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Application Number: 16718839

Document Date: 12/18/2019

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- Drawing

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Form Revision Date: March 1, 2019

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Progenics Pharmaceuticals, Inc.

Application No.: Not yet assigned

Confirmation No.: Not yet assigned

Filed: December 18, 2019

Art Unit: Not yet assigned

For: NETWORK FOR MEDICAL IMAGE
ANALYSIS, DECISION SUPPORT SYSTEM,
AND RELATED GRAPHICAL USER
INTERFACE (GUI) APPLICATIONS

Examiner: Not Yet Assigned

PRELIMINARY AMENDMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

Amendments to the Specification begin on page **2** of this paper;

Amendments to the Claims begin on page **3** of this paper.

Remarks/Arguments begin on page **7** of this paper.

**CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION
UNDER 37 CFR 1.102(e)** (Page 1 of 1)

First Named Inventor:	Mark R. Baker	Nonprovisional Application Number (if known):	Filed herewith
Title of Invention:	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:
 - I. ☒ **Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)**
 - i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
 - (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
 - ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.
- II. ☐ **Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)**
 - i. A request for continued examination has been filed with, or prior to, this form.
 - ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
 - iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
 - iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
 - v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature <u>/Ronen Adato/</u>	Date <u>2019-12-18</u>
Name (Print/Typed) <u>Ronen Adato</u>	Practitioner Registration Number <u>76,341</u>
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*	
☒ *Total of <u>1</u> forms are submitted.	

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		
First Named Inventor/Applicant Name:		Mark R. Baker		
Filer:		Ronen Adato/Logan Moss		
Attorney Docket Number:		2010358-0167		
Filed as Small Entity				
Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2000	2000
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				2855

Electronic Acknowledgement Receipt	
EFS ID:	38071033
Application Number:	16718839
International Application Number:	
Confirmation Number:	1052
Title of Invention:	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS
First Named Inventor/Applicant Name:	Mark R. Baker
Customer Number:	24280
Filer:	Ronen Adato/Logan Moss
Filer Authorized By:	Ronen Adato
Attorney Docket Number:	2010358-0167
Receipt Date:	18-DEC-2019
Filing Date:	
Time Stamp:	14:39:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$2855
RAM confirmation Number	E2019BHE39381501
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	2019-12-18_EXI-005USC2-T1_Declaration.PDF	409368	no	5
			aa5180a7a07bd0199d4726093492c2a29d420f36		
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
2	Transmittal Letter	2019-12-18_IDS_Transmittal.pdf	20060	no	2
			eab118faf464eae37d417d1a6e39a5e7dc277fec		
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	2019-12-18_IDS_SB08.pdf	75275	no	5
			ad2dde3ee9d15ab6f5cb0dd88f195a4fb191d984		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Application Data Sheet	2010358_0167_ADS.pdf	1255860	no	8
			0c066a7f61c1098f9f5117528c2223f8404c87de		
Warnings:					
Information:					
5		2010358_0167_Application.pdf	637428	yes	80
			b293b0c7d4065f347d2c34c221f0e2e140250ce6		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Abstract		80	80	

	Claims		63	79	
	Specification		1	62	
Warnings:					
Information:					
6	Drawings-only black and white line drawings	2010358_0167_Figures.pdf	1089696	no	11
			7d0f121c59a14f7a7ab04775bdb95b353363924d		
Warnings:					
Information:					
7		2010358_0167_PreliminaryAmendment.pdf	136996	yes	8
			c55961496b8a8e9eca58cc30e9000abfc81f16e3		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Applicant Arguments/Remarks Made in an Amendment		7	8	
	Claims		3	6	
	Specification		2	2	
	Preliminary Amendment		1	1	
Warnings:					
Information:					
8	TrackOne Request	2010358_0167_TrackOneRequest.pdf	114114	no	2
			d1612c9480fe42d1166a494f3af967c28482823c		
Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	40206	no	2
			2c26c9a2cacab683e1f42292bb2a96ac38e38028		
Warnings:					
Information:					
Total Files Size (in bytes):			3779003		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

