UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PROGENICS PHARMACEUTICALS, INC., and EXINI DIAGNOSTICS AB, Plaintiffs, v. MIM SOFTWARE INC., Defendant.	Civil Action No. 24-10437 **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT

Plaintiffs Progenics Pharmaceuticals, Inc. ("Progenics") and EXINI Diagnostics AB ("EXINI") (collectively, "Plaintiffs") hereby file this First Amended Complaint for patent infringement against Defendant MIM Software Inc. ("MIM"), alleging as follows:

NATURE OF THE ACTION

1. This case is about medical imaging technology that enables improved diagnosis and treatment of cancer and other serious diseases. Plaintiffs pioneered techniques to advance the reliability and accuracy of diagnostic imaging tests like computed tomography (CT) scans or positron emission tomography (PET) scans. More specifically, the inventors developed and patented new systems and methods to help physicians more consistently and accurately interpret the images produced by those types of scans.

2. Plaintiffs own numerous patents that claim inventions in the field of medical imaging analysis and interpretation, specifically including 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"), and U.S. Patent No. 11,721,428 ("the '428 patent") (the "Asserted Patents").

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3. Through this case, Plaintiffs seek to protect their significant investment in medical imaging technology, which facilitates their commitment to the advancement of disease diagnosis and treatment.

4. In doing so, Plaintiffs aim to redeem the basic principle that Defendant MIM cannot infringe Plaintiffs' patents simply because MIM would prefer not to pay for a license to Plaintiffs' coveted, patented technology.

5. Defendant MIM sells imaging tools for radiation oncology, radiology, and nuclear medicine, including software products like Contour ProtégéAI®, MIM SurePlan™ MRT, LesionID®, and LesionID Pro® (the "Infringing Products") that analyze and display scan results to physicians, and which are part of MIM's broader software suite along with MIM Encore®, PET Edge®, MIM Assistant®, and MIMcloud®. In 2020, MIM and Plaintiffs began discussing potentially integrating the inventions claimed in the Asserted Patents (amongst other technological advances) into MIM's nuclear imaging software platform. Pursuant to a Confidential Disclosure Agreement signed in 2021, Plaintiffs agreed to explore a possible integration with MIM. In other words, MIM was considering licensing Plaintiffs' patented technology so that the two companies could partner. As part of that effort, Plaintiffs shared their patented inventions with MIM and helped MIM consider how those inventions could improve MIM's software. An inventor of the '486 patent (Karl Sjöstrand) and an inventor of the '508 patent (Aseem Undvall Anand) even agreed to work with MIM on that project.

6. In October 2022, about two years after the partnership discussions began, Plaintiffs sent MIM a draft Collaboration Agreement. The Collaboration Agreement included a list of Plaintiffs' relevant patents and patent applications—including the Asserted Patents.

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7. Months went by, and Plaintiffs heard nothing back from MIM about the draft Collaboration Agreement, even though MIM continued to emphasize its interest in incorporating Plaintiffs' patented technology into MIM's software.

8. Clouds gathered around June 2023 when Plaintiffs discovered that MIM had begun publishing articles and website materials describing new features included in multiple MIM products, including the Infringing Products. MIM's publications were and are troubling to Plaintiffs. They plainly show that MIM took the inventions claimed in the Asserted Patents and, instead of licensing the technology from Plaintiffs, simply integrated the inventions into the Infringing Products without Plaintiffs' permission.

9. Making matters worse, MIM relied on Plaintiffs' patented innovations to induce GE HealthCare to acquire MIM in January of this year. Apparently, MIM had been pursuing acquisition by GE HealthCare for months while simultaneously incorporating Plaintiffs' patented inventions into MIM's software.

10. Upon information and belief, MIM disregarded the Asserted Patents after deciding that paying for a license would be inconvenient. MIM infringed the Asserted Patents to both improve its software and market itself to its eventual acquirer, GE HealthCare.

11. Plaintiffs thus bring this suit to put a stop to MIM's illegal conduct and obtain compensation for MIM's intentional wrongdoing.

THE PARTIES

12. Plaintiff Progenics is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 201 Burlington Road, South Building, Bedford, Massachusetts 01730. Progenics is an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight, and follow cancer. Progenics is a subsidiary of Lantheus Holdings, Inc., along with EXINI.

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13. Plaintiff EXINI is a corporation organized and existing under the laws of Sweden, having its principal place of business at Scheelevägen 27, Ideon Science Park, Gateway, 223 70 Lund, Sweden. EXINI develops advanced software for medical image analysis. EXINI's products are developed using unique image analysis derived from expert knowledge in nuclear medicine, image analysis, handling of large databases, and machine learning. Like Progenics, EXINI is a subsidiary of Lantheus Holdings, Inc.

14. Defendant MIM is a corporation organized and existing under the laws of the State of Ohio, having its principal place of business at 25800 Science Park Drive, Suite 180, Cleveland, Ohio, 44122. MIM sells imaging tools for radiation oncology, radiology, nuclear medicine, urology, neuroimaging, and cardiac imaging.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

16. This Court has personal jurisdiction over MIM because, upon information and belief, MIM, directly or through its affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes its software products throughout the United States, including in Massachusetts (including to various renowned Massachusetts-based hospitals and cancer centers, including, upon information and belief, Dana Farber, Massachusetts General Hospital, and Harvard Medical School). MIM, therefore, does business in Massachusetts, derives revenue from conducting business in Massachusetts, and maintains continuous and systematic contacts with Massachusetts. The Court also has personal jurisdiction over MIM because MIM has committed, induced, or contributed to acts of patent infringement in Massachusetts by selling its infringing software products throughout the United States, including in this judicial district.

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17. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

A. Medical Imaging for Cancer and Other Serious Diseases.

18. One major challenge in treating and managing cancer (and other serious diseases) has long been the difficulty of accurately and consistently interpreting the diagnostic images produced by medical imaging tools.

19. Both anatomical scans (like X-rays or CT) and functional scans (like PET or single-photon emission computed tomography (SPECT)) are valuable tools. But before the inventions claimed in the Asserted Patents, physicians faced major obstacles in using those scans to form a complete and trustworthy picture of a patient's disease.

20. One difficulty was that each type of scan could only capture part of the relevant picture for any given patient. Anatomical scans capture images of the anatomy or structure of organs and tissues within the body (but not the function); functional scans capture the activity and function of those organs or tissues (but not the anatomy/structure). As applied to cancer, an anatomical scan thus cannot reliably detect the activity of a tumor, whereas a functional scan can struggle to differentiate between the organs and tissue surrounding a tumor. Physicians were left to parse two different types of scans to try to piece together the full picture, and this often led to inaccurate or inconsistent diagnoses or treatments.

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

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22. Plaintiffs' claimed inventions were therefore major advances in overcoming the limitations of medical imaging interpretation, including in the field of (but not limited to) cancer diagnosis and treatment.

B. Plaintiffs' Asserted Patents Claim Major Advances in the Interpretation of Medical Imaging for Cancer and Other Diseases.

23. Plaintiffs spent at least five years and millions of dollars to develop solutions that unlock medical imaging's full potential. Plaintiffs' efforts culminated in the inventions claimed in the Asserted Patents (as well as other patents).

24. Plaintiffs' patented innovations improved the reliability and accuracy of medical imaging interpretation by (amongst other things): (a) using artificial intelligence-based ("AI") algorithms to reliably segment the organs and lesions captured in scans; (b) using a two-step segmentation technique to identify and flag organs, lesions, and/or other points of interest on a scan; (c) creating graphical interfaces, including overlays such as risk maps, that report scan results in a way that benefits from AI-based segmentation and/or two-step segmentation; and (d) automating Prostate Specific Membrane Antigen (PSMA) (or other biomarker) detection while compensating for normal physiological uptake to automatically assess the severity of identified lesions and overall disease burden, progression, and/or response to treatment. These innovations provide reliable risk insights to help ensure accurate diagnosis and treatment by physicians.

25. U.S. Patent No. 10,665,346 ("the '346 patent"), entitled "Network for Medical Image Analysis, Decision Support System, and Related Graphical User Interface (GUI) Applications," was duly and legally issued by the Patent Office on May 26, 2020, and has not expired. The '346 patent is assigned to Progenics. This patent claims, *inter alia*, a platform and supported graphical user interface (GUI) decision-making tools for use by medical practitioners (and/or their patients) to aid in the process of making decisions about a course of cancer treatment

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(and/or to track treatment and/or the progress of the disease). A true and correct copy of this patent is attached as Exhibit 1.

26. U.S. Patent No. 10,973,486 ("the '486 patent"), entitled "Systems and Methods for Rapid Neural Network-based Image Segmentation and Radiopharmaceutical Uptake Determination," was duly and legally issued by the Patent Office on April 13, 2021, and has not expired. The '486 patent is assigned to Progenics and EXINI. This patent claims, *inter alia*, systems and methods that provide for automated analysis of 3D medical images of a patient in order to automatically identify specific 3D volumes within the 3D images that correspond to specific organs and/or tissue. This kind of accurate identification of 3D volumes allows one to determine quantitative metrics that measure uptake of tracers in particular organs/tissues, which can in turn be used to assess disease state in a patient (including, but not limited to, prostate cancer). A true and correct copy of this patent is attached as Exhibit 2.

27. U.S. Patent No. 11,424,035 ("the '035 patent"), entitled "Network for Medical Image Analysis, Decision Support System, and Related Graphical User Interface (GUI) Applications," was duly and legally issued by the Patent Office on August 23, 2022, and has not expired. The '035 patent is assigned to Progenics. This patent claims, *inter alia*, a platform and supported graphical user interface (GUI) decision-making tools for use by medical practitioners and/or their patients to aid in the process of making decisions about a course of cancer treatment and/or to track treatment and/or the progress of the disease. A true and correct copy of this patent is attached as Exhibit 3.

28. U.S. Patent No. 11,894,141 ("the '141 patent"), entitled "Network for Medical Image Analysis, Decision Support System, and Related Graphical User Interface (GUI) Applications," was duly and legally issued by the Patent Office on February 6, 2024, and has not

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expired. The ’141 patent is assigned to Progenics. This patent also claims, *inter alia*, a platform and supported GUI decision-making tools for use by medical practitioners and/or their patients to help make decisions about cancer treatment and/or to track treatment and/or the progress of the disease. A true and correct copy of this patent is attached as Exhibit 4.

29. U.S. Patent No. 11,657,508 (“the ’508 patent”), entitled “Systems and Methods for Platform Agnostic Whole Body Image Segmentation,” was duly and legally issued by the Patent Office on May 23, 2023, and has not expired. The ’508 patent is assigned to EXINI. This patent claims, *inter alia*, systems and methods that provide for automated analysis of 3D medical images to automatically identify certain volumes within the images that correspond to specific anatomical regions (e.g., organs and/or tissue), thereby providing for consistent, efficient, and accurate detection of anatomical regions (including soft tissue organs) in the entire body, as well as use of these identified anatomical regions together with detected “hotspots” that represent potential cancerous lesions in nuclear medicine images to accurately assess disease burden in patients. A true and correct copy of this patent is attached as Exhibit 5.

30. U.S. Patent No. 11,721,428 (“the ’428 patent”), entitled “Systems and Methods for Artificial Intelligence-Based Image Analysis for Detection and Characterization of Lesions,” was duly and legally issued by the Patent Office on August 8, 2023, and has not expired. The ’428 patent is assigned to EXINI. This patent claims, *inter alia*, systems and methods that provide for improved detection and characterization of lesions within a subject via automated analysis of nuclear medicine images, such PET or SPECT images. These approaches leverage AI to detect regions of 3D nuclear medicine images corresponding to “hotspots” that represent potential cancerous lesions in the subject, along with techniques for improving the accuracy with which background radiopharmaceutical uptake in reference organs, such as a liver, can be automatically

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assessed and used to evaluate disease burden and progression in patients. A true and correct copy of this patent is attached as Exhibit 6.

31. The Asserted Patents generally describe inventions for improving the reliability, usability, and accuracy of medical imaging, including by: (a) using AI-based algorithms to help segment the 3D image into different organs (or tissues), thus allowing for clearer differentiation of organs, tissues, and lesions; (b) using a two-step segmentation technique, whereby volumes of interest (e.g., the pelvic region) are first localized within a large and complex 3D image, and are then analyzed by fine-grained segmentation modules, allowing those segmentation modules to efficiently and accurately identify critical organs, and tissue regions, such as the prostate, in medical images; (c) analyzing scan results to prepare a risk map that analyzes areas of importance of concern for physician and patient review; and (d) automating PSMA (or other biomarker) detection while compensating for normal physiological uptake by using anatomical context provided by AI-based organ segmentation, in order to accurately assess lesion severity and overall disease burden, progression, and/or response to treatment.

32. The inventions claimed in the Asserted Patents improve upon prior art by increasing the reliability, accuracy, and usability of medical imaging for cancer diagnoses and treatment.

33. For example, representative claim 1 of the ’346 patent recites:

A network-based system for generating a disease risk map for use as a decision-making support for evaluating risk of cancer or risk of recurrence of cancer, the system comprising:

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

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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 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.

34. 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, 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

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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.

35. Representative claim 1 of the ’035 patent recites:

A network-based decision support system comprising: a processor; and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to:

(i) receive and store a plurality of medical images in a database, each medical image associated with a corresponding patient;

(ii) access one or more of the medical images associated with a particular patient from the database upon user request for transmission to the user for display on a user computing device;

(iii) automatically analyze the one or more medical images using a machine learning algorithm; and

(iv) generate a radiologist report for the particular patient according to the one or more medical images for the patient,

wherein the one or more medical images comprise a composite image of the particular patient, the composite image comprising a CT scan overlaid with a nuclear medicine image obtained at a substantially same time as the CT scan and following administration to the patient of an imaging agent comprising a Prostate Specific Membrane Antigen (PSMA) binding agent comprising a radionuclide, wherein the instructions cause the processor to automatically analyze the composite image by:

(a) using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image; and

(b) computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s) a risk map comprising a graphical denotation marking a region of risk of cancer or risk of recurrence of cancer.

36. Representative claim 1 of the ’141 patent recites:

A network-based decision support system comprising: a processor; and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to:

(i) receive and store a plurality of medical images in a database, each medical image associated with a corresponding patient;

(ii) access one or more of the medical images associated with a particular patient from the database;

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(iii) automatically analyze the one or more medical images using a machine learning algorithm; and

(iv) generate a radiologist report for the particular patient according to the one or more medical images for the patient,

wherein the one or more medical images comprise a composite image of the particular patient, the composite image comprising a CT scan overlaid with a nuclear medicine image obtained at a substantially same time as the CT scan and following administration to the patient of an imaging agent comprising a Prostate Specific Membrane Antigen (PSMA) binding agent comprising a radionuclide, wherein the instructions cause the processor to automatically analyze the composite image by:

(a) using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image; and

(b) computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s), a value of each of one or more risk indices, each risk index value indicative of cancer state or progression in the patient, and wherein the system is a cloud-based system.

37. 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, 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;

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(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.

38. 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, 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 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 radio-pharmaceutical uptake within and underlying lesion to which the particular hotspot corresponds and/or (II) a size of an

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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.

39. The inventions of the Asserted Patents address technological limitations of medical imaging interpretation that were not routine or conventional at the time of the invention. A person of ordinary skill in the art reading the Asserted Patents and their claims would understand that (a) the Asserted Patents' disclosures and claims solve specific problems, and (b) the claimed inventions represent significant advances in the technical field.

