UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PROGENICS PHARMACEUTICALS, INC., AND EXINI DIAGNOSTICS AB, Plaintiffs v. MIM SOFTWARE, INC., Defendant.	Case No. 24-10437-PBS Hon. Patti B. Saris

DEFENDANT'S INVALIDITY AND NONINFRINGEMENT CONTENTIONS

Defendant MIM Software, Inc. ("MIM") discloses these Invalidity and Noninfringement Contentions pursuant to L.R. 16.6(d)(4). These Invalidity and Noninfringement Contentions are responsive to the Infringement Contentions served by Plaintiffs, Progenics Pharmaceuticals, Inc. and Exini Diagnostics AB ("Plaintiffs"), on April 17, 2025 and May 26, 2025.

These contentions are based on information currently available to MIM and its current understanding of Plaintiffs' interpretation of the asserted claims, as evidenced by Plaintiffs' Infringement Contentions. MIM's Invalidity and Noninfringement Contentions should not be interpreted as an admission regarding the meaning or scope of any asserted claim. MIM believes that the asserted claims, when properly construed, do not cover MIM's accused products. Nevertheless, where Plaintiffs have asserted that particular claims are broad enough to read on MIM's products, MIM has identified prior art that would invalidate the claims if Plaintiffs' interpretation is adopted. Where possible, MIM has provided alternative grounds for invalidity based on a range of possible claim interpretations, including interpretations with which MIM does not necessarily agree.

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These Invalidity and Noninfringement Contentions are provided before MIM has completed its investigation of the facts, before discovery is completed, and without the benefit of the Court's claim construction. Because MIM's investigation is ongoing, including its search of the prior art, these contentions are not to be construed as final contentions, and this disclosure is made without prejudice to MIM's rights to rely on or produce evidence of additional prior art references. MIM reserves the right to supplement, amend, or revise these contentions based on: (i) new or different infringement allegations by Plaintiffs; (ii) newly discovered prior art; (iii) claim interpretations expressly urged by Plaintiffs or adopted by the Court; or (iv) arguments offered by Plaintiffs in response to these Invalidity and Noninfringement Contentions, including arguments disputing that any identified prior art reference discloses one or more elements of the asserted claims. To the extent that MIM is required to seek leave of court for such an amendment, MIM reserves the right to do so.

MIM contends that the Accused Products do not infringe the asserted claims of the asserted patents for the reasons set forth in the supporting claim charts attached as Appendices C-1, C-2, D-1, D-2, and D-3.

I. GROUNDS FOR INVALIDITY UNDER 35 U.S.C. §§ 102 AND 103

Pursuant to L.R. 16-6(d)(4)(E), MIM contends that the asserted claims of the asserted patents are invalid under 35 U.S.C. §§ 102 and/or 103 as set forth herein and the supporting claim charts attached as Appendices A–B. To the extent any element of any asserted claim is not expressly described in the prior art references addressed in these Invalidity and Noninfringement Contentions, such element is nevertheless inherent or rendered obvious by the teachings of the identified prior art. To support these invalidity contentions, MIM reserves the right to rely on expert testimony regarding the knowledge of a person of ordinary skill in the art ("POSITA") at

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the time of the asserted patents, and/or background knowledge disclosed by or referred to in the asserted patent or any of the prior art patents identified herein.

The claim charts attached hereto as Appendices A–B provide direct citations to the locations where each recited element of each asserted claim can be found in the prior art. Where MIM has asserted, anywhere within these contentions or the supporting claim charts, that a prior art reference teaches a particular element of a claim, MIM reserves the right to cite such reference as teaching such element in any other combination of prior art that would render the claim obvious. For the sake of clarity and brevity, MIM has listed what it believes to be the most straightforward combinations of prior art references. To the extent that Plaintiffs dispute the teachings of the prior art or the motivations to combine certain references, MIM may provide additional or alternative combinations of the cited references that render the claims obvious.

