suehling. I disagree. As I explain in further detail below, it is my opinion that the Petition fails to establish that Suehling anticipates claims 1-10 and 13.

1. Claim 1

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

128. 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.

129. 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. Suehling does not disclose this limitation.

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). 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.

131. Therefore, Suehling does not disclose 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. Suehling therefore does not anticipate independent claim 13.

b. The Petition fails to establish that Suehling 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 claim 1.

132. As explained above in Section VIII.C, it is my opinion that the Petition fails to establish a construction for the term “machine learning algorithm,” as it is used in the ’346 Patent and in the context of the understanding of a POSA. Instead, the Petition’s arguments appear to rely on three different and inconsistent implied constructions, depending on the particular reference at hand. Moreover, in each case, any such implied interpretation is also at odds with the way one would understand the term “machine learning algorithm” as recited in the claims of the ’346 Patent. Accordingly, in my opinion, the Petition thus fails to establish that the limitation

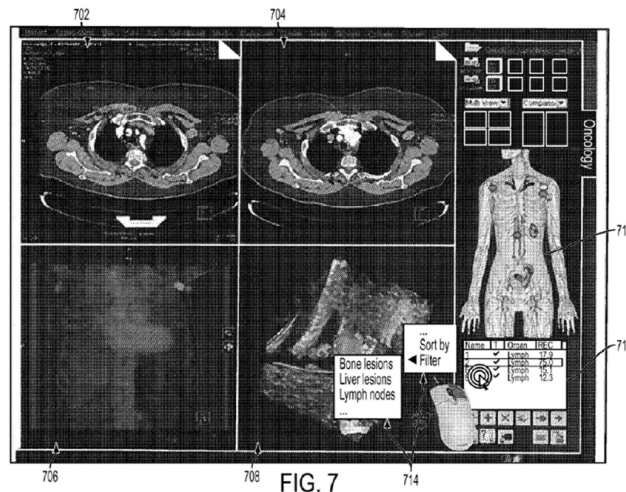
“perform[ing] an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map,” as stated in claim 1 is taught by Suehling.

- c. **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.**

133. 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). 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)

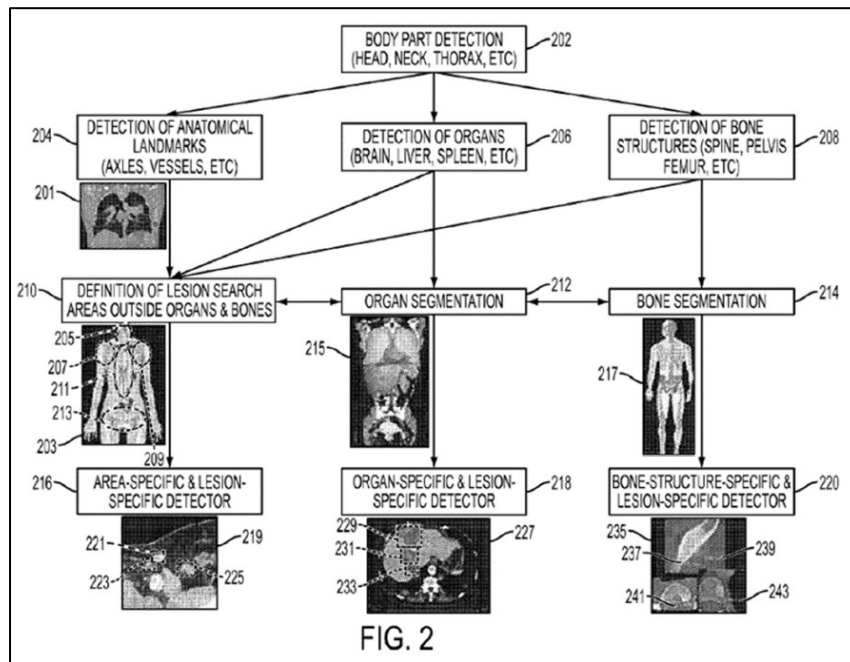
134. The Petition fails to show that Suehling discloses all elements of this limitation, for at least two reasons.

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



136. Nothing in Figure 7 shows a “segmented anatomical structure,” let alone a “graphical *overlay* of segmented lesions *on segmented anatomical structures*.”

137. Second, the Petition fails to point to a 3D image in Suehling that comprises both features (1) “regions of risk of cancer . . . overlaid on medical images;” and (2) “geographic identification of specific tissue region(s) overlaid on the medical images” as recited in claim 1. The Petition suggests that Figure 2 may reflect this disclosure, but the Petition misrepresents Figure 2:



Pet., 64-66.

138. 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. But images 215 and 217 are two separate sets of images. 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. Thus, the Petition fails to explain where each element the claim is in the cited art and, under any reading, fails to show how Suehling discloses the relevant claim limitations. 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.

139. 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. The Petition does not contend that Maier discloses the limitations absent from Suehling, which Patent Owner identified above. Accordingly, for at least the reasons above, Suehling and Maier fail to render claim 11 obvious.

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

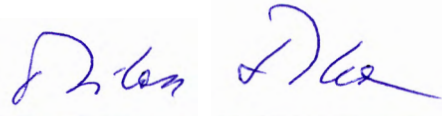
140. For Ground L, the Petition only alleges that Menon discloses elements specific to claim 12 that are not disclosed by Suehling, but otherwise relies on Suehling for every other element of claim 12. Pet., 73. The Petition does not contend that Menon discloses the other limitations absent from Suehling,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

X. CONCLUSION

141. For the reasons stated herein, it is my view that claims 1-13 of the '346 Patent are novel and nonobvious over the cited art. I reserve the right to expand or modify my opinions as my analysis continues, and to supplement my opinions in response to any additional information that becomes available to me and any matters raised by the parties, the Board, and/or the opinions provided by other experts.

142. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. I hereby declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code.

Date: 7/10/25

By: 
Milan Sonka