COMBINED ASSIGNMENT & DECLARATION

A. ASSIGNMENT

WHEREAS, I, Mark R. Baker of New York, New York, am aware of the patent application entitled:

**NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM,
AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS; and**

☐ prepared for filing in the United States Patent and Trademark Office; or

☒ identified by United States Application Serial No. 15/794220
filed in the United States Patent and Trademark Office on; October 26, 2017; and

☒ identified by International Patent Application No. PCT/US17/58418
filed on October 26, 2017; and

☒ and is also aware of the following priority applications:

Serial No.	Filed
62/413,936	October 27, 2016

WHEREAS Progenics Pharmaceuticals, Inc. (hereinafter "ASSIGNEE"), having a usual place of business at One World Trade Center, 47th Floor Suite J, New York, New York 10007, desires to acquire or confirm an interest therein;

NOW, THEREFORE, to all whom it may concern be it known that, in consideration of agreements previously and duly entered into between the parties, and/or for other good and valuable consideration, the receipt of which is hereby acknowledged, I have sold, assigned, and transferred and/or do hereby sell, assign, and transfer unto said ASSIGNEE, its successors, assigns, and legal representatives, my entire right, title, and interest in and throughout the United States of America, its territories and all foreign countries, in and to any and all inventions described in the patent application, and/or any priority applications noted above, including any right of priority thereto; and hereby confirm that my sale, assignment and transfer is and was effective at least as of the filing date of the patent application and/or priority application. My sale, assignment and transfer applies to the above-referenced patent application, and to any application that is based in whole or in part on the patent application, including any divisional, continuing, substitute, renewal, reissue, reexamination and other applications, for example that claim priority to the patent application. Also, this sale, assignment and transfer pertains to any and all other rights arising under or pursuant to any and all international agreements, treaties, or laws relating to the protection of industrial property, including all rights of priority under the International Convention for the Protection of Industrial Property, and in and to any such

patent(s) as may issue thereon including any and all original and reissued patents which have been or shall be issued in the United States and foreign countries; said inventions, applications, and patent(s) to be held and enjoyed by ASSIGNEE for its own use and for its successors, assigns and legal representatives, to the full end of the term for which said patent(s) may be granted as fully and entirely as the same would have been held by me had this sale, assignment and transfer not been made;

AND, I hereby acknowledge that this Assignment, being of my entire right, title, and interest in and to the inventions, carries with it the right in ASSIGNEE, by attorneys and agents of ASSIGNEE selection, to apply for and receive any and all patent(s) for said inventions in its own name;

AND, I hereby further agree for myself and my executors and administrators to execute upon request any other lawful documents and likewise to perform any other lawful acts which may be deemed necessary to secure fully the patent(s) to ASSIGNEE, its successors, assignees, and legal representatives, but at its expense and charges, including the execution of application for patents in foreign countries, the execution of substitution, reissue, divisional or continuation applications, and the giving of testimony, preliminary statements, or other statements in any interference or other proceeding in which the inventions or any applications or patents directed to the inventions may be involved by communicating to the ASSIGNEE all facts I know relating to the inventions and their history, and generally by doing everything possible which ASSIGNEE shall consider desirable for aiding in securing and maintaining proper patent protection for the inventions and for vesting title in the inventions and all applications for patent and all patents on the inventions in ASSIGNEE;

AND, I further hereby authorize ASSIGNEE or its attorneys or agents to insert the correct serial number(s) and/or filing date(s) into this assignment document, if appropriate;

AND, I hereby appoint ASSIGNEE as my common agent for purposes of prosecuting international patent applications and any national patent applications for which such common agency is recognized;

AND, I hereby request the Commissioner for Patents of the United States Patent and Trademark Office to issue any and all patent(s) as shall be granted upon said application or applications based thereon to ASSIGNEE, its successors, assigns, and legal representatives;

AND, I covenant with said ASSIGNEE that no assignment, grant, mortgage, license, or other agreement affecting the rights and property herein conveyed has been made to others by me, and that full right to convey the same as herein expressed is possessed by me.