Clear and logical rationales to combine any of the prior art references identified herein exist from the prior art references themselves, as well as from common sense and/or the knowledge, talent, and ingenuity possessed by a POSITA. Examples of such rationales are clearly articulated herein and/or in Appendices A–B attached hereto. MIM believes no more specific showing of a motivation to combine prior art is required, as each identified combination of prior art simply represents the combination of well-known techniques to those of ordinary skill in the relevant art. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415–18 (2007) (rejecting the Federal Circuit's "rigid" application of the teaching, suggestion, or motivation to combine test, and instead espousing an "expansive and flexible" approach). As the Supreme Court has held, a person of ordinary skill in the art is "a person of ordinary creativity, not an automaton" and "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 420–21.

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If and to the extent Plaintiffs challenge the motivation to combine any of the identified prior art references in the combinations identified here, MIM reserves the right to supplement these contentions with expert testimony addressing the knowledge and skill of a POSITA and the motivation of a POSITA to make such combinations.

A. U.S. Patent No. 10,973,486 (the "'486 patent")

Defendant's anticipation/obviousness invalidity contentions rely on the following prior art references: (**1**) United States Patent Application Publication 2012/0123253 ("Renisch"), which published on May 17, 2012; (**2**) United States Patent Application Publication 2005/0281381 ("Guendel"), which published on December 22, 2005; (**3**) United States Patent Application Publication 2018/0144828 ("Baker"), which published on May 24, 2018; (**4**) United States Patent Application Publication 2017/0189565 ("Miller"), which published on July 6, 2017; (**5**) United States Patent Application Publication 2011/0007954 ("Suehling"), which published on January 13, 2011; (**6**) a scientific journal article published online in November of 2017 in the Journal of Nuclear Medicine ("Eiber"); and (**7**) a scientific journal article published in April of 2016 in the journal Medical Physics ("Cha").

Claims 1, 7, 9–12, 14–15, 19–21, 27, 33, 39–42, and 48–50 are invalid as obvious under 35 U.S.C. § 103 based on: (1) Renisch in view of Guendel or Suehling, in further view of Baker; and/or (2) Baker in view of Guendel or Suehling, in further view of Renisch. Renisch discloses full-body segmentation of 3D anatomical images and 3D functional images, the determination of uptake metrics in segmented organs, and comparison to reference organs, including the liver, to normalize uptake measurements. Baker discloses segmentation of the prostate, specifically, to determine uptake metrics in the prostate. Both Guendel and Suehling provide the teaching and motivation to perform a two-step segmentation of anatomical structures, including structures in

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the pelvis. It would have been obvious to a POSITA to combine Renisch, Guendel/Suehling, and Baker (or Baker, Guendel/Suehling, and Renisch) because the references are within the same field of endeavor; the references themselves provide teachings, suggestions, and motivations to combine; the proposed combinations would merely be combining prior art elements according to known methods to yield a predicable result; and a POSITA would have had a reasonable expectation of success in combining these references.

Claims 1, 10–12, 14–15, 19–21, 27, 33, 39, 42, and 50 are invalid as obvious under 35 U.S.C. § 103 based on: (1) Baker in view of Suehling; and/or (2) Baker in view of Guendel, and in further view of Suehling. Baker performs 3D segmentation of organ structures in anatomical images. Suehling and Guendel both provide the teaching and motivation to segment anatomical structures using a two-part hierarchical segmentation process. It would have been obvious to a POSITA to combine Baker and Guendel/Suehling because the references are within the same field of endeavor; the references themselves provide teachings, suggestions, and motivations to combine; the proposed combination would merely be combining prior art elements according to known methods to yield a predicable result; and a POSITA would have had a reasonable expectation of success in combining these references.

Claims 1, 10–12, 14–15, 19–21, 27, 33, 39, 42, and 50 are invalid as obvious under 35 U.S.C. § 103 based on Baker in view of Guendel/Suehling and in further view of Eiber or Miller. Baker discloses segmenting the prostate and liver volumes. Guendel and Suehling both teach and suggest two-part hierarchical organ segmentation. Baker also discloses determining uptake metrics that include the ratio of uptake intensity in one organ compared to uptake intensity in another organ. Eiber and Miller both expressly teach using the uptake intensity of the liver as a reference intensity when determining uptake metrics for other parts of the body. It would have

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been obvious to a POSITA to combine Baker, Guendel/Suehling, and Eiber because the references are within the same field of endeavor; the references themselves provide teachings, suggestions, and motivations to combine; the proposed combination would merely be combining prior art elements according to known methods to yield a predicable result; and a POSITA would have had a reasonable expectation of success in combining these references.

