

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
PROGENICS PHARMACEUTICALS, INC.,)	
and EXINI DIAGNOSTICS AB,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action
)	No. 24-cv-10437-PBS
MIM SOFTWARE INC.,)	
)	
Defendant.)	
_____)	

MEMORANDUM AND ORDER

January 14, 2025

Saris, D.J.

INTRODUCTION

This patent infringement suit concerns computer systems designed to improve the analysis of medical images for diagnosing and monitoring cancer and other diseases. Plaintiffs Progenics Pharmaceuticals, Inc. and EXINI Diagnostics AB (together, "Progenics") allege that software products made by Defendant MIM Software Inc. ("MIM") infringe seven of Progenics' patents both directly and indirectly in violation of 35 U.S.C. § 271(a) and (b). The seven patents at issue ("the Asserted Patents") are U.S. Patent No. 10,665,346 ("the '346 patent"); U.S. Patent No. 10,973,486 ("the '486 patent"); U.S. Patent No. 11,424,035 ("the '035 patent"); U.S. Patent No. 11,894,141 ("the '141 patent"); U.S. Patent No. 11,657,508 ("the '508 patent"); U.S.

Patent No. 11,721,428 (“the ‘428 patent”); and U.S. Patent No. 11,941,817 (“the ‘817 patent”).

MIM has moved to dismiss under Federal Rule of Civil Procedure 12(b)(6) on two grounds. First, MIM argues that four of the Asserted Patents (the ‘346, ‘035, ‘141, and ‘817 patents) claim patent-ineligible subject matter under 35 U.S.C. § 101. Second, MIM contends that Progenics has failed to plausibly allege that its products infringe the remaining Asserted Patents (the ‘486, ‘508, and ‘428 patents).

After hearing, the Court **ALLOWS IN PART** and **DENIES IN PART** MIM’s motion to dismiss (Dkt. 43).

BACKGROUND

The following background is taken from Progenics’ Second Amended Complaint (“SAC”) and the Asserted Patents.

I. Medical Imaging Analysis

The Asserted Patents aim to improve physicians’ ability to interpret diagnostic images produced by medical imaging tools. Physicians use both anatomical and functional images when diagnosing and treating diseases like cancer. Anatomical images show the anatomy or structure of organs and tissues within the body. A computed tomography (“CT”) scan, for example, produces “detailed three-dimensional (3D) images of internal organs, bones, soft tissue, and blood vessels.” ‘346 patent at 26:40-43. With

anatomical images, physicians can “segment” (i.e., outline) 3D boundaries of specific organ and tissue regions of interest.

By contrast, functional images, also known as nuclear medicine images, measure organ and tissue activity and function. These images are created via administration of a radiopharmaceutical, which binds to specific receptors, enzymes, or proteins and can then be captured by a positron emission tomography (“PET”) or single-photon emission computed tomography (“SPECT”) camera. Certain radiopharmaceuticals accumulate at sites associated with cancerous tissue, thereby “produc[ing] identifiable hotspots -- localized regions of high intensity in nuclear medical images.” Id. at 15:47-53. Radiologists use functional images to create a “radiologist report” that “includes . . . the type of study performed, the clinical history, a comparison between images, the technique used to perform the study, [and] the radiologist’s observations and findings.” Id. at 2:11-16. Physicians, in turn, rely on functional images and radiology reports to determine the presence and extent of disease in a patient, recommend a course of treatment, and track disease progression.

The Asserted Patents owned by Progenics aim to ameliorate certain difficulties that physicians face when using these medical images. For instance, an anatomical image cannot reliably detect a cancerous tumor’s activity, while a functional image does not

differentiate the organs and tissue surrounding a tumor. Physicians must therefore manually parse and compare the two types of scans, which can lead to inaccurate or inconsistent diagnoses and treatments. Physicians also lack a standard method of communicating the likelihood of a particular prognosis or the risk associated with various treatment options.

II. The Asserted Patents

A. '346, '035, and '141 Patents

The '346, '035, and '141 patents share a title and specification. Entitled "Network for Medical Image Analysis, Decision Support System, and Related Graphical User Interface (GUI) Applications," the patents disclose "a cloud-based platform and supported graphical user interface (GUI) decision-making tools for use by medical practitioners and/or their patients, e.g., to aid[] in the process of making decisions about a course of cancer treatment and/or to track treatment and/or the progress of a disease." Id. at 1:1-4, 2:62-67.

Specifically, these patents describe systems for the automated analysis of medical images to generate a "risk map" and/or "risk index." Id. at 4:1-10. According to the specification, a "risk map" is "a visual representation (e.g., 3D representation) of tissue (e.g., an organ or other part of the body) with graphical denotations (e.g., texture- or color-coding) marking regions of risk of current disease or risk of recurrence of disease." Id. at

4:3-7. The specification defines a "risk index" as "a measure of disease state for the patient" that "can be determined based on features of detected hotspots," such as "a total number of detected hotspots within the region, a total volume of detected hotspots within the region, an average intensity of detected hotspots, [and] a maximal intensity of detected hotspots." Id. at 25:46-59; see id. at 27:11-25.

The common specification discloses certain embodiments that use a "composite image" comprising a CT (anatomical) scan overlaid with a PET or SPECT (functional) scan. Id. at 26:34-28:18. The composite image consists of "a mapping between coordinates and/or pixels or voxels of the two images that . . . represent the same physical locations." Id. at 26:35-40. Some of these embodiments call for the composite image to be "obtained using dedicated PET-CT [or SPECT-CT] scanner instruments common in many hospitals," id. at 27:1-5, while others use anatomical and functional scans obtained separately and "automatically fused to create a composite image," id. at 27:5-10.