B. DECLARATION (37 CFR 1.63)

As a below named inventor, I hereby declare that:

This declaration is directed to the patent application entitled:

**NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM,
AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS;** and

☐ attached hereto or prepared for filing in the United States Patent and Trademark Office; or

☒ identified by United States Application Serial No. 15/794220
filed in the United States Patent and Trademark Office on October 26, 2017; or

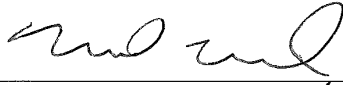
☐ identified by International Patent Application No. _____
filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

I have reviewed and understand the contents of the application, including the claims and am aware of the duty to disclose to the United States Patent and Trademark Office all information known to be material to patentability as defined in 37 CFR 1.56.

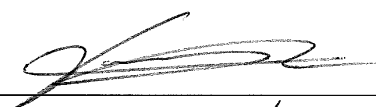
Signature: 
Mark R. Baker

Date: Nov 27, 2017

Witness Signature: 

Date: Nov 27, 2017

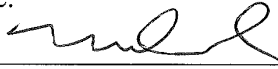
Witness Name (printed): Kerry Fox

Witness Signature: 

Date: Nov 27 2017

Witness Name (printed): Lucia Alessi

The undersigned (whose title is supplied below) is authorized to act on behalf of Progenics Pharmaceuticals, Inc.

Signature:  Date: Nov 27, 2017

Name (printed): Mark R. Baker

Title (printed): Chief Executive Officer

Docket No.: 2010358-0167
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Progenics Pharmaceuticals, Inc.

Application No.: Not Yet Assigned

Confirmation No.: Not Yet Assigned

Filed: Concurrently Herewith

Art Unit: Not Yet Assigned

For: NETWORK FOR MEDICAL IMAGE
ANALYSIS, DECISION SUPPORT SYSTEM,
AND RELATED GRAPHICAL USER
INTERFACE (GUI) APPLICATIONS

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Pursuant to 37 C.F.R. § 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. The documents cited in the attached form PTO/SB/08 containing an double asterisk (**) are not supplied because they were previously cited by or submitted to the Office in prior application numbers 16/418527 filed May 21, 2019 or 15/794220

filed October 26, 2017 and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(a) exists. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is “prior art” for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references.

Dated: December 18, 2019

Respectfully submitted,

By: /Ronen Adato/

Ronen Adato, PhD

Registration No.: 76,341

CHOATE, HALL & STEWART LLP

Two International Place

Boston, Massachusetts 02110

(617) 248-5000

Agent For Applicant

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Mark R. Baker
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	5	Attorney Docket Number	2010358-0167