Claims 1, 10–12, 14–15, 19-21, 27, 33, 39, 42, and 50 are invalid as obvious under 35 U.S.C. § 103 based on Suehling in view of Baker and in further view of Eiber or Miller. Suehling discloses the automatic segmentation of organs in 3D functional and anatomical images to determine uptake metrics for those organs. Baker discloses the segmentation of the prostate specifically to determine uptake metrics for the prostate. Eiber and Miller both teach and suggest the use of uptake in a reference organ, such as the liver, when characterizing the uptake metrics in other parts of the body. It would have been obvious to a POSITA to combine Suehling, Baker, and Eiber or Miller because the references are within the same field of endeavor; the references themselves provide teachings, suggestions, and motivations to combine; the proposed combination would merely be combining prior art elements according to known methods to yield a predicable result; and a POSITA would have had a reasonable expectation of success in combining these references.

Claims 9, 41, and 49 are invalid as obvious under 35 U.S.C. § 103 based on the Renisch-Guendel/Suehling-Baker combination discussed above in further view of Cha. Renisch discloses segmentation of the bladder, which is known to exhibit high physiological uptake that might not be associated with disease. Cha discloses the application of a morphological dilation operation to the bladder during segmentation of the bladder. It would have been obvious to a POSITA to combine Renisch, Guendel/Suehling, and Baker with Cha because the references are within the

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same field of endeavor; the references themselves provide teachings, suggestions, and motivations to combine; the proposed combination would merely be combining prior art elements according to known methods to yield a predicable result; and a POSITA would have had a reasonable expectation of success in combining these references.

Pursuant to L.R. 16-6(d)(4)(E)(i), based on MIM's preliminary investigation, MIM contends that the terms "first module" and "second module" are means-plus-function terms under 35 U.S.C. § 112(f).

The "first module" of the claimed "processor" performs the function of "determining … an initial volume of interest (VOI) within the 3D anatomical image[.]" '486 patent, 74:24–26 (claim 1, step (c)). The corresponding structure within the specification for performing this claimed function includes "a first machine learning module," *id.* at 6:44–45; 7:19–21; 13:47–48; 15:38–39, which the specification states can be a "first CNN (convolutional neural network)," *id.* at 12:51–52, and the structural equivalents thereof.

The "second module" of the claimed "processor" performs the function of "identifying … a prostate volume within the initial VOI corresponding to the prostate of the subject." *Id.* at 74:29–31. The corresponding structure within the specification for performing this claimed function includes "a second machine learning module," *id.* at 6:55–56; 15:48–49; 16:40–41, which the specification states can be a "second CNN module," *id.* at 12:52–53, and the structural equivalents thereof.

Because Plaintiffs' apparently take the position that "first module" and "second module" are not means-plus-function terms, claims 1, 39, 40–42, and 48–50 are invalid in view of the prior art cited above.

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B. U.S. Patent No. 11,721,428 (the "'428 patent")

Claims 1, 3–13, and 15–24 are anticipated under 35 U.S.C. § 102 by the LesionID® software system ("LesionID®"), which was in public use and first offered for sale before the priority filing date of the '428 patent, no later than 2018. LesionID® is a tool that identifies values at or above a specific threshold and identifies corresponding areas of a functional medical image as being potential lesions. Plaintiffs assert that LesionID®—through its alleged use of the Positron Emission Tomography Response Criteria in Solid Tumors criteria (the "PERCIST criteria"[1])—practices every element of claims 1, 3–13, and 15–24 of the '428 patent. *See* Plaintiffs' Preliminary Infringement Claim Charts Ex. 6A at 1–21. To the extent Plaintiffs would meet their burden to show that LesionID® infringes these asserted claims, MIM incorporates by reference Exhibit 6A of Plaintiffs' Preliminary Infringement Claim Charts as evidence that LesionID® anticipates[2] these claims.