As discussed below, the Court analyzes the '346 patent as an exemplar for this family of patents (and the '817 patent). Independent claim 1 of the '346 patent reads as follows:

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.

Id. at 35:46-36:7.

B. '817 and '508 Patents

The common title of the '817 and '508 patents is "Systems and Methods for Platform Agnostic Whole Body Image Segmentation." '508 patent at 1:1-3. The patents disclose "systems and methods that provide for automated analysis of three-dimensional (3D) medical images of a subject in order to automatically identify specific 3D volumes within the 3D images that correspond to specific anatomical

regions[,] e.g., organs and/or tissue.” Id. at 2:66-3:3. The shared specification explains that the inventions “allow for automated analysis of combinations of anatomical and functional images in order to accurately identify and grade cancerous lesions within a subject.” Id. at 3:45-47.

As relevant here, the specification describes the following approach covered by the '508 patent:

In certain embodiments, the ability to accurately and rapidly perform full body segmentation . . . is leveraged to provide a useful and uniform scale on which to evaluate and/or measure radiopharmaceutical uptake levels in physical lesions corresponding to detected hotspots In particular, in addition to detecting target [volumes of interest (VOIs)] corresponding to specific target tissue regions in which cancerous lesions may occur, additional target VOIs corresponding to reference tissue regions are also detected. These reference VOIs are also mapped to the PET image, to identify corresponding reference volumes therein. Measures of intensity . . . within these reference volumes are then computed and used as reference points against which to evaluate intensities of individual detected hotspots and convert them to index values on the scale.

For example, in certain embodiments, an aorta and a liver VOI, corresponding to a representation of a portion of an aorta and liver, respectively, are identified within the anatomical image and mapped to the functional image to identify corresponding reference volumes therein. Intensity levels of each of these reference volumes are determined . . . and assigned corresponding index levels on a scale. Then, for each particular individual hotspot, a hotspot intensity level is determined A corresponding individual hotspot index value is then determined based [on the] individual hotspot intensity level, the aorta reference intensity level, and the liver reference intensity level. This approach provides a standardized scale on which to evaluate and measure uptake associated with hotspots

across different images. This allows, for example, for comparison of multiple images obtained for a single subject at different time points, as well as comparison between images of different subjects.

Id. at 3:66-4:35.

Independent claim 1 of the '508 patent reads as follows:

A method for automatically processing 3D images to identify, and measure uptake of radiopharmaceutical in, cancerous lesions within a subject having or at risk for a cancer, the method comprising:

(a) receiving, by a processor of a computing device, a 3D anatomical image of a subject obtained using an anatomical imaging modality, wherein the 3D anatomical image comprises a graphical representation of tissue within the subject;

(b) automatically identifying, by the processor, using one or more machine learning modules, within the 3D anatomical image:

a first skeletal volume comprising a graphical representation of one or more bones of the subject;

a first aorta volume comprising a graphical representation of at least a portion of an aorta of the subject; and

a first liver volume comprising a graphical representation of a liver of the subject;

(c) determining, by the processor, a 3D segmentation map representing a plurality of 3D segmentation masks, including a skeletal mask representing the identified first skeletal volume, an aorta mask representing the identified first aorta volume, and a liver mask representing the identified first liver volume;

(d) receiving, by the processor, a 3D functional image of the subject obtained using a functional imaging modality;

(e) automatically identifying, within the 3D functional image, using the 3D segmentation map:

a second skeletal volume corresponding to the first identified skeletal volume, within the 3D anatomical image;

a second aorta volume corresponding to the first aorta volume, identified within the 3D anatomical image; and

a second liver volume corresponding to the first liver volume, identified within the 3D anatomical image;

(f) automatically detecting, by the processor, within the second skeletal volume, one or more hotspots determined to represent lesions based on intensities of voxels within the second skeletal volume; and

(g) determining, by the processor, for each of the one or more detected hotspots, an individual hotspot index value by:

determining an aorta reference intensity level based on a measure of intensity of voxels within the second aorta volume;

determining a liver reference intensity level based on a measure of intensity of voxels within the second liver volume; and

for each individual detected hotspot:

determining a corresponding individual hotspot intensity level based on a measure of intensity of voxels of the detected hotspot; and

determining a corresponding individual hotspot index level from the individual hotspot intensity level, the aorta reference intensity level, and the liver reference intensity level.

Id. at 79:64-80:55.

C. '486 Patent

The '486 patent is entitled "Systems and Methods for Rapid Neural Network-Based Image Segmentation and Radiopharmaceutical Uptake Determination." '486 patent at 1:1-5. The patent describes the invention as:

systems and methods that provide for automated analysis of three-dimensional (3D) medical images of a subject in order to automatically identify specific 3D volumes within the 3D images that correspond to specific organs and/or tissue. In certain embodiments, the accurate identification of one or more such volumes are used to automatically determine quantitative metrics that represent uptake of radiopharmaceuticals in particular organs and/or tissue regions. These uptake metrics can be used to assess disease state in a subject, determine a prognosis for a subject, and/or determine efficacy of a treatment modality.

Id. at 2:60-3:3. The claims in the patent are all limited to analysis of the prostate.