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Additional Information
		Number-Kind Code ² (if known)			
	A1*	US-2003/0215120-A1	11-20-2003	Uppaluri et al.	
	A2*	US-2006/0062425-A1	03-23-2006	Shen et al.	
	A3*	US-2007/0081712-A1	04-12-2007	Huang et al.	
	A4*	US-2007/0081713-A1	04-12-2007	Jerebko	
	A5*	US-2007/0100225-A1	05-03-2007	Maschke	
	A6*	US-7,450,747-B2	11-11-2008	Jabri et al.	
	A7*	US-7,970,194-B2	06-28-2011	Kimura	
	A8*	US-8,211,401	07-03-2012	Babich et al.	
	A9*	US-8,538,166	09-17-2013	Gordon et al.	
	A10*	US-8,705,887	04-22-2014	Ma et al.	
	A11*	US-8,778,305	07-15-2014	Pomper et al.	
	A12*	US-8,855,387	10-07-2014	Hamadeh et al.	
	A13*	US-8,962,799	02-24-2015	Babich et al.	
	A14*	US-9,002,081-B2	04-07-2015	Brown	
	A15*	US-2015/0110716-A1	04-23-2015	ARMOR	
	A16*	US-2015/0331995-A1	11-19-2015	Zhao et al.	
	A17*	US-2016/0203263-A1	07-14-2016	Maier et al.	
	A18*	US-2016/0335395-A1	11-17-2016	WU et al.	
	A19*	US-2018/0144828-A1	05-24-2018	Baker	
	A20*	US-RE47609-E	09-17-2019	Hamadeh et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Additional Information	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	B1**	WO-9905503-A2	02-04-1999	Arch Development Corporation		
	B2**	EP-1426903-A2	06-09-2004	GE Medical Systems Global Technology Company LLC		
	B3**	EP-1508872-A1	02-23-2005	Semeion		
	B4**	WO-2007/062135-A2	05-31-2007	Shiraishi, Junji		
	B5**	WO-2009/084995-A1	07-09-2009	Exini Diagnostics AB		
	B6**	WO-2018/081354-A1	05-03-2018	Progenics Pharmaceuticals, Inc		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ** CITE NO.: Those document(s) which are marked with a double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Mark R. Baker
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	2010358-0167
Sheet	2	of	5		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	C1**	ANAND, A. et al., Analytic Validation of the Automated Bone Scan Index as an Imaging Biomarker to Standardize Quantitative Changes in Bone Scans of Patients with Metastatic Prostate Cancer, J. Nucl. Med., 57(1):41-45 (2016).		
	C2**	ANAND, A. et al., Automated Bone Scan Index as a quantitative imaging biomarker in metastatic castration-resistant prostate cancer patients being treated with enzalutamide, EJNMMI Research, 6:23, 7 pages (2016).		
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	C4**	ANAND, A. et al., Translating Prostate Cancer Working Group 2 (PCWG2) progression criteria into a quantitative response biomarker in metastatic castration-resistant prostate cancer (mCRPC), Journal of Clinical Oncology, 35(6):170 (2017).		
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	C8**	BELAL, S. et al., Association of PET Index quantifying skeletal uptake in NaF PET/CT images with overall survival in prostate cancer patients, ASCO GU 2017, Poster 178, presented February 16, 2017.		
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	C10**	BELAL, S. L. et al, 3D skeletal uptake of ¹⁸ F sodium fluoride in PET/CT images is associate with overall survival in patients with prostate cancer, EJNMMI Research, 7(15):1-8 (2017).		
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Examiner Signature		Date Considered	
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Substitute for form 1449/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	Not Yet Assigned
			Filing Date	Concurrently Herewith
			First Named Inventor	Mark R. Baker
			Art Unit	Not Yet Assigned
			Examiner Name	Not Yet Assigned
			Attorney Docket Number	2010358-0167
Sheet	3	of	5	

C16**	GIESEL, F. L. et al., F-18 labelled PSMA-1007: biodistribution, radiation dosimetry and histopathological validation of tumor lesions in prostate cancer patients, Eur. J. Nucl. Med. Mol. Imaging, 44:678-688 (2017).
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C19**	HAJNAL, J. et al., 4.4 Intensity, Size, and Skew Correction; 7.1 Introduction; 7.2 Methods; 7.3 Image Interpretation--General, In: Medical Image Registration, CRC Press LLC, 80-81:144-148 (2001).
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C28**	KINAHAN, P.E. et al., PET/CT Standardized Update Values (SUVs) in Clinical Practice and Assessing Response to Therapy, Semin Ultrasound CT MR 31(6):496-505 (2010) retrieved 10/25/2017: < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3026294/ >.
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C31**	LITJENS, G. et al., A survey on deep learning in medical image analysis, Medical Image Analysis, 42:60-88, (2017).
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Substitute for form 1449/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	Not Yet Assigned
			Filing Date	Concurrently Herewith
			First Named Inventor	Mark R. Baker
			Art Unit	Not Yet Assigned
			Examiner Name	Not Yet Assigned
			Attorney Docket Number	2010358-0167
Sheet	4	of	5	

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C45**	SABBATINI, P. et al., Prognostic Significance of Extent of Disease in Bone in Patients With Androgen-Independent Prostate Cancer, Journal of Clinical Oncology, 17(3):948-957 (1999).	
C46**	SADIK, M. et al., 3D prostate gland uptake of 18F-choline - association with overall survival in patients with hormone-naïve prostate cancer, The Journal of Nuclear Medicine, 58(Suppl.1):Abstract 544 (2017).	
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				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Mark R. Baker
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	5	of	5	Attorney Docket Number	2010358-0167