C. 2020-2022: Plaintiffs and MIM Explore Possible Collaboration Involving the Inventions Claimed in Plaintiffs' Asserted Patents.

40. Upon information and belief, MIM infringed (and is infringing) the Plaintiffs' Asserted Patents because MIM decided—after years of negotiations with Plaintiffs about a possible collaboration—that it wanted to use Plaintiffs' patented inventions without paying for them.

41. Around June 2020, MIM and EXINI (and Plaintiffs' parent company, Lantheus Holdings, Inc.) began discussions about a potential collaboration involving (amongst other things) the inventions claimed by the Asserted Patents. More specifically, MIM was interested in integrating the claimed inventions into MIM's nuclear imaging software.

42. The following year, MIM worked with Karl Sjöstrand at EXINI (an inventor on the '486 patent) and Aseem Undvall Anand at EXINI (an inventor on the '508 patent) to explore powering MIM's systems with Plaintiffs' patented algorithms (including the inventions in the Asserted Patents).

43. Reflecting the substantiveness and seriousness of these discussions, the parties entered into a Confidential Disclosure Agreement in October 2021.

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44. These discussions continued into 2022 and included giving MIM access to Plaintiffs' systems to review the capabilities and function of Plaintiffs' patented inventions.

45. Around October 2022, Plaintiffs sent MIM a draft Collaboration Agreement.

46. The draft Collaboration Agreement included a list of Plaintiffs' patents and patent applications that claimed the inventions that the parties had discussed sharing.

47. The Asserted Patents were on that list, indicating that MIM was considering implementing and using Plaintiffs' patented technology. Plaintiffs, too, were considering a collaboration—*but only if* MIM agreed to partnership terms.

48. Plaintiffs followed up with MIM a few times in late 2022 and 2023, as Plaintiffs waited to hear back from MIM about the draft Collaboration Agreement.

49. Plaintiffs never heard back.

D. MIM Markets and Sells Infringing Products and Pursues Acquisition by GE HealthCare.

50. Instead, Plaintiffs discovered around June 2023 that MIM was publishing articles, brochures, and website information about the Infringing Products (Contour ProtégéAI®, MIM SurePlan™ MRT, LesionID®, and LesionID Pro®), as well as other products which are part of MIM's broader software suite including MIM Encore®, PET Edge®, MIM Assistant®, and MIMcloud®. These materials plainly indicate that the Infringing Products practice the inventions claimed in the Asserted Patents as discussed below.

51. MIM is making, using, offering to sell, and selling products that infringe the Asserted Patents.

52. Not only did MIM develop through imitation, market, and sell the Infringing Products, MIM also benefited from the Infringing Products because (upon information and belief) those products—and Plaintiffs' patented inventions embodied in those Infringing Products—

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enticed GE HealthCare to acquire MIM. *See* "GE HealthCare Announces Agreement to Acquire MIM Software" (Jan. 8, 2024), *available at* https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-announces-agreement-to-acquire-mim software.

53. GE HealthCare announced in a recent press release its plan to acquire MIM. In that press release, GE HealthCare emphasized how the inventions claimed by the Asserted Patents—which MIM integrated into the Infringing Products—were a main reason GE HealthCare decided to acquire MIM.

54. The press release states, in relevant part:

> MIM Software's portfolio of innovative imaging solutions provides a variety of beneficial features, including: **the integration of diagnostic images from multiple modalities into treatment plans**; **automation to help reduce repetitive tasks and manual interventions**; **quantitation and advanced processing in diagnostic imaging** and nuclear medicine to help determine therapy response . . . GE HealthCare expects to integrate MIM Software solutions into its advanced visualizations to facilitate **AI-based segmentation and contouring** as well as dosimetry analysis for patients across their treatment journeys and in the growing fields of radiology, molecular imaging, and radiation oncology.

Id. (emphasis added).

55. The release is replete with references to Plaintiffs' inventions. For example, the reference to "integration of diagnostic images from multiple modalities" is captured, *inter alia*, by claim 42 of the '486 patent, which describes integrating anatomical and functional diagnostic images into the creation of treatment plans. The reference to "quantitation and advanced processing in diagnostic imaging" refers to, *inter alia*, claim 1 of the '346 patent and the use of AI to create tailored risk maps of cancer/disease risk based on analysis of medical images. The reference to "automation to help reduce repetitive tasks and manual interventions" refers to, *inter alia*, claim 1 of the '508 patent, which describes the use of automation to identify specific 3D

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volumes and calculate radiopharmaceutical uptake. And the reference to "AI-based segmentation and contouring" refers to the AI-assisted organ segmentation described across multiple claims of the Asserted Patents. All of these GE HealthCare statements indicate that MIM's use of the patented inventions in its software was a key driver of GE HealthCare's decision to acquire MIM.

56. The GE HealthCare press release, however, is not the only public source that reveals MIM's unlawful use of the Asserted Patents in the Infringing Products.

57. MIM publishes information about the Infringing Products on its website, including via product brochures. MIM's website explains that the brochures "[t]ake a closer look at MIM's solutions and products in downloadable PDFs." *See* MIM Brochures, *available at* https://www.mimsoftware.com/literature/brochures (accessed on Mar. 14, 2024). MIM also publishes information about the Infringing Products in industry publications and on social media platforms like LinkedIn.

58. These publications reflect several ways that the Infringing Products practice the inventions claimed by the Asserted Patents.

59. For example, MIM's publications show that the Infringing Products possess each element of representative claim 1 of the '346 patent.

60. The preamble to claim 1 of the '346 patent describes "[a] network-based system for generating a disease risk map for use as a decision-making support for evaluating risk of cancer of 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:" (*see* '346 patent, at col. 35:46-49) (claim 1 preamble). MIM's brochure entitled "Molecular Radiotherapy Dosimetry" describes how the Infringing Products "Deliver AI on Premise or in the Cloud"—in other words, on a "network-based system." *See* "Molecular Radiotherapy Dosimetry"

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brochure, *available at* https://go.mimsoftware.com/hubfs/00_Website/02_Literature_Case_Studies/Brochures/TD1000-MIM_Nuclear_Medicine_MRT_Brochure-20230608.pdf, at 6 (accessed on Mar. 14, 2024). The brochure also describes how the Infringing Products provide a decision-support tool that "allow[s] for effective communication with patients and referring physicians," and for "track[ing] dose across therapy cycles and quickly review tumor progression." *Id*. at 10. A different MIM brochure entitled "Molecular Imaging and Nuclear Medicine Diagnostic Solutions" describes how the Infringing Products "Empower Clinical Decisions" by "mak[ing] capturing dosimetry information clinically feasible," and "offer[ing] deep-learning algorithms that expedite the segmentation process." *See* "Molecular Imaging and Nuclear Medicine Diagnostic Solutions", *available at* https://go.mimsoftware.com/hubfs/_Market/MIM%20General/Brochures /Radiology%20and%20Nuclear%20Medicine/MIM%20Nuclear%20Medicine%20Diagnostic%20Solutions%20Brochure.pdf, at 10 (accessed on Mar. 14, 2024). MIM's website also indicates that LesionID® is a component of MIM Encore®, which in turn includes the MIM Assistant® module that allows users to "access data off-site with VPN or other network extensions." *See* MIM Encore®, MIM Software Inc., *available at* https://www.mimsoftware.com/nuclear-medicine/mim-encore (accessed on Mar. 14, 2024); MIM Assistant®, MIM Software Inc., *available at* https://www.mimsoftware.com/remote-access/pacs (accessed on Mar. 14, 2024). These disclosures illustrate that the Infringing Products possess the preamble of claim 1.

61. The Infringing Products also possess the first limitation of claim 1 of the '346 patent[1] because the Infringing Products access scan images for particular patients from an electronic database, and then present those images to clinicians and patients. A MIM brochure,

[1] *See* '346 patent, claim 1(i) ("access one or more medical images associated with a particular patient from a database").

for example, notes how "Contour ProtégéAI for MIM SurePlan MRT has flexible deployment models that allow for easier adoption across any institution." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. The brochure also shows an image of a patient scan presented on a screen. *Id*. MIM's website also refers to how MIMcloud can "push and pull images, and easily share studies . . . " *See* MIMCloud, *available at* https://www.mimsoftware.com/remote-access/mimcloud (accessed on Mar. 14, 2024). According to MIM's publications, MIM Assistant® (which, as discussed above, is packaged with LesionID® in MIM Encore®) includes the capability to "[a]ccess patient studies with fast searching and viewing" and "[a]ccess data off-site with VPN or other network extensions." MIM Assistant®, *supra* ¶ 60.

62. The Infringing Products also possess the second limitation of claim 1 of the '346 patent[2] because MIM SurePlan™ MRT uses Contour ProtégéAI® which, according to a MIM brochure, "Segment[s] Normal Structures with Artific[i]al Intelligence." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6; *see also id.* ("Triggered automatically upon image arrival, Contour ProtégéAI for MIM SurePlan MRT uses a neural network for segmenting normal structures on CT images. Results are more accurate than atlas-based approaches so users spend less time editing."). The same brochure also discusses how MIM SurePlan™ MRT uses PET Edge® to create contoured tumor regions that are overlaid on a SPECT/CT image. *Id*. MIM's LinkedIn post states that LesionID Pro® can be used to calculate total tumor SUVmean from PET/CT scans:

[2] *See* claim 1(ii) ("perform an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate a 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 …").

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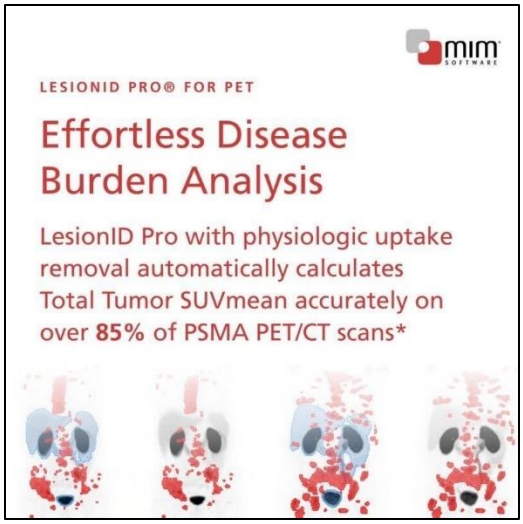
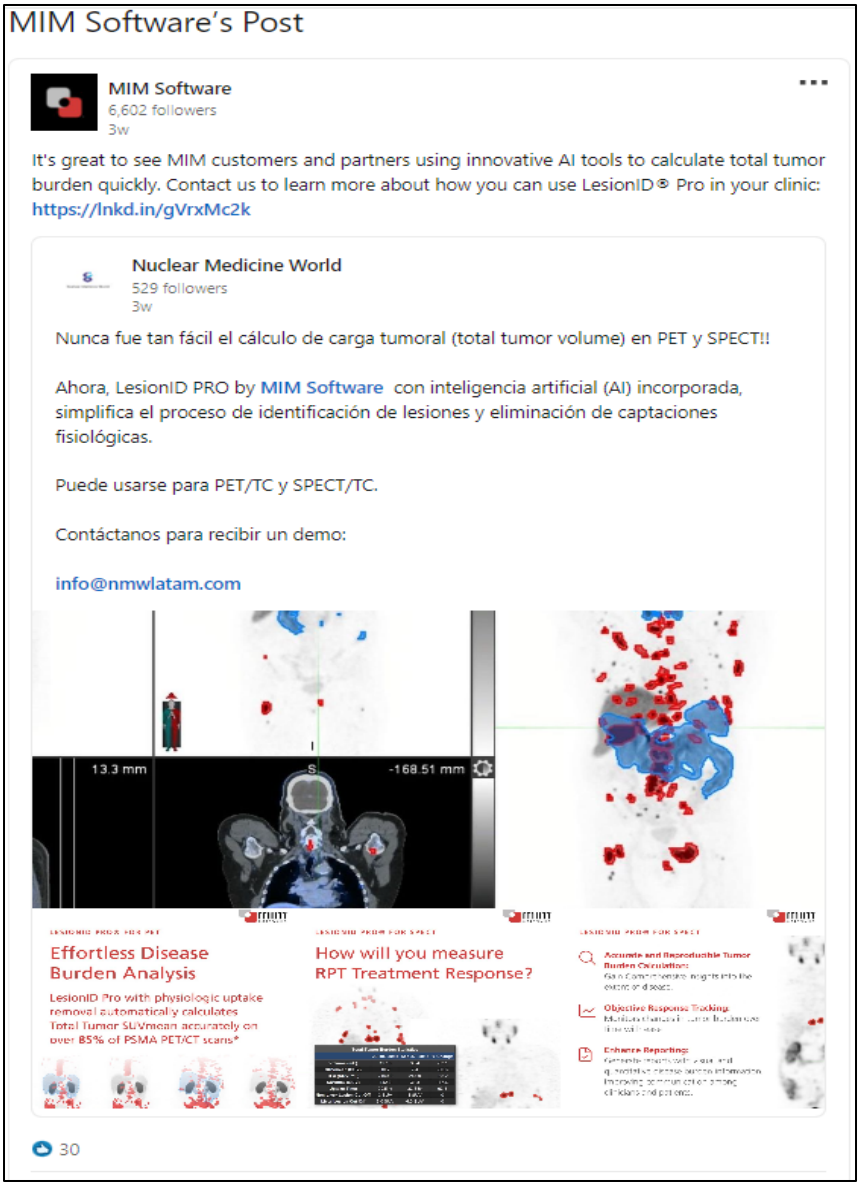


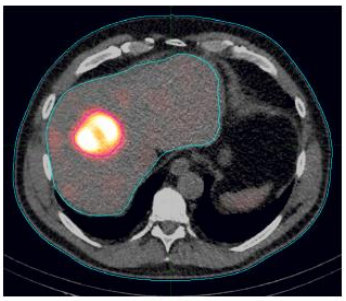
MIM Software Inc., LinkedIn, https://www.linkedin.com/posts/mim-software-inc%2E_nunca-fue-tan-f%C3%A1cil-el-c%C3%A1lculo-de-carga-tumoral-activity-7157842399761731585-27Bn (Feb. 2024) ("LinkedIn Post"). MIM also commented on the post by Nuclear Medicine World:



Id. Nuclear Medicine World's post translates as, "It has never been so easy to calculate tumor load (total tumor volume) in PET and SPECT!! Now, LesionID PRO by MIM Software with built-in artificial intelligence (AI), simplifies the process of identifying lesions and eliminating physiological uptakes. It can be used for PET/CT and SPECT/CT." MIM reposted this post, commenting, "It's great to see MIM customers and partners using innovative AI tools to calculate total tumor burden quickly. Contact us to learn more about how you can use LesionID® Pro in

your clinic." The post also shows tissue images with markings in red that denote regions identified as a potential tumor, i.e., regions of risk of cancer.

63. The Infringing Products also possess the third limitation of claim 1 of the '346 patent[3] because, as reflected in the image below from a MIM brochure, MIM SurePlan™ MRT displays the risk map (i.e., tumor segmentation) via a graphical user interface (GUI):



Id. at 7. The same image also reveals that the Infringing Products display normal organ contours and tumor contours overlaid on medical images. *See id*. (blue color outlining an organ, and red color outlining a tumor). Another image in the same brochure also shows images of a SPECT/CT with organs and tumors outlined:

[3] *See* claim 1(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 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").