The parties both identify independent claim 42 as a representative claim. This claim reads as follows:

A method for automatically processing 3D images to identify 3D volumes within the 3D images that correspond to a prostate of a subject and determining one or more uptake metrics indicative of radiopharmaceutical uptake therein, the method comprising:

- (a) receiving, by a processor of a computing device, a 3D anatomical image of the subject obtained using an anatomical imaging modality, wherein the 3D anatomical image comprises a graphical representation of tissue within a subject, at least a portion of which corresponds to a pelvic region of the subject;

(b) receiving, by the processor, a 3D functional image of the subject obtained using a functional imaging modality, wherein the 3D functional image comprises a plurality of voxels, each representing a particular physical volume within the subject and having an intensity value that represents detected radiation emitted from the particular physical volume, wherein at least a portion of the plurality of voxels of the 3D functional image represent physical volumes within the pelvic region of the subject;

(c) determining, by the processor, using a first module, an initial volume of interest (VOI) within the 3D anatomical image, the initial VOI corresponding to tissue within the pelvic region of the subject and excluding tissue outside the pelvic region of the subject;

(d) identifying, by the processor, using a second module, a prostate volume within the initial VOI corresponding to the prostate of the subject;

(e) determining, by the processor, the one or more uptake metrics using the 3D functional image and the prostate volume identified within the initial VOI of the 3D anatomical image;

[(f)] causing, by the processor, display of an interactive graphical user interface (GUI) for presentation to the user of a visual representation of the 3D anatomical image and/or the 3D functional image; and

(g) causing, by the processor, graphical rendering of, within the GUI, the 3D anatomical image and/or the 3D functional image as selectable and superimposable layers, such that either can be selected for display and rendered separately, or both selected for display and rendered together by overlaying the 3D anatomical image with the 3D functional image.

Id. at 80:33-81:9.

D. '428 Patent

The final Asserted Patent -- the '428 patent -- is entitled "Systems and Methods for Artificial Intelligence-Based Image Analysis for Detection and Characterization of Lesions." '428 patent at 1:1-4. The patent describes "systems and methods that provide for improved detection and characterization of lesions within a subject via automated analysis of nuclear medicine images." Id. at 2:50-52. The specification explains that:

once image hotspots representing lesions are detected, segmented, and classified, lesion index values can be computed to provide a measure of radiopharmaceutical uptake within and/or a size (e.g., volume) of the underlying lesion. The computed lesion index values can, in turn, be aggregated to provide an overall estimate of tumor burden, disease severity, metastasis risk, and the like, for the subject. In certain embodiments, lesion index values are computed by comparing measures of intensities within segmented hotspot volumes to intensities of specific reference organs, such as liver and aorta portions. Using reference organs in this manner allows for lesion index values to be measured on a normalized scale that can be compared between images of different subjects.

Id. at 3:5-18.

Both parties identify independent claim 1 as the representative claim. This claim reads as follows:

A method of measuring intensity values within a reference volume corresponding to a reference tissue region so as to avoid impact from tissue regions associated with low radiopharmaceutical uptake, the method comprising:

- (a) receiving, by a processor of a computing device, a 3D functional image of a subject, said 3D functional image obtained using positron emission

tomography (PET) and/or single-photon emission computed tomography (SPECT);

(b) identifying, by the processor, the reference volume within the 3D functional image;

(c) fitting, by the processor, a multi-component mixture model to a distribution of intensities of voxels within the reference volume;

(d) identifying, by the processor, a major mode of the multi-component model;

(e) determining, by the processor, a measure of intensities corresponding to the major mode, thereby determining a reference intensity value corresponding to a measure of intensity of voxels that are (i) within the reference tissue volume and (ii) associated with the major mode;

(f) detecting, by the processor, within the functional image, one or more hotspots corresponding [to] potential cancerous lesions; and

(g) determining, by the processor, for each particular hotspot of at least a portion of the detected hotspots, a lesion index value indicative of: (I) a level of radiopharmaceutical uptake within and underlying lesion to which the particular hotspot corresponds and/or (II) a size of an underlying lesion to which the particular hotspot corresponds, wherein the lesion index value is determined based on (i) a measure of intensity of the particular hotspot and (ii) the reference intensity value.

Id. at 48:62-49:27.

III. Lead-Up to the Lawsuit

Progenics develops targeted medicines for oncology and advanced software products for medical imaging analysis. MIM similarly sells imaging tools for radiation oncology, radiology, and nuclear medicine.

Around June 2020, Progenics and MIM started discussing a potential collaboration after MIM expressed interest in integrating the inventions claimed by the Asserted Patents into its software. During these discussions, Progenics gave MIM access to its systems to review the inventions' capabilities and functions. MIM abruptly ended talks in late 2022.

The following year, MIM began to publish articles, brochures, and information on its website about four products -- Contour ProtégéAI, MIM SurePlan MRT ("SurePlan MRT"), LesionID, and LesionID Pro -- that Progenics alleges infringe the Asserted Patents. These products "analyze and display scan results to physicians." Dkt. 25 ¶ 5. LesionID "supports the calculation of total tumor burden and individual statistics based on user-customizable cut-off criteria." Id. ¶ 78. Similarly, LesionID Pro "identif[ies] lesions," "eliminat[es] physiological uptakes," and "calculate[s] total tumor burden." Id. ¶ 65. Contour ProtégéAI "segments normal structures with artificial intelligence." Id. (cleaned up). Finally, SurePlan MRT displays images showing "normal organ contours and tumor contours overlaid on medical images" and "compute[s] . . . tumor burden." Id. ¶¶ 84, 93.

LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, a complaint must allege "a plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007). "While a complaint attacked by

a Rule 12(b)(6) motion does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." Id. at 555 (cleaned up). This standard requires a court to "separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited)." Kando v. R.I. State Bd. of Elections, 880 F.3d 53, 58 (1st Cir. 2018) (quoting Morales-Cruz v. Univ. of P.R., 676 F.3d 220, 224 (1st Cir. 2012)). The court must then determine whether the factual allegations permit it "to draw the reasonable inference that the defendant is liable for the misconduct alleged." Germanowski v. Harris, 854 F.3d 68, 72 (1st Cir. 2017) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). In assessing the plausibility of Progenics' claims, this Court considers both the allegations in the SAC and the contents of the Asserted Patents. See Ocean Semiconductor LLC v. Analog Devices, Inc., 664 F. Supp. 3d 195, 197, 201 (D. Mass. 2023).

DISCUSSION

I. Section 101 Patent Eligibility

MIM moves to dismiss the claims of infringement of four of the Asserted Patents -- the '346, '035, '141, and '817 patents -- on the basis that those patents are directed to patent-ineligible

subject matter under 35 U.S.C. § 101. At the hearing on MIM's motion to dismiss, the parties agreed that the '346 patent could serve as an exemplar for purposes of the patent eligibility analysis. That patent claims a "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." '346 patent at 35:46-48. Given the parties' agreement, the Court focuses its analysis on the '346 patent.

A. Alice Test for Patent Eligibility

Under 35 U.S.C. § 101, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor." The Supreme Court has read certain implicit exceptions into this statute, including that "abstract ideas are not patentable." Contour IP Holding LLC v. GoPro, Inc., 113 F.4th 1373, 1378 (Fed. Cir. 2024) (quoting Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 216 (2014)). The "exception for abstract ideas . . . embodies 'the longstanding rule that "[a]n idea of itself is not patentable.'" Id. (second alteration in original) (quoting Alice, 573 U.S. at 218).

"The Supreme Court has articulated a two-step test, commonly referred to as the 'Alice' test, to determine whether a patent claims patent-ineligible subject matter." Broadband iTV, Inc. v. Amazon.com, Inc., 113 F.4th 1359, 1367 (Fed. Cir. 2024); see Alice,

573 U.S. at 217-18. At Alice step one, a court “must determine whether the claims at issue are directed to patent-ineligible subject matter,” such as an abstract idea. Broadband iTV, Inc., 113 F.4th at 1367. If the claims are not directed to an abstract idea, “the inquiry ends.” Id. If they are, the court “proceed[s] to step two” and examines whether any claim “recites elements sufficient to transform it into a patent-eligible application of the abstract idea.” Id.

The inquiry under Alice step one asks “whether the claims ‘focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery.’” Miller Mendel, Inc. v. City of Anna, 107 F.4th 1345, 1352 (Fed. Cir. 2024) (quoting CardioNet, LLC v. InfoBionic, Inc., 955 F.3d 1358, 1368 (Fed. Cir. 2020)), cert. denied, ___ S. Ct. ___ (2024) [2024 WL 4874683]. In conducting this inquiry, courts “look to the character of the claims as a whole” as evidenced by “the claim language itself” and “the patent’s specification.” Broadband iTV, Inc., 113 F.4th at 1367.

The Federal Circuit has offered several guideposts for determining whether a claim is directed to an abstract idea under Alice step one. A claim is more likely to be directed to an abstract idea when it concerns “a longstanding or fundamental human practice” or “can be performed in the human mind or using a pencil

and paper.” Id. Moreover, claims “drafted using largely . . . result-focused functional language, containing no specificity about how the purported invention achieves those results[,] . . . are almost always found to be ineligible for patenting.” Beteiro, LLC v. DraftKings Inc., 104 F.4th 1350, 1356 (Fed. Cir. 2024).

In the context of “software-based inventions,” courts ask at Alice step one “whether the claims focus on the specific asserted improvement in computer capabilities or, instead, on a process that qualifies as an abstract idea for which computers are invoked merely as a tool.” Miller Mendel, Inc., 107 F.4th at 1352 (quoting In re Killian, 45 F.4th 1373, 1382 (Fed. Cir. 2022)). “[R]equiring the use of a computer alone does not change the focus of a claim directed towards an abstract idea into one directed towards ‘a specific improvement to computer functionality.’” Id. at 1353 (quoting TLI Commcn’s LLC v. AV Auto., LLC (In re TLI Commc’s ns LLC Pat. Litig.), 823 F.3d 607, 612 (Fed. Cir. 2016)). The Federal Circuit has consistently held that claims reciting generalized steps of receiving, storing, analyzing, transmitting, selecting, and displaying information are directed to abstract ideas. See, e.g., Broadband iTV, Inc., 113 F.4th at 1368; Mobile Acuity Ltd. v. Blippar Ltd., 110 F.4th 1280, 1293 (Fed. Cir. 2024); Miller Mendel, Inc., 107 F.4th at 1352; Beteiro, LLC, 104 F.4th at 1355; see also Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1353–54 (Fed. Cir. 2016) (discussing claims of this genre).