Claims 1, 3, 8–13, 15, and 20–24 are further anticipated under 35 U.S.C. § 102 by a scientific journal article published no later than March 2018 in the Journal of Nuclear Medicine ("Eiber"). Eiber is directed to efforts to standardize reporting of prostate cancer nuclear medicine imaging results following the introduction of new prostate-cancer-specific radiotracers. Eiber discloses every element of claims 1, 3, 8–13, 15, and 20–24.

Claims 1, 3–4, 7–13, 15–16, and 19–24 are also invalid as obvious under 35 U.S.C. § 103 based on Renisch in combination with Eiber. Renisch teaches the automatic detection of one or more hotspots corresponding to potential cancerous lesions. Eiber teaches and suggests the

[1] The PERCIST criteria are described in Joo Hyun O, "Practical PERCIST: A Simplified Guide to PET Response Criteria in Solid Tumors 1.0," Radiology 280(2), pp. 576–584 (August 2016) ("PERCIST").

[2] LesionID® anticipates the claims directly and/or, to the extent LesionID® uses the PERCIST criteria, inherently, as evidenced by, e.g., PERCIST.

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determination of lesion index values based on reference intensities measured within the liver and aorta. It would have been obvious to a POSITA to combine Renisch and Eiber because the references are within the same field of endeavor; the references themselves provide teachings, suggestions, and motivations to combine; the proposed combination would merely be combining prior art elements according to known methods to yield a predicable result; and a POSITA would have had a reasonable expectation of success in combining these references.

Claims 5–6 and 17–18 are also invalid as obvious under 35 U.S.C. § 103 based on Renisch in combination with Eiber and Baker. Renisch and Eiber make obvious every element of claims 1 and 13, from which claims 5–6 and 17–18 depend. Baker teaches the additional limitations of claims 5–6 and 17–18. Whereas Renisch identifies hotspots using simple thresholding or a watershed algorithm, Baker teaches that hotspots can also be detected in functional images using machine learning. It would have been obvious to a POSITA to combine Renisch, Eiber, and Baker because the references are within the same field of endeavor; the references themselves provide teachings, suggestions, and motivations to combine; the proposed combination would merely be combining prior art elements according to known methods to yield a predicable result; and a POSITA would have had a reasonable expectation of success in combining these references.

II. GROUNDS FOR INVALIDITY UNDER 35 U.S.C. § 112

Pursuant to L.R. 16-6(d)(4)(F), MIM contends the asserted claims of the asserted patents are invalid under 35 U.S.C. § 112 as set forth herein.

A. The ’486 patent

All claims of the ’486 patent are invalid under 35 U.S.C. § 112 because, to the extent the terms “first module” and “second module” are not construed as means-plus-function terms

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limited to the specific corresponding structures disclosed in the '486 patent specification (i.e., the "first machine learning module" and "second machine learning module," respectively), the claims do not recite sufficient structure to perform the recited functions or to particularly point out and distinctly claim the subject matter regarded as the invention, and the inventions are defined by improper functional claiming.

III. SUPPORTING EVIDENCE FOR INVALIDITY DEFENSE

Pursuant to L.R. 16-6(d)(4)(G), MIM is producing herewith MIM00001404–1524.

IV. TECHNICAL DOCUMENTS, SAMPLES, AND SOURCE CODE

Pursuant to L.R. 16-6(d)(4)(A)–(C), MIM is producing or making available the following: MIM00000243–1403 and samples per the terms of Jesse Jenike-Godshalk's email dated May 27, 2025 at 4:59 p.m.

V. IDENTITY OF REAL PARTIES IN INTEREST

Pursuant to L.R. 16-6(d)(4)(H), MIM identifies the following real parties in interest in this Action: MIM.

Respectfully submitted,

/s/ Marla R. Butler

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CERTIFICATE OF SERVICE

I hereby certify that this document was served via email to counsel of record on May 29, 2025.

/s/ Jesse Jenike-Godshalk

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