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	2010358-0167
		Application Number	
Title of Invention	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor	1 Remove				
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Mark	R.	Baker		
Residence Information (Select One) • US Residency Non US Residency Active US Military Service					
City	New York	State/Province	NY	Country of Residence	US
Mailing Address of Inventor:					
Address 1	One World Trade Center				
Address 2	47th Floor Suite J				
City	New York	State/Province	NY		
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All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. Add					

Correspondence Information:

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For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence information of this application.			
Customer Number	24280		
Email Address	patentdocket@choate.com	Add Email	Remove Email

Application Information:

Title of the Invention	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		
Attorney Docket Number	2010358-0167	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	11	Suggested Figure for Publication (if any)	4

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	2010358-0167
		Application Number	
Title of Invention	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
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When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	16/418527	2019-05-21

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		2010358-0167	
		Application Number			
Title of Invention	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS				

Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/418527	Continuation of	15/794220	2017-10-26	10340046	2019-07-02
Prior Application Status		Expired		Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
15/794220	Claims benefit of provisional	62/413936	2016-10-27		
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Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

☐ NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	2010358-0167
		Application Number	
Title of Invention	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

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The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	2010358-0167
		Application Number	
Title of Invention	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		

Applicant Information:

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Applicant 1		Remove	
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.			
		Clear	
☒ Assignee		Legal Representative under 35 U.S.C. 117	
☐ Joint Inventor		☐ Person to whom the inventor is obligated to assign.	
☐ Person who shows sufficient proprietary interest		☐ If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:	
Name of the Deceased or Legally Incapacitated Inventor:			
If the Applicant is an Organization check here. ☒			
Organization Name		Progenics Pharmaceuticals, Inc.	
Mailing Address Information For Applicant:			
Address 1		One World Trade Center	
Address 2		47th Floor Suite J	
City		New York	State/Province NY
Country US		Postal Code	10007
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	2010358-0167
		Application Number	
Title of Invention	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		

Assignee 1				
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.				
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	2010358-0167
		Application Number	
Title of Invention	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		

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NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS

Abstract

Described herein is a platform and supported graphical user interface (GUI) decision-making tools for use by medical practitioners and/or their patients, e.g., to aide in the process of making decisions about a course of cancer treatment and/or to track treatment and/or the progress of a disease.

What is claimed is:

1. 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 perform one or more of functions (i) to (v) as follows:
 - (i) receive and store medical images in a database, each medical image associated with a particular patient;
 - (ii) access one or more of the medical images and/or related data 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 one or more of the medical images;
 - (iv) generate a radiologist report for a patient according to one or more of the medical images for the patient; and
 - (v) apply a machine learning algorithm to update a process for automatically analyzing one or more of the medical images using accumulated image data in the database.
2. The system of claim 1, wherein the medical images in the database comprise a series of medical images of a first patient taken over time, and wherein the instructions cause the processor to determine a value of at least a first risk index for each medical image of the series, thereby tracking determined values of at least the first risk index for the first patient over time.

3. The system of any one of the preceding claims, wherein the medical images comprise a single-photon emission computerized tomography (SPECT) scan of a first patient obtained following administration to the first patient of an imaging agent comprising ^{140}Tl labeled with $^{99\text{m}}\text{Tc}$, and a computed tomography (CT) scan of the first patient, wherein the instructions cause the processor to overlay the SPECT scan with the CT scan to create a composite image (SPECT-CT) of the first patient.

4. The system of any one of the preceding claims, wherein the medical images comprise a positron emission tomography (PET) scan of a first patient obtained following administration to the first patient of an imaging agent comprising ^{18}F DCFPyL, and a CT scan of the first patient, wherein the instructions cause the processor to overlay the PET scan with the CT scan to create a composite image (PET-CT) of the first patient.

5. The system of any one of the preceding claims, wherein the medical images comprise a whole-body scan of a first patient made with a gamma camera following administration to the first patient of an imaging agent comprising technetium $^{99\text{m}}$ methylenediphosphonate ($^{99\text{m}}\text{Tc}$ MDP).

6. The system of any one of the preceding claims, wherein the medical images comprise a composite image of a first patient, the composite image comprising a CT scan overlaid with a nuclear medicine image obtained at substantially the same time as the CT scan and following administration to the first 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
- (c) computing (i) a value of each of one or more risk indices and/or (ii) a risk map using the nuclear medicine image with the identified 3D boundaries of the one or more region(s).