If the claim is directed to an abstract idea, the court advances to Alice step two. See Chewy, Inc. v. Int'l Bus. Machs. Corp., 94 F.4th 1354, 1365 (Fed. Cir. 2024). That step entails "examin[ing] the elements of the claim" -- "individually and as an ordered combination" -- "to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application.'" Id. (quoting Alice, 573 U.S. at 221). "[C]laim elements or combinations of claim elements that are routine, conventional or well-understood cannot transform the claim." Broadband iTV, Inc., 113 F.4th at 1370. If "the patent's specification 'describes the components and features listed in the claims generically,' it 'support[s] the conclusion that these components and features are conventional.'" Id. (alteration in original) (quoting Weisner v. Google LLC, 51 F.4th 1073, 1083-84 (Fed. Cir. 2022)). "When a claim directed to an abstract idea contains no restriction on how the result is accomplished and the mechanism is not described, then the claim cannot be patent eligible at step two." Ocean Semiconductor LLC, 664 F. Supp. 3d at 203.

For software technology, the "inventive concept that transforms the abstract idea into a patent-eligible invention must be significantly more than the abstract idea itself, and cannot simply be an instruction to implement or apply the abstract idea on a computer." CosmoKey Sols. GmbH & Co. KG v. Duo Sec. LLC, 15

F.4th 1091, 1097 (Fed. Cir. 2021) (quoting BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC, 827 F.3d 1341, 1349 (Fed. Cir. 2016)). Put differently, mere “[a]utomation of an abstract idea does not constitute an inventive concept.” Broadband iTV, Inc., 113 F.4th at 1370. Nor are the improved speed, efficiency, and accuracy “inherent with applying the abstract idea using a computer.” Trinity Info Media, LLC v. Covalent, Inc., 72 F.4th 1355, 1366 (Fed. Cir. 2023).

The patent challenger bears the burden of proving the ineligibility of any patent claim. See Mobile Acuity Ltd., 110 F.4th at 1291. A court may address patent eligibility on a motion to dismiss “when there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law.” Beteiro, LLC, 104 F.4th at 1355 (quoting Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121, 1125 (Fed. Cir. 2018)). “Although Alice step two involves a question of law, whether a claim limitation or combination of limitations is well-understood, routine, and conventional may involve an underlying factual question.” AI Visualize, Inc. v. Nuance Commc’ns, Inc., 97 F.4th 1371, 1379 (Fed. Cir. 2024). Thus, “patentees who adequately allege their claims contain inventive concepts survive a § 101 eligibility analysis under Rule 12(b)(6).” Id. (quoting Aatrix Software, Inc., 882 F.3d at 1126-27).

B. Parties' Arguments

MIM contends that the claims in the '346 patent are directed to abstract ideas at Alice step one "because they claim methods and systems for accessing, analyzing, and displaying analysis of medical images, activities that can and are conventionally conducted by humans to identify cancer risk." Dkt. 44 at 14. In MIM's view, the claims simply "automate aspects of medical image review historically performed by physicians" to identify hotspots of cancer risk. Id. at 16. The requirements of "machine learning" and a "risk map" do not render the claims non-abstract, MIM continues, because the claims recite use of a generic machine learning algorithm and the concept of a "risk map" is not inventive. See id. at 18-20. MIM argues that the claims fail at Alice step two for similar reasons, as they "lack any technological improvements or inventive concepts, and merely purport to cover the abstract idea of automating the review of medical images with generic computer technology." Id. at 14. MIM asserts that the claims "follow a conventional approach to accessing and analyzing a patient's medical images to assess cancer risk." Id. at 22.

Progenics responds that the claims in the '346 patent survive both steps of the Alice test. At step one, Progenics contends that the claims recite "an inventive process for identifying regions of cancer risk and creating a new, 3D visualization from a combination of anatomical and functional images" and that this invention

improves the reliability and accuracy of cancer diagnosis compared to the manual methods previously used by physicians to analyze medical images. Dkt. 48 at 13-15. Progenics posits that MIM ignores that the creation of 3D visualizations with “risk maps” amounts to “much more than merely gathering, analyzing, and displaying information.” Id. at 16-17. Progenics argues too that humans cannot perform the complex method claimed in the patent and that the Court must, at this stage, accept the allegations that the claimed method is an improvement to the conventional way of analyzing medical images. See id. at 18-20. As for Alice step two, Progenics emphasizes that the patent “contain[s] multiple inventive concepts,” including “the creation of novel 3D visualizations of cancer risk that are overlaid on medical images.” Id. at 7. Progenics points to assertions in the SAC and in the specifications that the claimed method involves novel and inventive improvements to the reliability and accuracy of analyzing medical images to detect cancer risk. See id. at 20-21.¹

C. Analysis

For the reasons discussed below, the Court concludes that Progenics has plausibly alleged that the claims in the '346 patent

¹ The parties also dispute whether the dependent claims in the '346 patent add an inventive concept at Alice step two. Because the Court concludes that Progenics has plausibly alleged that a common feature of all of the claims amounts to an inventive concept, there is no need to address the parties' arguments about the dependent claims.

contain an inventive concept sufficient to transform any abstract idea into a patent-eligible application at Alice step two. See AI Visualize, Inc., 97 F.4th at 1379. The Court therefore assumes solely for present purposes that, as MIM argues, the claims are directed to the abstract ideas of accessing, analyzing, and displaying medical imaging data to identify regions of cancer risk. See CosmoKey Sols., 15 F.4th at 1097 (taking this approach to the Alice test); Amdocs (Isr.) Ltd. v. Openet Telecom, Inc., 841 F.3d 1288, 1304 (Fed. Cir. 2016) (same); see also Personalized Media Commc'ns, LLC v. Netflix Inc., 475 F. Supp. 3d 289, 298 (S.D.N.Y. 2020) ("Although courts ordinarily resolve step one before proceeding to step two, it is within a court's discretion to skip straight to step two.").