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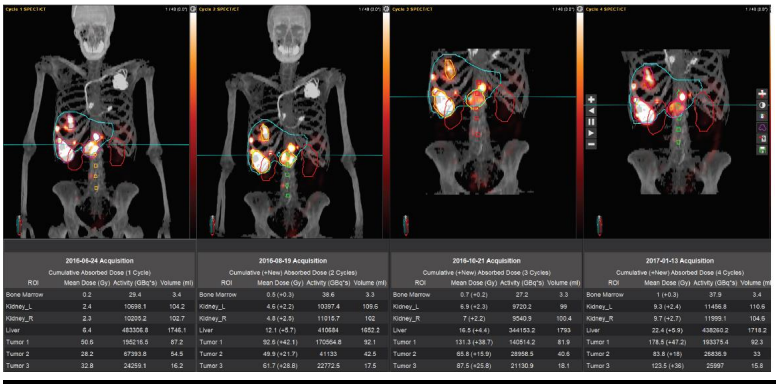

Id. at 10. The MIM LinkedIn post above shows GUI displays for presentation and review by a user, as well as markings identifying potential tumors as overlaid on PET/CT scan images, which are 3D medical images. LinkedIn Post, *supra* ¶ 62.

64. Turning next to the ’486 patent, the Infringing Products also possess all the elements of exemplary claim 42.

65. The preamble to claim 42 describes “[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:” *See* ’486 patent, at col. 80:33-37 (claim 42 preamble). The Infringing Products possess this limitation because: (a) MIM SurePlan™ MRT uses Contour ProtégéAI® to perform organ segmentation (*see* “Molecular Radiotherapy Dosimetry” brochure, *supra* ¶ 60, at 6); (b) MIM SurePlan™ MRT provides dose accumulation statistics (*id*. at 10) (“Dose accumulation runs in the background through MIM Assistant®. Cumulative doses and volume changes across cycles can be reviewed.”); and (c) Contour ProtégéAI® segments a variety of organs, including the prostate, listing “Prostate” as one of the “Available Structures for Organ Contouring” (*see* “Contour ProtégéAI+™: Zero-Click AI Auto-Contouring”, *available at* https://www.mimsoftware.com/radiation-oncology/contour-protegeai-plus (accessed on Mar. 14, 2024)). The brochure also refers to how “MIM SurePlan™ MRT has been helping institutions

drastically reduce the clinical requirements for dosimetry by including AI-based auto-segmentation and support for quantitative SPECT reconstruction with existing SPECT/CT cameras," with CT providing 3D anatomical images. *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 2.

66. The Infringing Products also possess the first limitation of claim 42 of the '486 patent[4] because, as MIM's brochures proclaim, "MIM SurePlan™ MRT has been helping institutions drastically reduce the clinical requirements for dosimetry by including AI-based auto-segmentation and support for quantitative SPECT reconstruction with existing SPECT/**CT cameras**." *Id*. at 2 (emphasis added). CT cameras provide anatomical images. And, as discussed above, MIM directs that physicians and patients can use the Infringing Products on images relating to the patient's pelvic region. *Supra* at ¶ 65. The Contour ProtégéAI® website lists several applications in the pelvic region, including (but not limited to) the prostate:

[4] *See* '486 patent, claim 42(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").

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See "Contour ProtégéAI+™: Zero-Click AI Auto-Contouring", *supra* ¶ 65 (yellow box added).

67. The Infringing Products also possess the second limitation of claim 42 of the '486 patent[5] for the reasons already discussed above. The MIM brochure refers to how "MIM SurePlan™ MRT has been helping institutions drastically reduce the clinical requirements for dosimetry by including AI-based auto-segmentation and support for quantitative SPECT reconstruction with existing SPECT/CT cameras," with CT cameras providing 3D anatomical images. *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 2. SPECT imaging is

[5] *See* claim 42(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").

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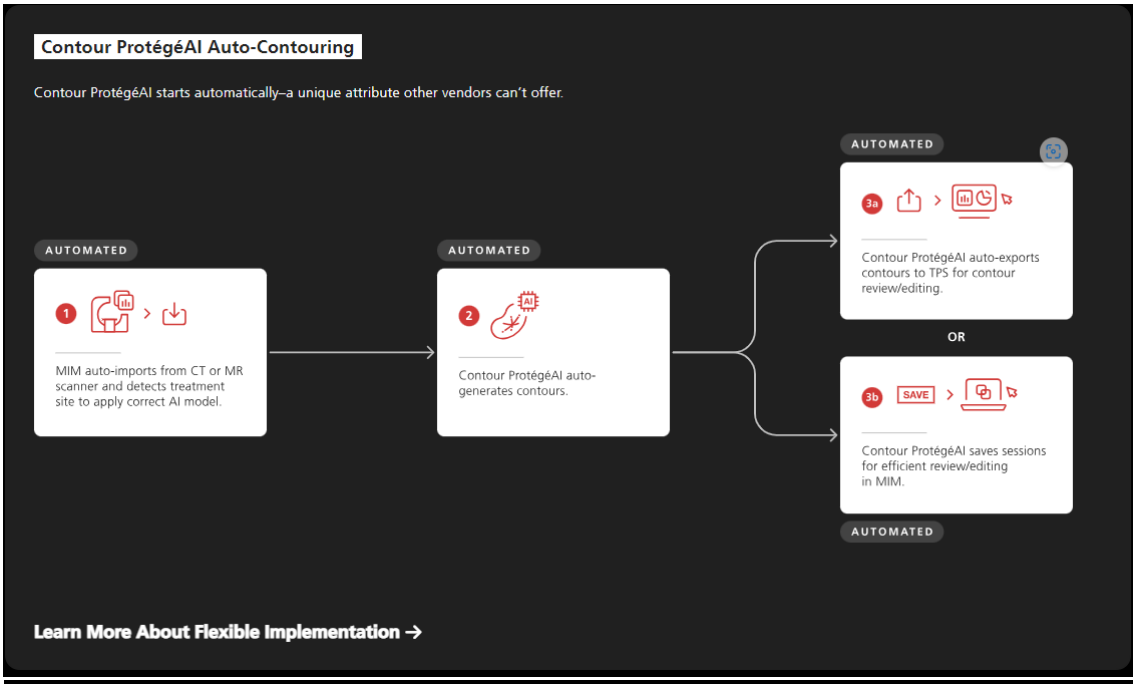
a 3D functional image. And, as discussed above, the Infringing Products are targeted at multiple applications within the pelvic region. *Supra* at ¶ 65.

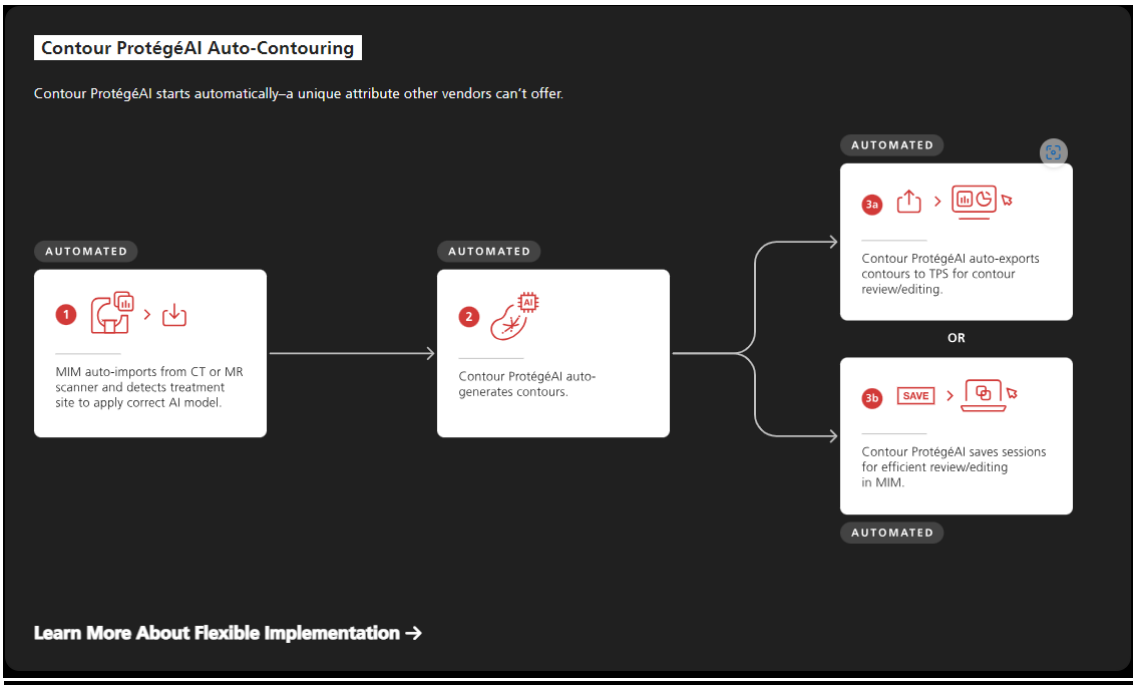
68. The Infringing Products also possess the third limitation of claim 42 of the '486 patent[6] because MIM SurePlan™ MRT uses Contour ProtégéAI® to segment normal structures in a CT image. In other words, when Contour ProtégéAI® "detects [the] treatment site to apply correct AI model" as described in the image below, it is determining, using a first module, an initial volume of interest ("VOI"):



See "Contour ProtégéAI+™: Zero-Click AI Auto-Contouring", *supra* ¶ 65. As discussed above, Contour ProtégéAI® includes a "Pelvis CT" model for segmenting organs within the pelvic region, i.e., where the initial VOI corresponds to a pelvic region. *Id.*

[6] *See* claim 42(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").

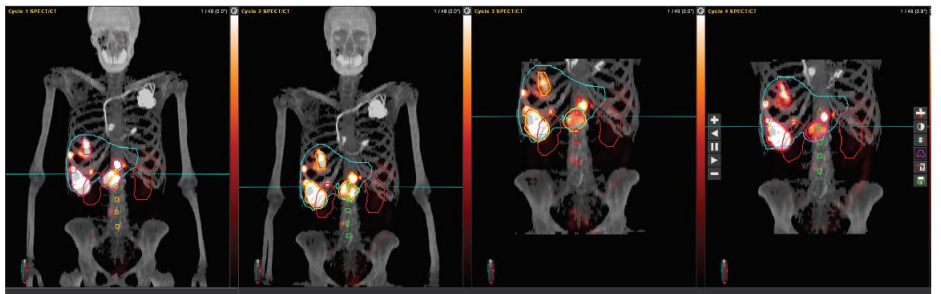
69. The Infringing Products also possess the fourth limitation of claim 42 of the '486 patent[7] because, when Contour ProtégéAI® uses the "Pelvis CT" model to segment the prostate, *supra* at ¶ 65, it uses a second module to identify a prostate volume within the initial VOI:



See id. In other words, the left-most box in the image above shows the initial segmentation step (as discussed in the preceding paragraph), and then the reference in the center box to "auto-generat[ing] contours" refers to the Infringing Products' use of the Pelvic CT model to segment the prostate.

70. The Infringing Products also possess the fifth limitation of claim 42 of the '486 patent[8] because, as discussed above, the MIM brochure shows uptake measurements (in bone, kidneys, liver, and tumors):

[7] *See* claim 42(d) ("identifying, by the processor, using a second module, a prostate volume within the initial VOI corresponding to the prostate of the subject").
[8] *See* claim 42(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").



2016-06-24 Acquisition
Cumulative Absorbed Dose (1 Cycle)

ROI	Mean Dose (Gy)	Activity (GBq*s)	Volume (ml)
Bone Marrow	0.2	29.4	3.4
Kidney_L	2.4	10698.1	104.2
Kidney_R	2.3	10205.2	102.7
Liver	6.4	483306.8	1746.1
Tumor 1	50.6	195216.5	87.2
Tumor 2	28.2	67393.8	54.5
Tumor 3	32.8	24259.1	16.2

2016-08-19 Acquisition
Cumulative (+New) Absorbed Dose (2 Cycles)

ROI	Mean Dose (Gy)	Activity (GBq*s)	Volume (ml)
Bone Marrow	0.5 (+0.3)	38.6	3.3
Kidney_L	4.6 (+2.2)	10397.4	109.6
Kidney_R	4.8 (+2.5)	11015.7	102
Liver	12.1 (+5.7)	410684	1652.2
Tumor 1	92.6 (+42.1)	170564.8	92.1
Tumor 2	49.9 (+21.7)	41133	42.5
Tumor 3	61.7 (+28.8)	22772.5	17.5

2016-10-21 Acquisition
Cumulative (+New) Absorbed Dose (3 Cycles)

ROI	Mean Dose (Gy)	Activity (GBq*s)	Volume (ml)
Bone Marrow	0.7 (+0.2)	27.2	3.3
Kidney_L	6.9 (+2.3)	9720.2	99
Kidney_R	7 (+2.2)	9540.9	100.4
Liver	16.5 (+4.4)	344153.2	1793
Tumor 1	131.3 (+38.7)	140614.2	81.9
Tumor 2	65.8 (+15.9)	28958.5	40.6
Tumor 3	87.5 (+25.8)	21130.9	18.1

2017-01-13 Acquisition
Cumulative (+New) Absorbed Dose (4 Cycles)

ROI	Mean Dose (Gy)	Activity (GBq*s)	Volume (ml)
Bone Marrow	1 (+0.3)	37.9	3.4
Kidney_L	9.3 (+2.4)	11456.8	110.6
Kidney_R	9.7 (+2.7)	11999.1	104.6
Liver	22.4 (+5.9)	438260.2	1718.2
Tumor 1	178.5 (+47.2)	193375.4	92.3
Tumor 2	83.8 (+18)	26836.9	33
Tumor 3	123.5 (+36)	25997	15.8

See "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 10. As discussed above, Contour ProtégéAI® also includes a specific model that segments these organs, as well as the prostate. *Id*. Therefore, the Infringing Products calculate dose within a prostate volume segmented by the Pelvic CT model of Contour ProtégéAI®.

71. The Infringing Products also possess the sixth limitation of claim 42 of the '486 patent[9] as reflected in the image immediately above, which displays SPECT/CT image overlays, which are, respectively, 3D functional and anatomical images. *See id*.

72. The Infringing Products also possess the seventh limitation of claim 42 of the '486 patent[10] as reflected by the same image above, which shows that SurePlan™ MRT displays SPECT/CT image overlays. *Id*.

73. Turning next to the '035 patent, the Infringing Products also possess all the limitations of exemplary claim 1.

[9] *See* claim 42(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").
[10] *See* claim 42(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.").

74. The preamble to claim 1 of the ’035 patent describes “[a] network-based decision support system comprising: a processor; and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to:” *See* ’035 patent, at col. 36:18-20) (claim 1 preamble). MIM’s brochure entitled “Molecular Radiotherapy Dosimetry” describes how the Infringing Products “Deliver AI on Premise or in the Cloud”—in other words, on a ‘network-based system’:

See “Molecular Radiotherapy Dosimetry” brochure, *supra* ¶ 60, at 6. MIM’s website also notes that the Infringing Products leverage MIM Assistant®, which allows users to “[a]ccess data off-site with VPN or other network extensions,” and/or MIMcloud®, which provides “a secure, internet-based medical image service that provides an easily accessible resource for storing, sharing, and viewing your data.” *See* MIM Assistant®, *supra* ¶ 60; MIMcloud®, *supra* ¶ 61; *see also* 510(k) Summary of Safety and Effectiveness, Food & Drug Admin., No. K231765 (Nov. 8, 2023), *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231765.pdf, at 2 (“Contour ProtégéAI is deployed on a remote server using the MIMcloud service for data management and transfer . . . ”).