7. The system of claim 6, wherein the instructions cause the processor to, for at least one risk index of the one or more risk indices, compute the value of the risk index by:

determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the 3D boundary of the region; and

computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.

8. The system of either of claims 6 or 7, wherein the nuclear medicine image is a SPECT scan.

9. The system of claim 8, wherein the imaging agent comprises a metal chelated to the PSMA binding agent, and wherein the metal is the radionuclide.

10. The system of claim 9, wherein the imaging agent comprises ^{99m}Tc-MIP-1404.

11. The system of either of claims 6 or 7, wherein the nuclear medicine image is a PET scan.
12. The system of claim 11, wherein the radionuclide is a radioisotope of a halogen.
13. The system of claim 12, wherein the imaging agent comprises [18F]DCFPyL.
14. The system of claim 11, wherein the radionuclide is a radioisotope of gallium (Ga).
15. The system of any one of the preceding claims, wherein the medical images comprise a nuclear medicine image of a first patient following administration to the first patient of an imaging agent comprising a radionuclide, wherein the instructions cause the processor to automatically analyze the nuclear medicine image by:
 - (a) geographically identifying a boundary for each of one or more regions of imaged tissue within the nuclear medicine image; and
 - (c) computing (i) a value of each of one or more risk indices and/or (ii) a risk map using the nuclear medicine image with the identified boundaries of the one or more region(s).
16. The system of claim 15, wherein the instructions cause the processor to, for at least one risk index of the one or more risk indices, compute the value of the risk index by:

determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the boundary of the region; and

computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.

17. The system of any one of the preceding claims, wherein the system is a cloud-based system.

18. The system of any one of the preceding claims, wherein the processor is a processor of one or more network or Internet host servers.

19. A method comprising any one or more of (i) to (v) as follows:

- (i) receiving and storing, by a processor of a server computing device medical images in a database, each medical image associated with a particular patient;
- (ii) accessing, by the processor, one or more of the medical images and/or related data 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 analyzing, by the processor, one or more of the medical images;
- (iv) generating, by the processor, a radiologist report for a patient according to one or more of the medical images for the patient; and

(v) applying, by the processor, a machine learning algorithm to update a process for automatically analyzing one or more of the medical images using accumulated image data in the database.

20. The method of claim 19, wherein the medical images in the database comprise a series of medical images of a first patient taken over time, and wherein the method comprises determining a value of at least a first risk index for each medical image of the series, thereby tracking determined values of at least the first risk index over time.

21. The method of claim 20, wherein the receiving and storing of the medical images comprises repeatedly receiving and storing, over time, a plurality of medical images of the first patient, each obtained at a different time, to obtain the series of medical images of the first patient.

22. The method of any one of claims 19 to 21, wherein the medical images comprise a single-photon emission computerized tomography (SPECT) scan of a first patient obtained following administration to the first patient of an imaging agent comprising ^{140}Tl labeled with $^{99\text{m}}\text{Tc}$, and a computed tomography (CT) scan of the first patient, wherein the method comprises overlaying the SPECT scan with the CT scan to create a composite image (SPECT-CT) of the first patient.

23. The method of any one of claims 19 to 22, wherein the medical images comprises a positron emission tomography (PET) scan of a first patient obtained following administration to

the first patient of an imaging agent comprising [18F]DCFPyL, and a CT scan of the first patient, wherein the method comprises overlaying the PET scan with the CT scan to create a composite image (PET-CT) of the first patient.

24. The method of any one of claims 19 to 23, wherein the medical images comprise a whole-body scan of a first patient made with a gamma camera following administration to the first patient of an imaging agent comprising technetium 99m methylenediphosphonate (^{99m}Tc MDP).

25. The method of any one of claims 19 to 24, wherein the medical images comprise a composite image of a first patient, the composite image comprising a CT scan overlaid with a nuclear medicine image acquired at substantially the same time and following administration to the first patient of an imaging agent comprising a Prostate Specific Membrane Antigen (PSMA) binding agent comprising a radionuclide, wherein the method comprises automatically analyzing 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
- (c) computing (i) a value of each of one or more risk indices and/or a (ii) risk map using the nuclear medicine image with the identified 3D boundaries of the one or more region(s).