The second limitation of independent claim 1 of the '346 patent requires the processor to "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." '346 patent at 35:56-62. The claim further describes this step as follows: "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.” Id. at 36:1-7. All twelve other claims in the ’346 patent (eleven of which are dependent on claim 1) recite the same limitation requiring creation of a risk map overlaid on one or more medical images.

Progenics asserts that this creation of a risk map overlaid on medical images plausibly constitutes an inventive concept sufficient to survive step two of the Alice test at the motion-to-dismiss stage. I agree. According to the SAC, physicians traditionally have received separate anatomical and functional images and have had to “parse [the] two different types of scans to try to piece together the full picture” of a patient’s cancer risk. Dkt. 25 ¶ 20. This manual analysis “often led to inaccurate or inconsistent diagnoses or treatments.” Id. The SAC plausibly alleges that the automated creation of a risk map -- a visual depiction of geographic boundaries of regions of cancer risk -- overlaid on medical images provides a technological improvement over the traditional, manual method of analyzing medical scans for cancer risk. See id. ¶¶ 22, 24. Creation of this overlay with a risk map is “significantly more” than merely the automation of the abstract idea of analyzing medical images to determine cancer risk. CosmoKey Sols., 15 F.4th at 1097 (quoting BASCOM Glob., 827 F.3d

at 1349). Rather, it is “a concrete application of [that] abstract idea.” AI Visualize, Inc., 97 F.4th at 1380.

MIM retorts that creation of a risk map overlaid on medical images is not inventive because the claims “use standard computing equipment and invoke generic ‘machine learning’ to perform the same analysis that radiologists and oncologists already routinely do.” Dkt. 44 at 7. MIM is right that the claims’ use of machine learning is not enough by itself to survive Alice step two because the claims do not recite any improvement in machine learning technology. See Dental Monitoring SAS v. Align Tech., Inc., No. C 22-07335 WHA, 2024 WL 2261931, at *7 (N.D. Cal. May 16, 2024), appeal docketed, No. 24-2270 (Fed. Cir. Aug. 29, 2024); Recentive Analytics, Inc. v. Fox Corp., 692 F. Supp. 3d 438, 456-57 (D. Del. 2023), appeal docketed, No. 23-2437 (Fed. Cir. Sept. 29, 2023); see also Miller Mendel, Inc., 107 F.4th at 1354 (explaining that a “patent’s use of generic computer components . . . confirms that these components do not provide an inventive concept”). Given the allegations in the SAC, though, the Court cannot adopt MIM’s characterization of the claimed method as an automated version of the process traditionally used by physicians to analyze medical images to identify regions of cancer risk. And interpreting the claims at issue as simply mirroring the conventional practices of segmenting tissue or organs, comparing different images, creating radiology reports, and presenting diagnoses amounts to the type of

oversimplification of claims that the Federal Circuit has warned against in the context of a patent eligibility analysis. See CardioNet, LLC, 955 F.3d at 1371. The SAC plausibly alleges that a risk map overlaid on medical images as described in the claims of the '346 patent is not a conventional tool used in analyzing medical images for cancer risk.

Finally, insofar as MIM argues that a risk map overlaid on medical images is no different than a conventional composite PET-CT or SPECT-CT medical image, this argument is unconvincing. It is true that the concept of a composite image is not inventive, as the specification mentions certain embodiments that use "composite images comprising CT scans overlaid with PET scans . . . obtained using dedicated PET-CT scanner instruments common in many hospitals." '346 patent at 27:1-4. But the risk map described in the claims contains "graphical denotations marking one or more regions of risk of cancer or risk of recurrence of cancer." Id. at 35:59-62. Neither the SAC nor the specification suggests that a conventional composite image contains such denotations.

In sum, Progenics plausibly alleges that the creation of a risk map overlaid on medical images described in the claims of the '346 patent is an inventive concept. Accordingly, those claims "survive a § 101 eligibility analysis under Rule 12(b)(6)." AI Visualize, Inc., 97 F.4th at 1379 (quoting Aatrix Software, Inc., 882 F.3d at 1126-27). Having found this exemplar patent to claim

patent-eligible subject matter, the Court denies MIM's motion to dismiss the claims of infringement of the '346, '035, '141, and '817 patents.

II. Failure to Plausibly Allege Infringement

MIM moves to dismiss the claims of infringement of the remaining three Asserted Patents -- the '486, '508, and '428 patents -- on the basis that Progenics has failed to plausibly allege that the four products at issue (Contour ProtégéAI, SurePlan MRT, LesionID, and LesionID Pro) infringe those patents.

A. Standard for Plausibly Alleging Infringement

The Court begins with two threshold matters regarding the standard for pleading a claim of patent infringement.