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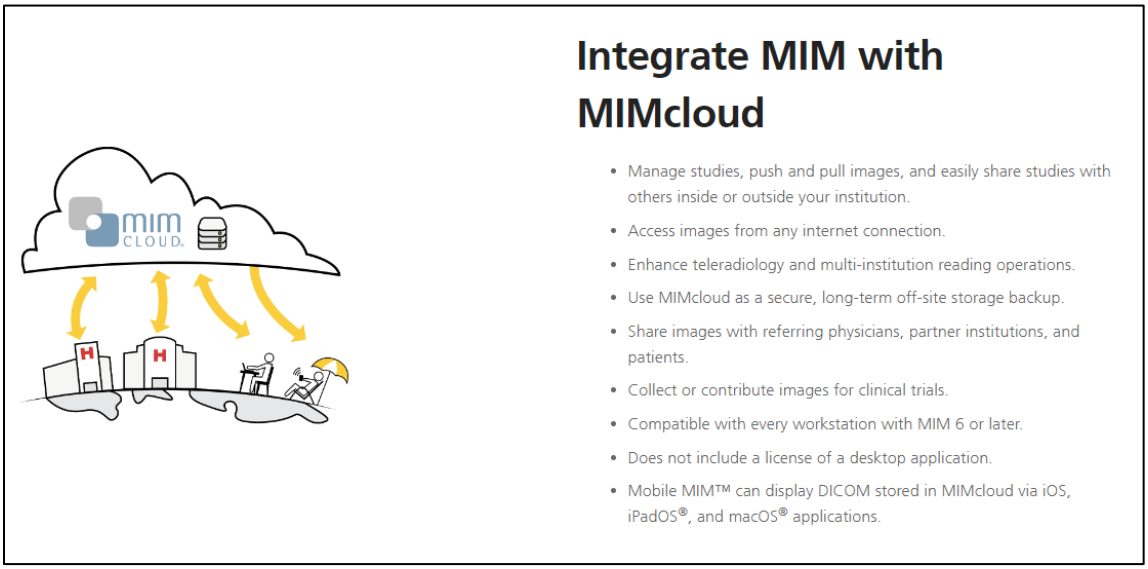
75. The Infringing Products possess the first limitation of claim 1 of the '035 patent[11] because MIM's Molecular Radiotherapy Dosimetry brochure refers to how the Infringing Products "Deliver AI on Premise or in the Cloud." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. MIMcloud® provides an "easily accessible resource for storing, sharing, and viewing your data," and "secure, long-term off-site storage backup." MIMcloud®, *supra* ¶ 61. MIM's website represents it as follows:



Id. MIM's website also reflects that LesionID® is packaged with MIM Assistant® as part of MIM Encore®:

[11] *See* '035 patent, claim 1(i) ("receive and store a plurality of medical images in a database, each medical image associated with a corresponding patient").

MIM Innovations Advance Nuclear Medicine

Powering Innovation

Advanced Reporting and Workflow Efficiency

LesionID®

- Quantitative Image Guidance
- Enables clinicians to make decisions confidently.
- LesionID supports the calculation of total tumor burden and individual statistics based on user-customizable cut-off criteria, including PERCIST.

PET Edge®

- Industry-Leading Auto-Segmentation Tool
- Provides accurate contours, no matter who is doing the contouring.
- A gradient-based technique that detects the steepest drop-off in SUV values to create the contour boundary automatically.
- Statistically more accurate than a common thresholding technique.

Read the Study →

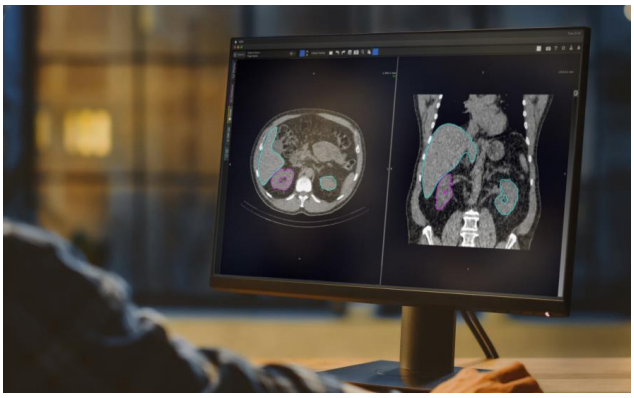
MIM Assistant®

- Process, Store, and Back Up Data Efficiently
- All-in-one software system.
- Nuclear Medicine MiniPACS. Fully integrated with all MIM Software applications.
- Automated data management and workflow tools.
- Long-term backup for raw Nuclear Medicine exams.

MIM's website states that MIM Assistant® "function[s] as an imaging server," "cache[s] a subset of data for mobile access," and "[k]eep[s] data within your local network." MIM Assistant®, *supra* ¶ 60.

76. The Infringing Products also possess the second limitation of claim 1 of the '035 patent[12] because the Infringing Products access scan images for particular patients upon request from an electronic database, and then present those images to clinicians and patients. A MIM brochure, for example, notes how "Contour ProtégéAI for MIM SurePlan MRT has flexible deployment models that allow for easier adoption across any institution." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. The brochure also shows an image of a patient scan presented on a screen, reflecting how the Infringing Products allow for access to such images upon request for display on a computer:

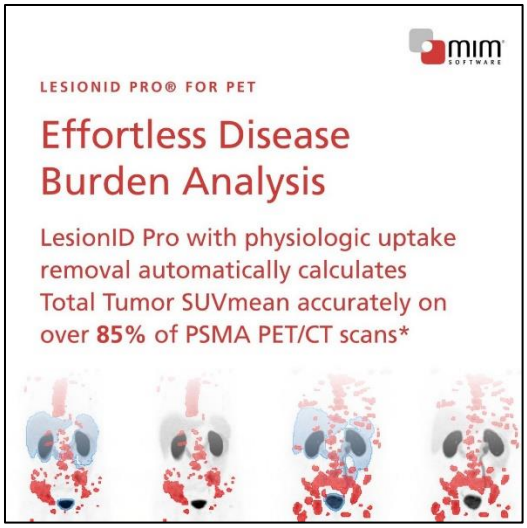
[12] *See* claim 1(ii) ("access one or more of the medical images associated with a particular patient from the database upon user request for transmission to the user for display on a user computing device").



Id. MIM's website also refers to how MIMcloud® can "push and pull images, and easily share studies . . ." *See* MIMcloud®, *supra* ¶ 61. Furthermore, according to MIM's website, MIM Assistant® lets users "[a]ccess patient studies with fast searching and viewing" and "[a]ccess data off-site with VPN or other network extensions," thereby indicating the transmission of patient medical images upon request for display on a computing device. MIM Assistant®, *supra* ¶ 60.

77. The Infringing Products possess the third limitation of claim 1 of the '035 patent[13] because MIM SurePlan™ MRT uses Contour ProtégéAI® which, according to a MIM brochure, "segment[s] normal structures with artificial intelligence." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6; *see also id.* ("Triggered automatically upon image arrival, Contour ProtégéAI™ and MIM SurePlan MRT uses a neural network for segmenting normal structures on CT images. Results are more accurate than atlas-based approaches so users spend less time editing."). The same brochure also discusses how MIM SurePlan™ MRT uses PET Edge® to create contour tumor regions that are then overlaid on a SPECT/CT image. *Id.* at 7. Further, MIM posted on LinkedIn a graphic indicating that LesionID® Pro for PET can be used to calculate total tumor SUVmean from PSMA PET/CT scans, which MIM described as an "innovative AI tool." LinkedIn Post, *supra* ¶ 62.

[13] *See* claim 1(iii) ("automatically analyze the one or more medical images using a machine learning algorithm").



78. The Infringing Products possess the fourth limitation of claim 1 of the '035 patent[14] because the MIM website describes LesionID® as being used for "Advanced Reporting and Workflow Efficiency" and explains how it "[e]nables clinicians to make decisions confidently." MIM Encore®, *supra* ¶ 60. Additionally, the MIM Molecular Radiotherapy Dosimetry brochure indicates that MIM SurePlan™ MRT generates a customizable dosimetry report that "allows for effective communication with patients and referring physicians." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 10. Further, the MIM Molecular Radiotherapy Dosimetry brochure contains the following section indicating that SurePlan™ MRT perform dosimetry analysis on SPECT/CT images:

[14] *See* claim 1(iv) ("generate a radiologist report for the particular patient according to the one or more medical images for the patient, wherein the one or more medical images comprise a composite image of the particular patient, the composite image comprising a CT scan overlaid with a nuclear medicine image obtained at a substantially same time as the CT scan and following administration to the patient of an imaging agent comprising a Prostate Specific Membrane Antigen (PSMA) binding agent comprising a radionuclide, wherein the instructions cause the processor to automatically analyze the composite image by: (a) using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image; and (b) computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s) a risk map comprising a graphical denotation marking a region of risk of cancer or risk of recurrence of cancer.").

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IMPLEMENTATION

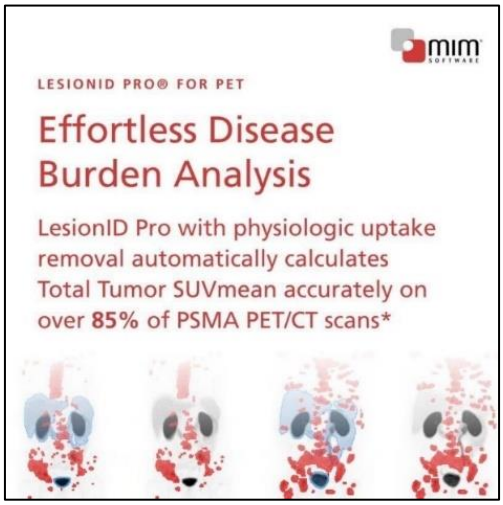
Accurate Dosimetry Performed at Scale

MIM SurePlan™ MRT has been helping institutions drastically reduce the clinical requirements for dosimetry by including AI-based auto-segmentation tools and support for quantitative SPECT reconstruction with existing SPECT/CT cameras, in addition to integrating automation into every facet of its design. This remains a primary focus for continued development.

Hospital administrators can take comfort in knowing that resources are being used efficiently. Likewise, patients and physicians alike will gain insight into these therapies and begin to characterize dose-response relationships for future planning.

Id. at 2. A SPECT/CT image is a composite image comprising a CT scan overlaid with a nuclear medicine image (since a SPECT image is a nuclear medicine image). Other publications indicate that the Infringing Products are used in connection with a PSMA-binding agent therapeutic that can be imaged via SPECT/CT to monitor its biodistribution. A 2023 article co-authored by a group including multiple MIM employees examined this kind of imaging with PSMA-binding agent-based therapeutics. In particular, the article describes performing CT-based deep learning (Convolutional Neural Network) segmentation of organs with physiological uptake to identify and remove VOIs (e.g., representing lesions) within those physiological uptake-associated organs. *See* Wilson et al., "Automating Total Tumor Volume (TTV) Generation on 177Lu-PSMA SPECT/CT Using Deep Learning to Create Normal Organs on the CT for Automatic Physiological Uptake Removal in Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC)," J. of Nuclear Med. (2023), *available at* https://jnm.snmjournals.org/content/64/supplement_1/P914, at 1-3 ("Wilson (2023)"). The authors analyzed 177Lu-PSMA SPECT/CT images, which are composite images comprising a CT scan overlaid with a nuclear medicine image (i.e., a PET image), where the nuclear medicine image is obtained after administering a PSMA binding agent, which is a molecule designed to target and bind to PSMA proteins to detect the presence and location of prostate cancer cells in the body. MIM also published an article discussing the use of SurePlan™

MRT in connection with PSMA binding agents like 177Lu (Pluvicto). *See* David Mirando, "How Will You Handle the Rise in MRT Patient Volumes?", 3 European Fed'n of Orgs. for Med. Physicians 72, 72-73, *available at* https://www.efomp.org/uploads/702479dc-a5a8-45d3-9e15-9670c9a949bd/EFOMP%20Newsletter%20Autumn%202023.pdf (accessed on March 14, 2024). As further evidence, the MIM LinkedIn graphic below states that LesionID Pro® can be used to "calculate[] Total Tumour SUVmean accurately on . . . PSMA PET/CT scans":



LinkedIn Post, *supra* ¶ 62. The PSMA PET/CT scans illustrated above are composite images comprising a CT scan overlaid with a nuclear medicine image obtained at a substantially same time as the CT scan. The images follow administration to the patient of a PSMA imaging agent.

79. The fourth limitation of claim 1 of the '035 patent also includes two sub-steps performed in automatically analyzing the aforementioned composite image. These are: "(a) using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image; and (b) computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s) a risk map comprising a graphical denotation marking a region of risk of cancer or risk of recurrence of cancer." The Infringing Products practice both steps.

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80. With regard to sub-step (a), several MIM employee-authored articles describe using a composite image to geographically identify a 3D boundary within tissue in a nuclear medicine image. The articles discuss identifying boundaries of particular organs—i.e., specific tissue region(s)—via segmentation of a CT image. *See* Wilson (2023) at 1-3; James Patrick Buteau et al., "Time-Savings Analysis of Total Tumor Burden Quantification on 68Ga-PSMA-11 PET/CT with Deep Learning Auto-Segmentation of Organs for Automatic Physiological Uptake Removal in Men with Metastatic Castration-Resistant Prostate Cancer (mCRPC)", J. of Nuclear Medicine (2022), available at https://jnm.snmjournals.org/content/63/supplement_2/2205, at 1-3 ("Buteau (2022)"). These identified contours are then transferred to PET images and compared with segmented VOIs representing potential lesions to remove physiological uptake, which can hinder accurate reading of the images. Additionally, a MIM brochure states that MIM SurePlan™ MRT uses Contour ProtégéAI® to identify 3D boundaries of an imaged tissue. See "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. Therefore, when LesionID Pro® transfers organ contours identified in CT images to a PET image and compares segmented VOIs with these contours, LesionID Pro® is "using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image" as in claim 1 of the '035 patent.