26. The method of claim 25, wherein step (c) comprises, for at least one risk index of the one or more risk indices, computing the value of the risk index by:

determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the 3D boundary of the region; and

computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.

27. The method of either of claims 25 or 26, wherein the nuclear medicine image is a SPECT scan.

28. The method of claim 27, wherein the imaging agent comprises a metal chelated to the PSMA binding agent, and wherein the metal is the radionuclide.

29. The method of claim 28, wherein the imaging agent comprises ^{99m}Tc-MIP-1404.

30. The method of either of claims 25 or 26, wherein the nuclear medicine image is a PET scan.

31. The method of claim 30, wherein the radionuclide is a radioisotope of a halogen.

32. The method of claim 31, wherein the imaging agent comprises [18F]DCFPyL.

33. The method of claim 30, wherein the radionuclide is a radioisotope of gallium (Ga).

34. The method of any one of claims 19 to 33, wherein the medical images comprise a nuclear medicine image of a first patient obtained following administration to the first patient of an imaging agent comprising a radionuclide, wherein the method comprises automatically analyzing the nuclear medicine image by:

- (a) geographically identifying a boundary for each of one or more regions of imaged tissue within the nuclear medicine image; and
- (c) computing (i) a value of each of one or more risk indices and/or (ii) a risk map using the nuclear medicine image with the identified boundaries of the one or more region(s).

35. The method of claim 34, wherein step (c) comprises, for at least one risk index of the one or more risk indices, computing the value of the risk index by:

determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the boundary of the region; and

computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.

36. The method of any one of claims 19 to 35, wherein the processor is a processor of a cloud-based system.

37. The method of any one of claims 19 to 36, wherein the processor is a processor of one or more network or Internet host servers.

38. A system comprising:

a processor; and

a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to generate and cause display of an interactive graphical user interface (GUI) element, the GUI element having user-selectable and/or user-adjustable graphical controls for selecting and/or adjusting a digital presentation of a 3D risk picture of a patient for comparison with reference images caused to be displayed by the processor.

39. The system of claim 38, wherein the interactive GUI element is produced from medical images of the patient and/or other images or information.

40. A method for tracking prostate cancer progression and treatment efficacy over time, for one or more patient(s), the method comprising:

(a) repeatedly receiving and storing in a database, over time, by a processor of a computing device, a plurality of medical images for each of the one or more patient(s) to obtain, for each of the one or more patient(s), a series of medical images taken over time;

(b) for each of the one or more patient(s), automatically analyzing, by the processor, the series of medical images for the patient to determine values of one or more risk indices for each medical image of the series, thereby tracking determined values of the one or more risk indices over a course prostate cancer progression and treatment for the patient; and

(c) for each of the one or more patient(s), storing, by the processor, the determined values of the one or more risk indices for the patient for further processing and/or causing, by the

processor, display of a graphical representation of the determined values of the one or more risk indices for the patient.

41. The method of claim 40, wherein the series of medical images for a particular patient of the one or more patient(s) comprises:

(i) a first image subseries comprising one or more medical images obtained using a first nuclear imaging modality each following administration to the particular patient of a first radiopharmaceutical; and

(ii) a second image subseries comprising one or more medical images obtained using a second nuclear imaging modality each following administration to the particular patient of a second radiopharmaceutical,

such that the values of the one or more risk indices determined in step (b) for the particular patient comprise a first subseries of values of a first risk index determined by automated analysis of the first image subseries and a second subseries of values of a second risk index determined by automated analysis of the second image subseries.

42. The method of claim 41, wherein the medical images of first image subseries are obtained over a first period of time, when prostate cancer of the particular patient is localized, and the medical images of the second image subseries are obtained over a second period of time, when prostate cancer of the particular patient is metastatic.