First, MIM argues that "Progenics must allege that the accused product includes every limitation of the asserted claim." Dkt. 44 at 29. Not so. The Federal Circuit has rejected the notion that a plaintiff must "plead infringement on an element-by-element basis." AlexSam, Inc. v. Aetna, Inc., 119 F.4th 27, 35 (Fed. Cir. 2024) (quoting Bot M8 LLC v. Sony Corp. of Am., 4 F.4th 1342, 1352 (Fed. Cir. 2021)); see Ocean Semiconductor LLC v. Analog Devices, Inc., 698 F. Supp. 3d 204, 208 (D. Mass. 2023). Instead, the plaintiff must offer "some factual allegations that, when taken as true, articulate why it is plausible that the accused product infringes the patent claim." AlexSam, Inc., 119 F.4th at 35 (quoting Bot M8 LLC, 4 F.4th at 1353). "The level of detail

required in any given case will vary depending upon a number of factors, including the complexity of the technology, the materiality of any given element to practicing the asserted claim(s), and the nature of the allegedly infringing device.” Id. at 42 (quoting Bot M8 LLC, 4 F.4th at 1353). “[A] plaintiff cannot assert a plausible claim for infringement . . . by reciting the claim elements and merely concluding that the accused product has those elements.” Bot M8 LLC, 4 F.4th at 1353.

Second, the parties spar over whether Progenics may plead infringement via use of an illustrative product or products for each patent. As just noted, the baseline pleading rule demands “some factual allegations that, when taken as true, articulate why it is plausible that the accused product infringes the patent claim.” AlexSam, Inc., 119 F.4th at 35 (quoting Bot M8 LLC, 4 F.4th at 1353). A complaint need not “identify all allegedly infringing products . . . and map those products to patent claims.” Kawasaki Jukogyo Kabushiki Kaisha v. Rorze Corp., 677 F. Supp. 3d 1079, 1084 (N.D. Cal. 2023). When multiple products are at issue, a plaintiff may satisfy the pleading requirement by plausibly alleging both that one product infringes a claim in the patent and that that one product is representative of the others in material respects. See id. If, however, the plaintiff fails to plausibly allege that one product is representative of another, it cannot rely on factual allegations about the former product to establish

a plausible case of infringement with regard to the latter product. See id. at 1085.²

With these standards in mind, the Court addresses MIM's arguments regarding the three patents at issue.

B. '486 Patent

Representative claim 42 of the '486 patent recites "[a] method for automatically processing 3D images to identify 3D volumes within the 3D images that correspond to a prostate of a subject and determining one or more uptake metrics indicative of radiopharmaceutical uptake therein." '486 patent at 80:33-36. Limitation (c) of this claim requires the processor to "determin[e] . . . an initial volume of interest (VOI) within the 3D anatomical image, the initial VOI corresponding to tissue within the pelvic region of the subject and excluding tissue outside the pelvic region of the subject." Id. at 80:54-58 (emphasis added). According to the specification, this step -- the "identification of a bounding box" -- "improves computational efficiency by removing a large portion of the initial 3D anatomical image." Id. at 4:10, 4:45-50. MIM asserts that Progenics has failed to

² At the hearing on MIM's motion to dismiss, Progenics argued that all four products at issue are part of MIM's medical imaging software suite and that this suite is the sole infringing "product." Although the SAC mentions "MIM's broader software suite" in passing, it specifically defines the "Infringing Products" as "Contour ProtégéAI, MIM SurePlan MRT, LesionID, and LesionID Pro." Dkt. 25 ¶¶ 5, 52. The Court therefore analyzes the four products separately.

plausibly allege that Contour ProtégéAI and SurePlan MRT exclude tissue outside the pelvic region as required by this limitation.

Progenics plausibly alleges that Contour ProtégéAI and SurePlan MRT practice the limitation at issue. According to the SAC, SurePlan MRT “uses Contour ProtégéAI to perform organ segmentation,” including for the prostate, with anatomical and functional images. Dkt. 25 ¶¶ 68-70. After importing the images, Contour ProtégéAI “detects [the] treatment site to apply [the] correct AI model” and “includes a ‘Pelvis CT’ model for segmenting organs within the pelvic region.” Id. ¶ 71 (first alteration in original). Because the prostate is within the pelvic region, detection of the treatment site for segmenting the prostate plausibly focuses on tissue “within the pelvic region” and “exclud[es] tissue outside the pelvic region.” ‘486 patent at 80:56-58. MIM’s argument that limitation (c) requires an active step of excluding tissue outside the pelvic region is a matter of claim construction that is “not suitable for resolution on a motion to dismiss.” Nalco Co. v. Chem-Mod, LLC, 883 F.3d 1337, 1349 (Fed. Cir. 2018).

MIM also points out that the SAC does not offer any factual detail indicating that LesionID and LesionID Pro practice limitation (c) of claim 42. Indeed, Progenics sets out no facts about these two products when describing how MIM is infringing the ‘486 patent. See Dkt. 25 ¶¶ 68-75.

The Court dismisses the claim of infringement of the '486 patent with regard to LesionID but not LesionID Pro. The SAC alleges that "LesionID Pro uses Contour ProtégéAI in order to segment organs using [artificial intelligence], which is part of LesionID Pro's physiological uptake removal approach." Id. ¶ 93. Thus, because the Court declines to dismiss this claim of infringement with regard to Contour ProtégéAI, the claim survives with regard to LesionID Pro too. But Progenics does not allege that LesionID either uses Contour ProtégéAI or performs a comparable two-step method of identifying the prostate within the anatomical image as required by limitations (c) and (d) of claim 42. Nor does the SAC allege with any clarity that any of the other three purportedly infringing products are representative of LesionID in material respects. Progenics does not, therefore, adequately plead that LesionID infringes the '486 patent. The dismissal of this claim with regard to LesionID is without prejudice to the filing of a third amended complaint with additional factual allegations that state a plausible claim of infringement.