81. Sub-step (b) describes "computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s) a risk map comprising a graphical denotation marking a region of risk of cancer or risk of recurrence of cancer." The Infringing Products possess the claimed invention because, as reflected in the image below from a MIM brochure, MIM SurePlan™ MRT displays the risk map (i.e., tumor segmentation) via a graphical user interface (GUI):

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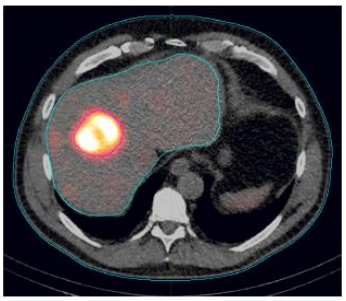

See "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 7. The same image also reveals that the Infringing Products display normal organ contours and tumor contours overlaid on medical images. *See id.* (blue color outlining an organ, and red color outlining a tumor). Another image in the same brochure also shows images of a SPECT/CT with organs and tumors outlined:

2016-08-24 Acquisition			
Cumulative Absorbed Dose (1 Cycle)			
ROI	Mean Dose (Gy)	Activity (GBq*s)	Volume (ml)
Bone Marrow	0.2	29.4	3.4
Kidney_L	2.4	10698.1	104.2
Kidney_R	2.3	10205.2	102.7
Liver	6.4	483306.6	1746.1
Tumor 1	50.6	156216.5	87.2
Tumor 2	28.2	67893.8	54.8
Tumor 3	32.8	24259.1	16.2

2016-09-19 Acquisition			
Cumulative (+New) Absorbed Dose (2 Cycles)			
ROI	Mean Dose (Gy)	Activity (GBq*s)	Volume (ml)
Bone Marrow	0.5 (+0.3)	38.6	3.3
Kidney_L	4.6 (+2.2)	10397.4	109.6
Kidney_R	4.8 (+2.5)	11015.7	102
Liver	12.1 (+5.7)	410584	1652.2
Tumor 1	92.6 (+42.1)	170954.8	92.1
Tumor 2	49.9 (+21.7)	41133	42.5
Tumor 3	61.7 (+28.8)	22772.5	17.5

2016-10-21 Acquisition			
Cumulative (+New) Absorbed Dose (3 Cycles)			
ROI	Mean Dose (Gy)	Activity (GBq*s)	Volume (ml)
Bone Marrow	0.7 (+0.2)	27.2	3.3
Kidney_L	6.9 (+2.3)	9720.2	99
Kidney_R	7 (+2.2)	9540.9	100.4
Liver	16.5 (+4.4)	344153.2	1793
Tumor 1	131.3 (+38.7)	140814.2	81.9
Tumor 2	65.8 (+15.9)	28998.5	40.6
Tumor 3	87.5 (+25.8)	21130.9	18.1

2017-01-13 Acquisition			
Cumulative (+New) Absorbed Dose (4 Cycles)			
ROI	Mean Dose (Gy)	Activity (GBq*s)	Volume (ml)
Bone Marrow	1 (+0.3)	37.9	3.4
Kidney_L	9.3 (+2.4)	11456.8	110.6
Kidney_R	9.7 (+2.7)	11999.1	104.6
Liver	22.4 (+5.9)	438260.2	1718.2
Tumor 1	178.5 (+47.2)	193375.4	92.3
Tumor 2	83.8 (+18)	26838.3	33
Tumor 3	123.5 (+36)	25997	15.8

Id. at 10. Further, as described in the MIM employee-authored articles, LesionID Pro® removes VOIs (prospective lesions) that overlap with organs associated with physiological uptake. For example, Wilson (2023) shows red and blue masks, representing identified VOIs (prospective lesions) outside and within regions associated with physiological uptake, followed by removal of the blue portion, to leave a final mask (right hand side of the below)—i.e., a risk map:

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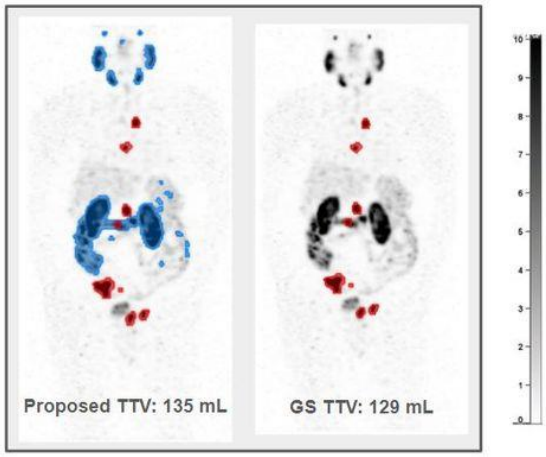

Wilson (2023) at 3.

82. Turning next to the ’141 patent, the Infringing Products also possess all the elements of exemplary claim 1.

83. The preamble to claim 1 of the ’141 patent describes “[a] network-based decision support system comprising: a processor; and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to:” (*see* ’141 patent, at col. 37:8-12) (claim 1 preamble). MIM’s brochure entitled “Molecular Radiotherapy Dosimetry” describes how the Infringing Products “Deliver AI on Premise or in the Cloud”—in other words, on a ‘network-based system’:

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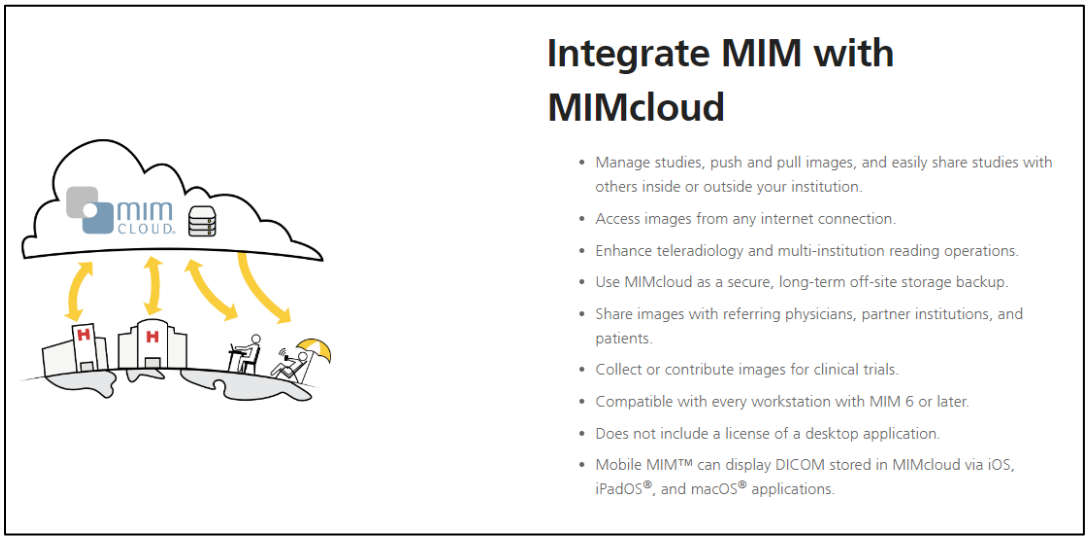
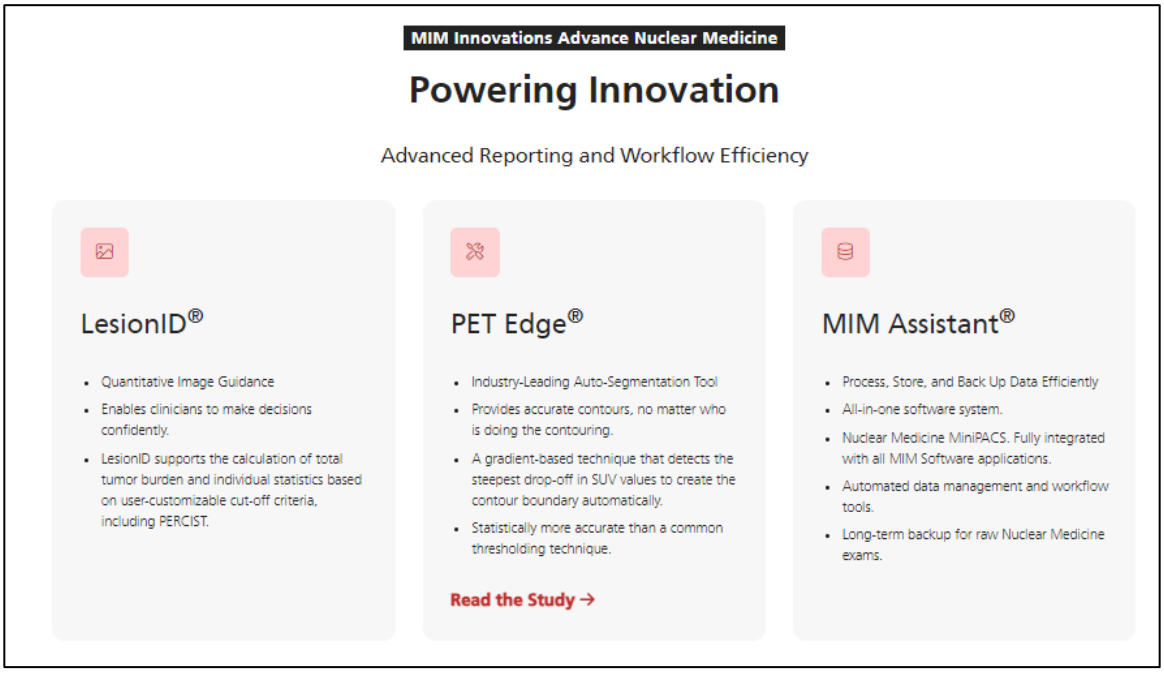
See "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. MIM's website also notes that the Infringing Products leverage MIM Assistant®, which allows users to "[a]ccess data off-site with VPN or other network extensions," and/or MIMcloud®, which provides "a secure, internet-based medical image service that provides an easily accessible resource for storing, sharing, and viewing your data." *See* MIM Assistant®, *supra* ¶ 60; MIMcloud®, *supra* ¶ 61; *see also* 510(k) Summary of Safety and Effectiveness, *supra* ¶ 74, at 2 ("Contour ProtégéAI is deployed on a remote server using the MIMcloud service for data management and transfer . . . ").

84. The Infringing Products possess the first limitation of claim 1 of the '141 patent[15] because MIM's Molecular Radiotherapy Dosimetry brochure refers to how the Infringing Products "Deliver AI on Premise or in the Cloud." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. MIMcloud® provides an "easily accessible resource for storing, sharing, and viewing your data," and "secure, long-term off-site storage backup." MIMcloud®, *supra* ¶ 61. MIM's website represents it as follows:



[15] *See* '141 patent, claim 1(i) ("receive and store a plurality of medical images in a database, each medical image associated with a corresponding patient").

Id. MIM's website also reflects that LesionID® is packaged with MIM Assistant® as part of MIM Encore®:



MIM Encore®, *supra* ¶ 60. MIM's website also states that MIM Assistant® "function[s] as an imaging server," "cache[s] a subset of data for mobile access," and "[k]eep[s] data within your local network." MIM Assistant®, *supra* ¶ 60.

85. The Infringing Products also possess the second limitation of claim 1 of the '141 patent[16] because the Infringing Products access scan images for particular patients from a database. A MIM brochure, for example, notes how "Contour ProtégéAI for MIM SurePlan MRT has flexible deployment models that allow for easier adoption across any institution." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. The brochure also shows an image of a patient scan presented on a screen, reflecting how the Infringing Products allow for access to such images in a database:

[16] *See* claim 1(ii) ("access one or more of the medical images associated with a particular patient from the database").

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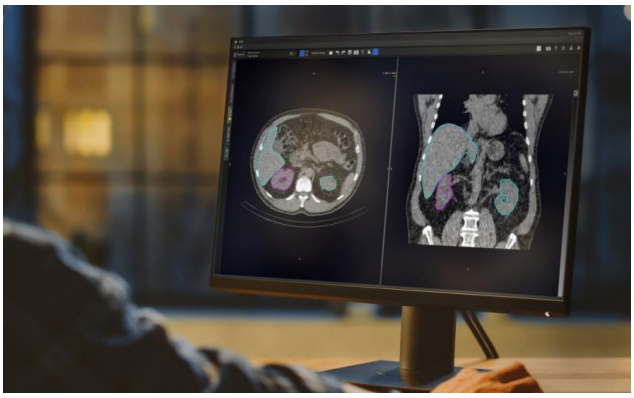
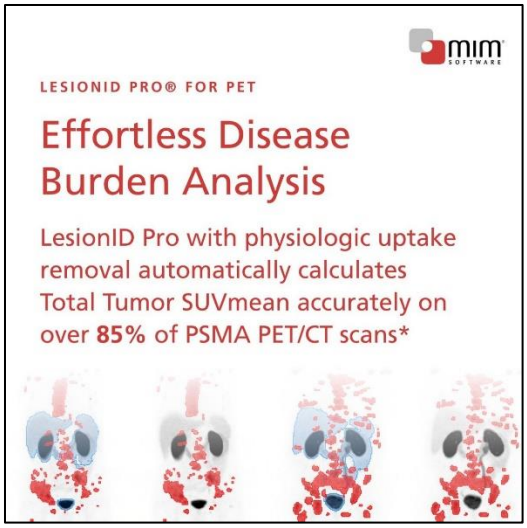


Id. MIM's website also refers to how MIMcloud® can "push and pull images, and easily share studies . . ." *See* MIMcloud®, *supra* ¶ 61. Moreover, MIM's website states that MIM Assistant® lets users "[a]ccess patient studies with fast searching and viewing" and "[a]ccess data off-site with VPN or other network extensions," thereby indicating MIM provides access to a database that stores patient data. MIM Assistant®, *supra* ¶ 60.

86. The Infringing Products possess the third limitation of claim 1 of the '141 patent[17] because MIM SurePlan™ MRT uses Contour ProtégéAI® which, according to a MIM brochure, "segment[s] normal structures with artificial intelligence." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6; *see also id.* ("Triggered automatically upon image arrival, Contour ProtégéAI for MIM SurePlan MRT uses a neural network for segmenting normal structures on CT images. Results are more accurate than atlas-based approaches so users spend less time editing."). The same brochure also discusses how MIM SurePlan™ MRT uses PET Edge® to create contour tumor regions that are then overlaid on a SPECT/CT image. *Id.* Further, MIM posted on LinkedIn a graphic that indicates LesionID® Pro for PET can be used to calculate total tumor SUVmean from PSMA PET/CT scans, which MIM described as an "innovative AI tool." LinkedIn Post, *supra* ¶ 62.

[17] *See* claim 1(iii) ("automatically analyze the one or more medical images using a machine learning algorithm").



87. The Infringing Products possess the fourth limitation of claim 1 of the '141 patent[18] because the MIM website describes LesionID® as being used for "Advanced Reporting and Workflow Efficiency" and explains how it "[e]nables clinicians to make decisions confidently." MIM Encore®, *supra* ¶ 60. Additionally, the MIM Molecular Radiotherapy Dosimetry brochure indicates that MIM SurePlan™ MRT generates a customizable dosimetry report that "allows for effective communication with patients and referring physicians." *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 10. Further, the MIM Molecular Radiotherapy Dosimetry brochure contains the following section indicating that SurePlan™ MRT performs dosimetry analysis on SPECT/CT images:

[18] *See* claim 1(iv) ("generate a radiologist report for the particular patient according to the one or more medical images for the patient, wherein the one or more medical images comprise a composite image of the particular patient, the composite image comprising a CT scan overlaid with a nuclear medicine image obtained at a substantially same time as the CT scan and following administration to the patient of an imaging agent comprising a Prostate Specific Membrane Antigen (PSMA) binding agent comprising a radionuclide, wherein the instructions cause the processor to automatically analyze the composite image by: (a) using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image; and (b) computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s), a value of each of one or more risk indices, each risk index value indicative of cancer state or progression in the patient, and wherein the system is a cloud-based system.").