C. '508 Patent

Representative claim 1 of the '508 patent recites "[a] method for automatically processing 3D images to identify, and measure uptake of radiopharmaceutical in, cancerous lesions within a subject having or at risk for a cancer." '508 patent at 79:64-67.

The method uses the level of radiopharmaceutical uptake in the aorta and the liver as references with which to compare uptake in the potentially cancerous lesions. See id. at 4:16-35. Specifically, limitation (g) involves “determining an aorta reference intensity level”; “determining a liver reference intensity level”; and “for each individual detected hotspot[,] determining a corresponding individual hotspot intensity level” and “a corresponding individual hotspot index level from the individual hotspot intensity level, the aorta reference intensity level, and the liver reference intensity level.” Id. at 80:42-55 (emphasis added).

MIM contends that Progenics’ allegations are inconsistent with infringement because the SAC describes PERCIST, the approach employed by LesionID to measure tumor burden, as involving calculation of a hotspot intensity level using an aorta reference level or a liver reference level, but not both. See Bot M8 LLC, 4 F.4th at 1354 (“Where . . . the factual allegations are actually inconsistent with and contradict infringement, they are . . . insufficient to state a plausible claim.”).

The Court agrees with MIM, at least as Progenics’ claim is currently pled. The SAC contains conflicting allegations as to whether the PERCIST method used by LesionID calculates tumor burden using reference levels from both the aorta and the liver or from only one of the two. In fact, Progenics alleges in a single

paragraph that PERCIST uses “liver and/or aorta reference intensities,” “liver or aorta references,” and “liver and aorta-derived thresholds.” Dkt. 25 ¶ 102. Given these conflicting allegations, the Court cannot reasonably infer that, as required by limitation (g) of claim 1, LesionID calculates a hotspot index level using reference levels from both the aorta and the liver rather than from only one of the two. Progenics’ claim that the other three products -- LesionID Pro, Contour ProtégéAI, and SurePlan MRT -- infringe this patent suffers from the same flaw because the SAC alleges that all the purportedly infringing products use PERCIST. See id. ¶ 109.

The Court therefore dismisses Progenics’ claim of infringement of the ‘508 patent. This dismissal is without prejudice to the filing of a third amended complaint clarifying how the PERCIST method calculates a hotspot index level.

D. ‘428 Patent

Lastly, representative claim 1 of the ‘428 patent recites “[a] method of measuring intensity values within a reference volume corresponding to a reference tissue region so as to avoid impact from tissue regions associated with low radiopharmaceutical uptake.” ‘428 patent at 48:62-65. Limitations (c), (d), and (e) require the following steps after receipt of a 3D functional image and identification of a reference volume within that image: 1) “fitting . . . a multi-component mixture model to a

distribution of intensities of voxels within the reference volume"; 2) "identifying . . . a major mode of the multi-component model"; and 3) "determining . . . a measure of intensities corresponding to the major mode, thereby determining a reference intensity value corresponding to a measure of intensity of voxels that are (i) within the reference tissue volume and (ii) associated with the major mode." Id. at 48:66-49:15. MIM argues that the SAC fails to plausibly allege that its products practice these limitations.

Progenics' allegations are sufficient to raise a reasonable inference that LesionID and LesionID Pro infringe claim 1. The SAC alleges that LesionID "implements a technique that involves measuring reference intensities within [the] liver or other reference tissue" and that LesionID and LesionID Pro "use reference organs (such as the liver) to determine reference intensities for evaluating and calibrating radiopharmaceutical uptake and lesion severity." Dkt. 25 ¶ 107. Taken as true, these allegations demonstrate that LesionID and LesionID Pro calculate a reference intensity in a reference organ. While the SAC does not directly state that these two products do so via the exact mathematical methodology described in limitations (c), (d), and (e) of claim 1, that level of element-by-element specificity is not necessary to establish a plausible claim of infringement. See AlexSam, Inc., 119 F.4th at 35. A comparison of mathematical methodologies

employed by the patent and MIM's products is better suited to resolution at the summary judgment stage.

Moreover, while Progenics does not offer detailed factual allegations about Contour ProtégéAI or SurePlan MRT when describing how MIM's products infringe claim 1 of the '428 patent, the Court concludes that Progenics has also sufficiently alleged infringement by those products. Progenics' claim of infringement of this patent, like that of the '508 patent, is premised on MIM's products' use of the PERCIST approach to calculate tumor burden. See Dkt. 25 ¶¶ 104, 107-09. As previously noted, the SAC alleges that all of the purportedly infringing products use PERCIST. See id. ¶ 109. Thus, Progenics' allegations about LesionID and LesionID Pro are plausibly representative of Contour ProtégéAI or SurePlan MRT.³

ORDER

For the reasons stated above, MIM's motion to dismiss (Dkt. 43) is **ALLOWED** as to the claim of infringement of the '486 patent (Count II) with regard to LesionID and as to the claim of infringement of the '508 patent (Count V), without prejudice to

³ Claim 1 of the '428 patent requires the "lesion index value" be calculated from a "reference intensity value" without specifying that this reference value come from any particular organ or tissue. '428 patent at 49:19-27. Thus, Progenics' claim of infringement of this patent does not suffer from the same deficiency as its claim of infringement of the '508 patent.

filing a third amended complaint within 30 days. The motion is otherwise **DENIED**.

SO ORDERED.

/s/ PATTI B. SARIS
Hon. Patti B. Saris
United States District Judge