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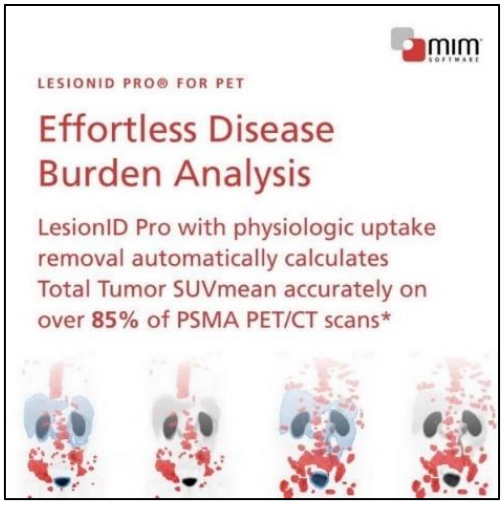
IMPLEMENTATION

Accurate Dosimetry Performed at Scale

MIM SurePlan™ MRT has been helping institutions drastically reduce the clinical requirements for dosimetry by including AI-based auto-segmentation tools and support for quantitative SPECT reconstruction with existing SPECT/CT cameras, in addition to integrating automation into every facet of its design. This remains a primary focus for continued development.

Hospital administrators can take comfort in knowing that resources are being used efficiently. Likewise, patients and physicians alike will gain insight into these therapies and begin to characterize dose-response relationships for future planning.

Id. at 2. A SPECT/CT image is a composite image comprising a CT scan overlaid with a nuclear medicine image (since a SPECT image is a nuclear medicine image). Other publications indicate that the Infringing Products are used in connection with a PSMA-binding agent therapeutic that can be imaged via SPECT/CT to monitor its biodistribution. Wilson (2023) examined this kind of imaging with PSMA-binding agent-based therapeutics. Wilson (2023) at 1-3. In particular, the article describes performing CT-based deep learning (Convolutional Neural Network) segmentation of organs with physiological uptake to identify and remove VOIs (e.g., representing lesions) within those physiological uptake-associated organs. *Id.* at 1-2. The authors analyzed 177Lu-PSMA SPECT/CT images, which are composite images comprising a CT scan overlaid with a nuclear medicine image (i.e., a PET image), where the nuclear medicine image is obtained after administering a PSMA binding agent. MIM also published an article discussing the use of SurePlan™ MRT in connection with PSMA binding agents like 177Lu (Pluvicto). *See* David Mirando, "How Will You Handle the Rise in MRT Patient Volumes?", 3 European Fed'n of Orgs. For Med. Physicians 72, 72-73, *available at* https://www.efomp.org/uploads/702479dc-a5a8-45d3-9e15-9670c9a949bd/EFOMP%20Newsletter%20Autumn%202023.pdf (accessed on March 14, 2024). As further evidence, the MIM LinkedIn graphic below states that LesionID Pro® can be used to "calculate[] Total Tumour SUVmean accurately on . . . PSMA PET/CT scans":



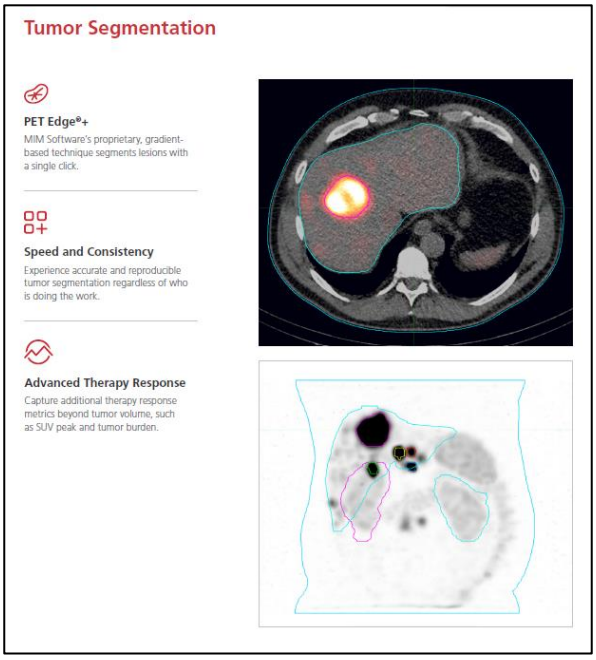
LinkedIn Post, *supra* ¶ 62. The PSMA PET/CT scans here are composite images comprising a CT scan overlaid with a nuclear medicine image obtained at a substantially same time as the CT scan; here, they follow administration to the patient of a PSMA imaging agent.

88. The fourth limitation of claim 1 of the '141 patent also includes two sub-steps to be performed in automatically analyzing the aforementioned composite image. These are: "(a) using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image; and (b) computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s), a value of each of one or more risk indices, each risk index value indicative of cancer state or progression in the patient, and wherein the system is a cloud-based system." The Infringing Products practice both steps.

89. With regard to sub-step (a), "using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image," several MIM employee-authored articles describe using a composite image to geographically identify a 3D boundary within tissue in a nuclear medicine image. The articles discuss identifying boundaries of particular organs—i.e., specific tissue region(s)—via segmentation of a CT image. *See* Wilson (2023) at 1-3; Buteau (2022) at 1-3. These identified

contours are then transferred to PET images and compared with segmented VOIs representing potential lesions to remove physiological uptake, which can hinder accurate reading of the images. Additionally, a MIM brochure states that MIM SurePlan™ MRT uses Contour ProtégéAI® to identify 3D boundaries of an imaged tissue. *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. Therefore, when LesionID Pro® transfers organ contours identified in CT images to a PET image and comparing segmented VOIs with these contours, it is "using the composite image to geographically identify a 3D boundary for each of one or more regions of imaged tissue within the nuclear medicine image" as in claim 1 of the '141 patent.

90. Sub-step (b) of the '141 patent describes "computing, using the nuclear medicine image with the identified 3D boundary(ies) of the one or more region(s), a value of each of one or more risk indices, each risk index value indicative of cancer state or progression in the patient[.]" The Infringing Products possess the claimed invention because MIM SurePlan™ MRT also segments tumors along with the 3D boundaries of tissue, and uses those segmentations to compute "Advanced Therapy Response" statistics like SUV peak and tumor burden:



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See "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 7. This reflects that, when the Infringing Products calculate a therapy response like tumor burden, the Infringing Products calculate risk index values that indicate cancer state or progression. Wilson (2023) also describes how the Infringing Products remove VOIs (prospective lesions) that overlap with organs associated with physiological uptake, and then use the final set of VOIs (once those overlapping with organs associated with physiological uptake have been removed) to compute Total Tumor Volume (TTV) and Whole Body SUVmean. Wilson (2023) at 1-2. TTV and SUVmean are risk indices that indicate cancer state or progression in a patient. *Id*. Furthermore, with regard to the final wherein clause of the fourth limitation of the '141 patent, "wherein the system is a cloud-based system," the Contour ProtégéAI® 510(k) states that "Contour ProtégéAI is deployed on a remote server using the MIMcloud® service for data management and transfer; or locally on the workstation or server running MIM software." 510(k) Summary of Safety and Effectiveness, *supra* ¶ 74, at 2. MIM SurePlan™ MRT uses Contour ProtégéAI® to perform organ segmentation in CT images. *See* "Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 6. MIMcloud®, as discussed above, is a cloud-based system. MIMcloud®, *supra* ¶ 61. LesionID Pro® uses Contour ProtégéAI® in order to segment organs using AI, which is part of LesionID Pro®'s physiological uptake removal approach.

91. Turning next to the '508 patent, the Infringing Products also possess all the elements of exemplary claim 1.

92. The preamble to claim 1 describes "[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:" *See* '508 patent, at col. 79:64-67 (claim 1 preamble). MIM's LinkedIn post regarding "LesionID Pro® for PET" states that

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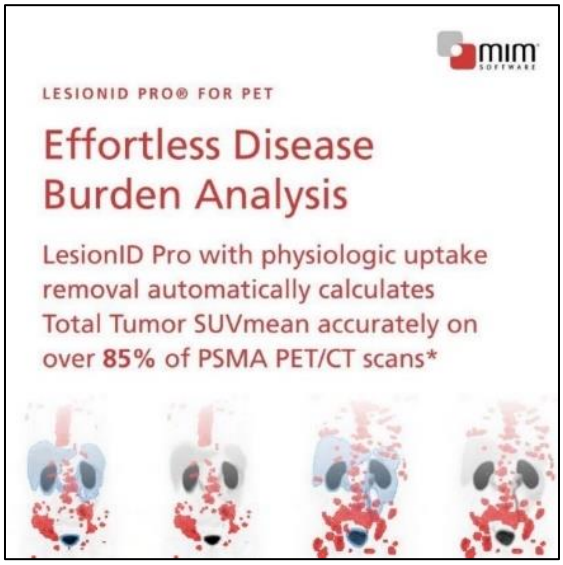
"LesionID Pro with physiologic uptake removal automatically calculates Total Tumor SUVmean on . . . PET/CT scans":



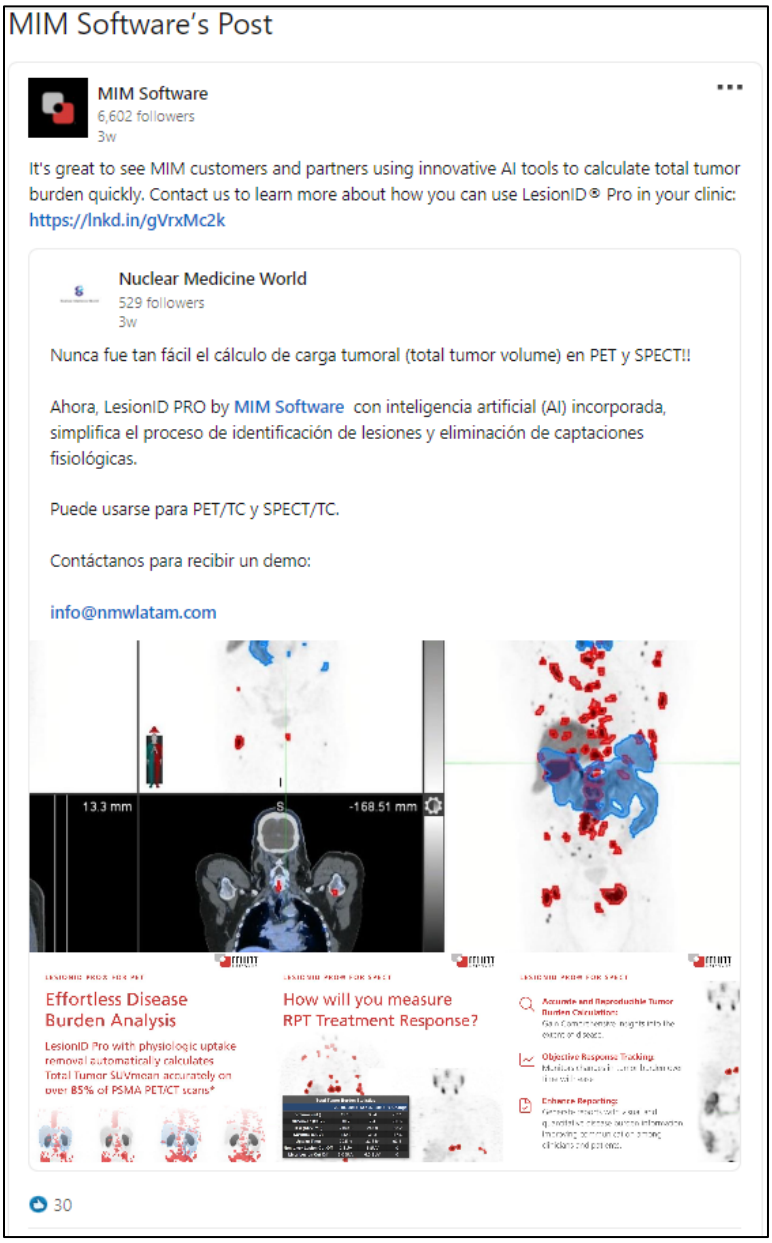
See LinkedIn Post, *supra* ¶ 62. PET and CT scans are 3D images. Tumors are cancerous lesions. These disclosures illustrate that the Infringing Products possess the preamble of claim 1.

93. The Infringing Products also possess the first limitation of claim 1 of the '508 patent[19] because, as indicated in the paragraph immediately above, the LesionID® software involves receiving a PET or CT scan image, which are types of "3D anatomical image[s]." *Id*. And, as indicated above, the same image presents a graphical representation of a subject's tissue.

94. The Infringing Products also possess the second limitation of claim 1 of the '508 patent[20] because, as discussed in the two paragraphs above, LesionID® analyzes 3D anatomical images. A MIM LinkedIn post also demonstrates that the Infringing Products use machine

[19] *See* '508 Patent, claim 1(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 a subject").
[20] *See* claim 1(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 portion of an aorta of the subject; and a first liver volume comprising a graphical representation of a liver of the subject").

learning modules. The post states that "[i]t's great to see MIM customers and partners using innovative **AI tools to calculate tumor burden quickly**. Contact us to learn more about how you can use LesionID Pro® in your clinic." LinkedIn Post, *supra* ¶ 62 (emphasis added). Machine learning is a form of AI:



Id. Wilson (2023) also describes approaches for removing physiological uptake, including machine learning-based organ segmentation. The publication states that "**utilizing normal**

structures created by a CT-based deep learning convolutional neural network, VOIs [volumes of interest] contained within organs with physiological uptake were removed from the proposed segmentation. **Organ contours used in the algorithm included**: **liver**, kidneys, parotids, submandibular glands, lacrimal glands, **bone,** bowel, pelvic lymph nodes, prostate, and bladder[.]" Wilson (2023) at 2 (emphasis added). This indicates that the Infringing Products focus on both the skeleton/bones, as well as the liver. MIM's November 2023 510(k) for Contour ProtégéAI® also indicates that its module for "Whole Body – Physiological Uptake Organs" segments the heart, which includes at least a portion of the aorta (an artery originating, and partially contained within, the heart):

Whole Body - Physiological Uptake Organs	Bladder	N/A	95
	Bone	N/A	100
	Bowel	N/A	100
	BowelBag	N/A	100
	Brain	N/A	100
	Cavity_Oral	N/A	100
	Glnd_Lacrimal_L	N/A	100
	Glnd_Lacrimal_R	N/A	100
	Glnd_Submand_L	N/A	100
	Glnd_Submand_R	N/A	100
	Heart	N/A	100
	Kidney_L	N/A	95
	Kidney_R	N/A	100
	Liver	N/A	100
	LN_Iliac	N/A	64

510(k) Summary of Safety and Effectiveness, *supra* ¶ 74, at 18 (also noting the reference to bone/skeleton, and liver) (highlighting added). The same 510(k) also reflects the connection between Contour ProtégéAI® and the "Whole Body – Physiological Uptake Organs" module:

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ITEM	Subject Device: Contour ProtégéAI (K231765)	Predicate Device: Contour ProtégéAI (K223774)	Reference Predicate: MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
	SurePlan MRT CT **(4.1.0 models)** Head and Neck CT Thorax CT Whole Body – Physiological Uptake Organs CT	SurePlan MRT CT	

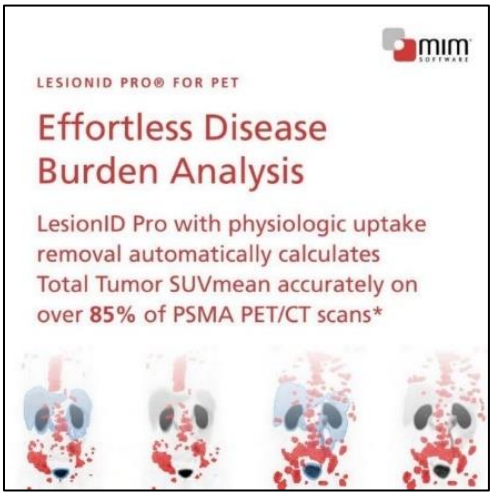
Id.

95. The Infringing Products also possess the third limitation of claim 1 of the '508 patent[21] because, as reflected in both Wilson (2023)[22] and Buteau (2022)[23], the Infringing Products involve a physiological uptake removal technique that creates organ contours and transfers them to nuclear medicine (e.g., SPECT and/or PET) images. The articles expressly reference organ contours including "bone" and "liver." *See* Wilson (2023) at 2 and Buteau (2022) at 2. As referenced above, the Contour ProtégéAI® 510(k) references "bone," "liver," and "heart" (which would necessarily include the aorta) as organs segmented by the "Whole

[21] *See* claim 1(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").
[22] Wilson (2023) at 2 ("The proposed algorithm segmented all VOIs in the image with a 3 SUV threshold. Then, utilizing normal structures created by a CT-based deep learning convolutional neural network, VOIs contained within organs with physiological uptake were removed from the proposed segmentation. Organ contours used in the algorithm included: liver, kidneys, parotids, submandibular glands, lacrimal glands, bone, bowel, pelvic lymph nodes, prostate, and bladder . . .").
[23] Buteau 2022 at 2 ("The second method (PUR) involved the same semi-automatic segmentation tool, with the addition of PUR-specific steps, to automatically remove physiological uptake before the reader started editing. These steps included running a deep learning organ segmentation algorithm to create CT-based organ VOIs for areas of physiological uptake (submandibular glands, parotid glands, lacrimal glands, spleen, kidneys, bowel, and bladder) and organs in which PSMA-avid lesions are expected (liver, brain, bone, pelvic lymph nodes, and prostate) . . . The contours were rigidly transferred from the CT to the PET and automatically modified to better adhere to the PET organ borders. Lesions that significantly overlapped the physiological uptake organs were removed automatically."). Buteau (2022) is another article with many MIM co-authors.

Body – Physiological Uptake Organs" model. 510(k) Summary of Safety and Effectiveness, *supra* ¶ 74, at 18.

96. The Infringing Products also possess the fourth limitation of claim 1 of the '508 patent[24] because, as discussed above, the MIM post describing the Infringing Products below expressly references the calculation of "Tumor SUVmean" on a PET/CT scan. PET/CT scans are both types of 3D functional images from a subject:



LinkedIn Post, *supra* ¶ 62. MIM's Molecular Radiotherapy Dosimetry brochure also describes how MIM SurePlan™ MRT operates in relation to SPECT scans, which produce 3D functional images:

[24] *See* '508 patent, claim 1(d) ("receiving, by the processor, a 3D functional image of the subject obtained using a functional imaging modality").

IMPLEMENTATION

Accurate Dosimetry Performed at Scale

MIM SurePlan™ MRT has been helping institutions drastically reduce the clinical requirements for dosimetry by including AI-based auto-segmentation tools and support for quantitative SPECT reconstruction with existing SPECT/CT cameras, in addition to integrating automation into every facet of its design. This remains a primary focus for continued development.

Hospital administrators can take comfort in knowing that resources are being used efficiently. Likewise, patients and physicians alike will gain insight into these therapies and begin to characterize dose-response relationships for future planning.

"Molecular Radiotherapy Dosimetry" brochure, *supra* ¶ 60, at 2.

97. The Infringing Products also possess the fifth limitation of claim 1 of the '508 patent[25] because, as described in Buteau (2022), organ contours for bone, liver, and other regions are transferred to a PET image, thereby identifying corresponding volumes in the PET image (i.e., within the functional image). *See* Buteau (2022) at 2 ("The contours were rigidly transferred from the CT to the PET and automatically modified to better adhere to the PET organ borders."). Additionally, the Contour ProtégéAI® "Whole Body – Physiological Uptake Organs" model references the heart (and thus at least a portion of the aorta) as one of the applicable organs:

[25] *See* claim 1(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").

Whole Body - Physiological Uptake Organs	Bladder	N/A	95
	Bone	N/A	100
	Bowel	N/A	100
	BowelBag	N/A	100
	Brain	N/A	100
	Cavity_Oral	N/A	100
	Glnd_Lacrimal_L	N/A	100
	Glnd_Lacrimal_R	N/A	100
	Glnd_Submand_L	N/A	100
	Glnd_Submand_R	N/A	100
	Heart	N/A	100
	Kidney_L	N/A	95
	Kidney_R	N/A	100
	Liver	N/A	100
	LN_Iliac	N/A	64

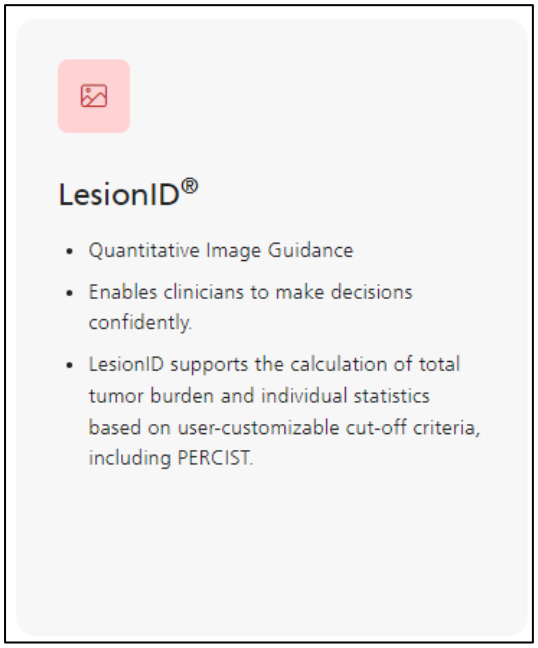
510(k) Summary of Safety and Effectiveness, *supra* ¶ 74, at 18. The 510(k) reflects that the Infringing Products also transfer organ contours from the CT image to the PET image for the aorta, thereby identifying corresponding volumes in the PET image. *Id*. at 1-2.

98. The Infringing Products also possess the sixth limitation of claim 1 of the '508 patent[26] because the Infringing Products' technique for removal of physiological uptake involves detecting lesions within PET or SPECT images (i.e., 'hotspots'). *See, e.g.*, Wilson (2023) at 2; Buteau (2022) at 2. Buteau (2022) describes the Infringing Products' technique for removal of physiological uptake segments organ VOIs for (i) areas of physiological uptake (submandibular glands, parotid glands, lacrimal glands, spleen, kidneys, bowel, and bladder), and (ii) organs in which PSMA-avid lesions are expected (liver, brain, bone, pelvic lymph nodes, and prostate). Buteau (2022) at 2. The publication then states that "[l]esions that significantly overlapped the physiological uptake organs were removed automatically," which indicates that the Infringing Products retain lesions that are detected within identified bone contours (i.e., "in which PSMA-

[26] *See* claim 1(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").

avid lesions are expected"). *Id.* The Infringing Products thus detect and retain hotspots within bone regions in a PET or SPECT image.

99. The Infringing Products also possess the seventh limitation of claim 1 of the '508 patent[27] because the Infringing Products compute various metrics, such as tumor burden, volume, SUV mean, and so forth. For example, the MIM Encore® webpage lists LesionID® as a tool/component of MIM Encore® that "supports the calculation of total tumor burden and individual statistics based on user-customizable cut-off criteria, including PERCIST":



MIM Encore®, *supra* ¶ 60. PERCIST is an approach for measuring and tracking tumor burden over time. PERCIST involves, among other things, comparing lesion peak standardized update values (SUV's) to cut-off thresholds derived from liver and/or aorta reference intensities, and then

[27] *See* claim 1(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 with 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.").

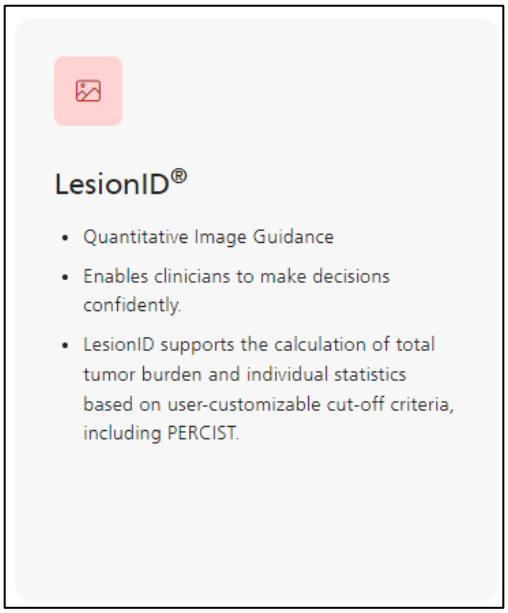
measuring the peak intensities of detected hotspots to identify the intensities that satisfy (i.e., exceed) the cut-off thresholds. *See, e.g.*, Joo Hyun O et al., "Practical PERCIST: A Simplified Guide to PET Response Criteria in Solid Tumors 1.0", 280 Radiology 576, 577 (2016). PERCIST criteria involve measuring an aorta reference intensity, *see id*. at 578 (col. 1) ("If the liver is diseased, the mean background SUL[28] and standard deviation can be measured in a cylindrical VOI with a diameter of 1 cm and a long axis (parallel to the descending aorta) of 2 cm in the center of the descending thoracic **aorta** . . .") (emphasis added), and a liver reference intensity. *See id*. at 577 ("For background activity, a 3-cm diameter spherical volume of interest (VOI) is placed in the right side of **liver**, midway between the dome and inferior margin, excluding central ducts and vessels") (emphasis added). PERCIST also requires at baseline the "measurement of the 'hottest' single tumor and background area on images[.]" *Id*. at 577. To identify the 'hottest' single tumor, PERCIST performs two steps for each detected hotspot: (1) PERCIST evaluates a peak SUL intensity for each hotspot (which will be compared with liver or aorta references (*see id*. at 578 (third column)) ("For a tumor to be measurable at baseline, the **SULpeak** must be greater than or equal to one and a half times the mean SUL in the 3-cm diameter spherical VOI plus two times its standard deviation to have a minimum threshold for evaluation . . . . When the SULpeak of the tumor at baseline is lower than this threshold, the tumor is considered not measurable with PERCIST 1.0.") (emphasis added); and (2) PERCIST compares the peak SUL intensity for each hotspot with liver or aorta references, retaining those hotspots with SULpeak values above the liver and aorta-derived thresholds and recording their SULpeak (e.g., to identify a maximum). *See id*. ("When the activity in the descending thoracic aorta is measured instead of that in the liver, the minimum threshold for evaluation is two times the mean SUL of the thoracic aorta in a tubular

[28] SUL is standardized uptake value (SUV) corrected for lean body mass.

VOI plus two times its standard deviation. This is proposed because blood SUL is typically lower than liver SUL.”). Therefore, the Infringing Products possess the seventh limitation of claim 1 of the ’508 patent.

100. Turning next to the ‘428 patent, the Infringing Products also possess all the elements of exemplary claim 1.

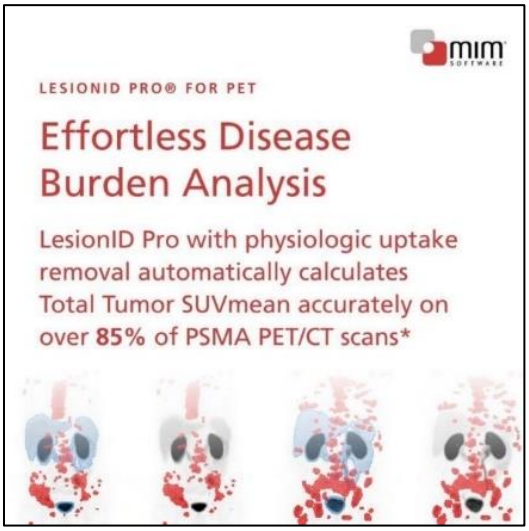
101. The preamble to claim 1 of the ’428 patent describes “[a] method of measuring intensity values within a reference volume corresponding to a reference tissue region so as to avoid impact from tissue regions associated with low radiopharmaceutical uptake, the method comprising:” *See* ’428 patent, at col. 48:62-65 (claim 1 preamble). The Infringing Products compute various metrics, such as tumor burden, volume, SUV mean, and so forth. For example, the MIM Encore® webpage lists LesionID® as a component of MIM Encore® that “supports the calculation of total ***tumor burden*** and individual statistics based on user-customizable cut-off criteria, including PERCIST”:



MIM Encore®, *supra* ¶ 60 (emphasis added). PERCIST is an approach for measuring and tracking tumor burden over time. PERCIST involves, among other things, comparing lesion peak SUV’s

to cut-off thresholds derived from liver and/or aorta reference intensities and then measuring peak intensities of detected hotspots for those satisfying (i.e., exceeding) the cut-off thresholds. *See, e.g.*, Hyun O (2016) at 576-84. These disclosures illustrate that the Infringing Products possess the preamble of claim 1.

102. The Infringing Products also possess the first limitation of claim 1 of the '428 patent.[29] As demonstrated by the MIM LinkedIn post graphic below, LesionID Pro® "automatically calculates Total Tumor SUVmean accurately on . . . PET/CT scans":



LinkedIn Post, *supra* ¶ 62. A PET scan image is a 3D functional image of a subject. Therefore, the Infringing Products implement a method that receives a 3D functional image of a subject using PET and/or SPECT.

103. The Infringing Products also possess the second limitation of claim 1 of the '428 patent[30] because, as discussed immediately above, the Infringing Products involve the use of 3D functional images. Furthermore, the MIM Encore® webpage lists LesionID® as a component of

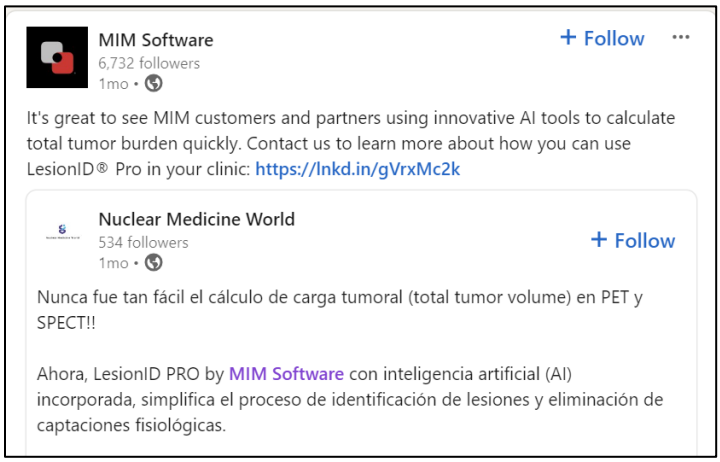
[29] *See* '428 patent, claim 1(a) ("receiving, by a processor of a computing device, a 3D functional image of a subject, said 3D functional image obtained using positron emission tomography (PET) and/or single-photon emission computed tomography (SPECT)").
[30] *See* claim 1(b) ("identifying, by the processor, the reference volume within the 3D functional image").

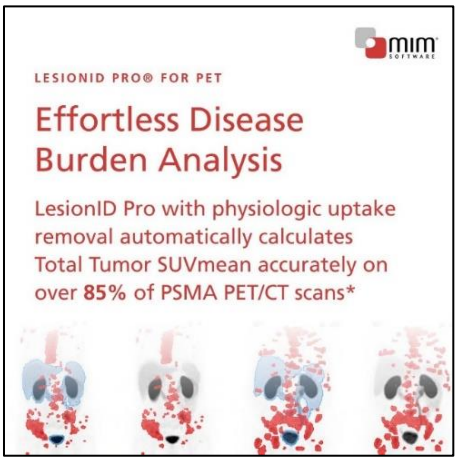
MIM Encore® that "supports the calculation of total tumor burden and individual statistics based on user-customizable cut-off criteria, including PERCIST." MIM Encore®, *supra* ¶ 60. PERCIST is a reporting method that utilizes (i.e., compares hotspot intensities to) reference volumes that are determined using regions within the liver and/or aorta reference regions. *See, e.g.*, Hyun O (2016) at 576-84.

104. The Infringing Products also possess the third, fourth, and fifth limitations of claim 1 of the '428 patent.[31] As discussed above, the MIM Encore® webpage lists LesionID® as a tool/component of MIM Encore® that "supports the calculation of total tumor burden and individual statistics based on user-customizable cut-off criteria, including PERCIST." MIM Encore®, *supra* ¶ 60. Implementing PERCIST involves manually placing or drawing a marker—such as a "3-cm diameter spherical volume of interest (VOI) in the right side of a liver"—to define a selection of voxels to compute a liver reference intensity (e.g., an average, peak, or other distributional statistic of intensity). *See, e.g.*, Hyun O (2016) at 577-78. The VOI marker is necessary to exclude irrelevant anatomy and/or diseased tissue (e.g., "central ducts and vessels," obvious metastatic tumor present in the liver, and other diseased tissue). *Id*. Measured liver references can thus be compromised by user placement of VOI markers and/or subject to inter-operator variability. *Id*. MIM lists LesionID® as a component of MIM Encore® that "supports the calculation of total tumor burden and individual statistics based on user-customizable cut-off criteria, including PERCIST." *See* MIM Encore®, *supra* ¶ 60. As a result, LesionID® also uses liver references and implements a technique that involves measuring reference intensities within

[31] *See* claim 1(c) ("fitting, by the processor, a multi-component mixture model to a distribution of intensities of voxels within the reference volume"); claim 1(d) ("identifying, by the processor, a major mode of the multi-component model"); and claim 1(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").

liver or other reference tissue, as claimed by the patent. MIM also indicates in public posts that LesionID Pro® utilizes AI tools to segment organs in CT images, including the liver, and transfers those segmentations to functional (e.g., PET, SPECT) images in order to compute tumor burden measurements:





See LinkedIn Post, *supra* ¶ 62. This reflects 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. LesionID Pro® also uses AI tools to automate lesion identification and calculation of disease burden statistics.

105. The Infringing Products also possess the sixth limitation of claim 1 of the '428 patent[32] because, as described in Wilson (2023) and Buteau (2022), LesionID® identifies volumes of interest (VOIs") that represent potential lesions (i.e., hotspots) within PET and/or SPECT images. *See, e.g.*, Wilson (2023) at 2 ("The proposed algorithm segmented all VOIs in the image with a 3 SUV threshold. Then, utilizing normal structures created by a CT-based deep learning convolutional neural network, VOIs contained within organs with physiological uptake were removed from the proposed segmentation. Organ contours used in the algorithm included: liver,

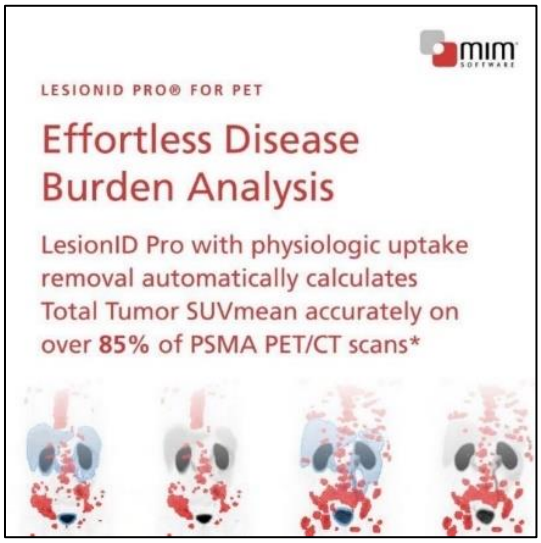
[32] *See* claim 1(f) ("detecting, by the processor, within the functional image, one or more hotspots corresponding potential cancerous lesions").

kidneys, parotids, submandibular glands, lacrimal glands, bone, bowel, pelvic lymph nodes, prostate, and bladder."); Buteau (2022) at 2 ("The second method (PUR) involved the same semi-automatic segmentation tool, with the addition of PUR-specific steps, to automatically remove physiological uptake before the reader started editing. These steps included running a deep learning organ segmentation algorithm to create CT-based organ VOIs for areas of physiological uptake (submandibular glands, parotid glands, lacrimal glands, spleen, kidneys, bowel, and bladder) and organs in which PSMA-avid lesions are expected (liver, brain, bone, pelvic lymph nodes, and prostate) . . . The contours were rigidly transferred from the CT to the PET and automatically modified to better adhere to the PET organ borders. Lesions that significantly overlapped the physiological uptake organs were removed automatically.").

106. The Infringing Products also possess the seventh limitation of claim 1 of the '428 patent[33] because, as discussed above, the Infringing Products use PERCIST criteria to identify and select lesions for inclusion in tumor burden analysis. For example, in PERCIST, "[m]easurement of the 'hottest' single tumor and background area on images, usually of the liver, is required at baseline." *See* Hyun O (2016) at 577 (first and second columns). To identify the 'hottest' single tumor using PERCIST criteria, one must perform two steps for each detected hotspot. First, evaluate a peak SUL intensity for each hotspot, and compare it with liver or aorta references. *Id*. at 578 (third column) ("For a tumor to be measurable at baseline, the SULpeak must be greater than or equal to one and a half times the mean SUL in the 3-cm diameter spherical VOI plus two times its standard deviation to have a minimum threshold for evaluation."). Second,

[33] *See* claim 1(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.").

"[w]hen the SULpeak of the tumor at baseline is lower than this threshold, the tumor is considered not measurable with PERCIST 1.0." *Id*. Therefore, when the Infringing Products evaluate whether a hotspot is considered a detectable lesion according to PERCIST, the Infringing Products compare the hotspot intensity with a reference intensity, and then store (for that hotspot) its intensity and/or volume in order to compute its tumor burden (e.g., SUVmean, total tumor volume). This approach is an example of automating tumor burden analysis in a manner that accounts for physiological uptake. MIM has touted the use of LesionID Pro® to account for physiological uptake, for example, in the MIM image below:



LinkedIn Post, *supra* ¶ 62; *see also* MIM Encore®, *supra* ¶ 60 (referencing LesionID®'s use of PERCIST).

107. MIM has known of the existence of the Asserted Patents. MIM's infringement has been and is willful and in disregard for the Asserted Patents. MIM has no reasonable basis for believing that it has a right to engage in the infringing conduct. As discussed above, MIM and Plaintiffs negotiated for years about a potential collaboration involving MIM purchasing the right to integrate Plaintiffs' patented inventions into MIM's software. During those negotiations, Plaintiffs even sent MIM, upon agreement to do so, a draft Collaboration Agreement that expressly

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listed the Asserted Patents. Yet, MIM willfully developed, marketed, and sold (and continues to market and sell) the Infringing Products containing Plaintiffs' patented inventions.

108. Plaintiffs have suffered substantial damage (and MIM has unlawfully benefitted) from MIM's infringement of the Asserted Patents. As discussed above, GE HealthCare chose to acquire MIM (rather than enter into a profitable commercial relationship of some kind with Plaintiffs) in large part because of MIM's infringing conduct. *Supra* at ¶¶ 52-55. Plaintiffs have also lost substantial advantage in the market as the only companies permitted to use the claimed inventions, which (as discussed above) represent major breakthroughs in the performance, reliability, and usability of nuclear medicine imaging for cancer and other serious ailments. As a result, Plaintiffs have begun to lose both existing and prospective business to MIM. MIM and Plaintiffs continue to compete for specific customers, and Plaintiffs expect future losses of their existing and prospective business unless MIM ceases its unlawful infringement. Plaintiffs have also lost a licensing and partnership opportunity in view of MIM's actions. Plaintiffs are thus entitled to the full measure of their damages from MIM's infringement, including (without limitation) lost profits, a reasonable royalty, and damages for MIM's willful infringement.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,665,346

109. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

110. MIM has been and is directly and/or indirectly infringing the '346 patent, either literally or under the doctrine of equivalents, by making, using, selling, or offering for sale in the United States, including within this judicial district, the Infringing Products, in violation of 35 U.S.C. § 271(a).

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111. MIM has been and is inducing infringement of the ’346 patent, either literally or under the doctrine of equivalents, by actively and knowingly inducing its customers to use the Infringing Products that embody or use the inventions claimed in the ’346 patent, in violation of 35 U.S.C. § 271(b).

112. MIM’s infringement has been, and continues to be knowing, intentional, and willful.

113. MIM’s infringement of the ’346 patent has caused, and will continue to cause, Plaintiffs damages for which Plaintiffs are entitled to compensation pursuant to 35 U.S.C. § 284.

114. MIM’s infringement of the ’346 patent has caused, and will continue to cause, Plaintiffs immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Plaintiffs have no adequate remedy at law.

115. This case is exceptional and Plaintiffs are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,973,486

116. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

117. MIM has been and is directly and/or indirectly infringing the ’486 patent, either literally or under the doctrine of equivalents, by making, using, selling, or offering for sale in the United States, including within this judicial district, the Infringing Products, in violation of 35 U.S.C. § 271(a).

118. MIM has been and is inducing infringement of the ’486 patent, either literally or under the doctrine of equivalents, by actively and knowingly inducing its customers to use the

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Infringing Products that embody or use the inventions claimed in the ’486 patent, in violation of 35 U.S.C. § 271(b).

119. MIM’s infringement has been, and continues to be knowing, intentional, and willful.

120. MIM’s infringement of the ’486 patent has caused, and will continue to cause, Plaintiffs damages for which Plaintiffs are entitled to compensation pursuant to 35 U.S.C. § 284.

121. MIM’s infringement of the ’486 patent has caused, and will continue to cause, Plaintiffs immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Plaintiffs have no adequate remedy at law.

122. This case is exceptional and Plaintiffs are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,424,035

123. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

124. MIM has been and is directly and/or indirectly infringing the ’035 patent, either literally or under the doctrine of equivalents, by making, using, selling, or offering for sale in the United States, including within this judicial district, the Infringing Products, in violation of 35 U.S.C. § 271(a).

125. MIM has been and is inducing infringement of the ’035 patent, either literally or under the doctrine of equivalents, by actively and knowingly inducing its customers to use the Infringing Products that embody or use the inventions claimed in the ’035 patent, in violation of 35 U.S.C. § 271(b).

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126. MIM's infringement has been, and continues to be knowing, intentional, and willful.

127. MIM's infringement of the '035 patent has caused, and will continue to cause, Plaintiffs damages for which Plaintiffs are entitled to compensation pursuant to 35 U.S.C. § 284.

128. MIM's infringement of the '035 patent has caused, and will continue to cause, Plaintiffs immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Plaintiffs have no adequate remedy at law.

129. This case is exceptional and Plaintiffs are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 11,894,141

130. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

131. MIM has been and is directly and/or indirectly infringing the '141 patent, either literally or under the doctrine of equivalents, by making, using, selling, or offering for sale in the United States, including within this judicial district, the Infringing Products, in violation of 35 U.S.C. § 271(a).

132. MIM has been and is inducing infringement of the '141 patent, either literally or under the doctrine of equivalents, by actively and knowingly inducing its customers to use the Infringing Products that embody or use the inventions claimed in the '141 patent, in violation of 35 U.S.C. § 271(b).

133. MIM's infringement has been, and continues to be knowing, intentional, and willful.

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134. MIM's infringement of the '141 patent has caused, and will continue to cause, Plaintiffs damages for which Plaintiffs are entitled to compensation pursuant to 35 U.S.C. § 284.

135. MIM's infringement of the '141 patent has caused, and will continue to cause, Plaintiffs immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Plaintiffs have no adequate remedy at law.

136. This case is exceptional and Plaintiffs are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 11,657,508

137. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

138. MIM has been and is directly and/or indirectly infringing the '508 patent, either literally or under the doctrine of equivalents, by making, using, selling, or offering for sale in the United States, including within this judicial district, the Infringing Products, in violation of 35 U.S.C. § 271(a).

139. MIM has been and is inducing infringement of the '508 patent, either literally or under the doctrine of equivalents, by actively and knowingly inducing its customers to use the Infringing Products that embody or use the inventions claimed in the '508 patent, in violation of 35 U.S.C. § 271(b).

140. MIM's infringement has been, and continues to be knowing, intentional, and willful.

141. MIM's infringement of the '508 patent has caused, and will continue to cause, Plaintiffs damages for which Plaintiffs are entitled to compensation pursuant to 35 U.S.C. § 284.

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142. MIM's infringement of the '508 patent has caused, and will continue to cause, Plaintiffs immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Plaintiffs have no adequate remedy at law.

143. This case is exceptional and Plaintiffs are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 11,721,428

144. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

145. MIM has been and is directly and/or indirectly infringing the '428 patent, either literally or under the doctrine of equivalents, by making, using, selling, or offering for sale in the United States, including within this judicial district, the Infringing Products, in violation of 35 U.S.C. § 271(a).

146. MIM has been and is inducing infringement of the '428 patent, either literally or under the doctrine of equivalents, by actively and knowingly inducing its customers to use the Infringing Products that embody or use the inventions claimed in the '428 patent, in violation of 35 U.S.C. § 271(b).

147. MIM's infringement has been, and continues to be knowing, intentional, and willful.

148. MIM's infringement of the '428 patent has caused, and will continue to cause, Plaintiffs damages for which Plaintiffs are entitled to compensation pursuant to 35 U.S.C. § 284.

149. MIM's infringement of the '428 patent has caused, and will continue to cause, Plaintiffs immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Plaintiffs have no adequate remedy at law.

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150. This case is exceptional and Plaintiffs are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that MIM has infringed the Asserted Patents;

(B) A judgment that MIM's infringement of the Asserted Patents has been willful;

(C) An award against MIM of damages sufficient to compensate Plaintiffs for MIM's infringement of the Asserted Patents;

(D) An award against MIM of all other damages permitted by 35 U.S.C. § 284, including increased damages up to three times the amount of compensatory damages found;

(E) A declaration that this is an exceptional case and an award against MIM and to Plaintiffs of their reasonable attorneys' fees incurred in this action as provided by 35 U.S.C. § 285;

(F) An order preliminarily and permanently enjoining MIM, and its officers, directors, agents, employees, affiliates, and all others acting in privity or in concert with it, and its parents, subsidiaries, divisions, successors, and assigns from further acts of infringement of the Asserted Patents; and

(G) All such other relief that this Court deems just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs hereby demand a jury trial on all issues triable of right by a jury.

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Dated: March 15, 2024

Respectfully submitted,

/s/ Michael H. Bunis

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: March 15, 2024

/s/ *Michael H. Bunis*

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