43. The method of either of claims 41 or 42, wherein:

the first image subseries comprises one or more composite SPECT-CT image(s), each composite SPECT-CT image comprising a CT scan overlaid with a SPECT scan acquired at substantially the same time;

the second image subseries comprises one or more composite PET-CT image(s), each composite PET-CT image comprising a CT scan overlaid with a PET scan acquired at substantially the same time; and

step (b) comprises:

automatically analyzing each of the one or more composite SPECT-CT images

by:

using the composite SPECT-CT image to geographically identify a 3D boundary of a prostate region within the SPECT scan of the composite SPECT-CT image; and

computing a value of the first risk index using the SPECT scan with the identified 3D boundary of the prostate region; and

automatically analyzing each of the one or more composite PET-CT images by:

using the composite PET-CT image to geographically identify a 3D boundary of one or more metastatic regions within the PET scan of the composite PET-CT image, the one or metastatic regions including regions corresponding to patient tissue locations outside of the prostate; and

computing a value of the second risk index using the PET scan with the identified 3D boundaries of the one or more metastatic region(s).

44. The method of either of claims 41 or 42, wherein:

the first image subseries comprises one or more composite SPECT-CT image(s), each composite SPECT-CT image comprising a CT scan overlaid with a SPECT scan acquired at substantially the same time;

the second image subseries comprises one or more whole-body scan(s); and

step (b) comprises:

automatically analyzing each of the one or more composite SPECT-CT images

by:

using the composite SPECT-CT image to geographically identify a 3D boundary of a prostate region within the SPECT scan of the composite SPECT-CT image; and

computing a value of the first risk index using the SPECT scan with the identified 3D boundary of the prostate region; and

automatically analyzing each of the one or more whole-body scan(s) by:

geographically identifying a boundary of one or more metastatic regions within the whole-body scan, the one or metastatic regions including regions corresponding to patient tissue locations outside of the prostate; and

computing a value of the second risk index using the PET scan with the identified 3D boundaries of the one or more metastatic region(s).

45. A system for tracking prostate cancer progression and treatment efficacy over time, for one or more patient(s), the system comprising:

a processor; and

a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to:

(a) repeatedly receive and store in a database, over time, a plurality of medical images for each of the one or more patient(s) to obtain, for each of the one or more patient(s), a series of medical images taken over time;

(b) for each of the one or more patient(s), automatically analyze the series of medical images for the patient to determine values of one or more risk indices for each medical image of the series, thereby tracking determined values of the one or more risk indices over a course prostate cancer progression and treatment for the patient; and

(c) for each of the one or more patient(s), store the determined values of the one or more risk indices for the patient for further processing and/or cause display of a graphical representation of the determined values of the one or more risk indices for the patient.

46. The system of claim 45, wherein the series of medical images for a particular patient of the one or more patient(s) comprises:

(i) a first image subseries comprising one or more medical images obtained using a first nuclear imaging modality each following administration to the particular patient of a first radiopharmaceutical; and

(ii) a second image subseries comprising one or more medical images obtained using a second nuclear imaging modality each following administration to the particular patient of a second radiopharmaceutical,

such that the values of the one or more risk indices determined in step (b) for the particular patient comprise a first subseries of values of a first risk index determined by automated analysis of the first image subseries and a second subseries of values of a second risk index determined by automated analysis of the second image subseries.

47. The system of claim 46, wherein the medical images of first image subseries are obtained over a first period of time, when prostate cancer of the particular patient is localized, and the medical images of the second image subseries are obtained over a second period of time, when prostate cancer of the particular patient is metastatic.

48. The system of either of claims 46 or 47, wherein:

the first image subseries comprises one or more composite SPECT-CT image(s), each composite SPECT-CT image comprising a CT scan overlaid with a SPECT scan acquired at substantially the same time;

the second image subseries comprises one or more composite PET-CT image(s), each composite PET-CT image comprising a CT scan overlaid with a PET scan acquired at substantially the same time; and

the instructions cause the processor to, at step (b):

automatically analyze each of the one or more composite SPECT-CT images by:

using the composite SPECT-CT image to geographically identify a 3D boundary of a prostate region within the SPECT scan of the composite SPECT-CT image; and

computing a value of the first risk index using the SPECT scan with the identified 3D boundary of the prostate region; and
automatically analyze each of the one or more composite PET-CT images by:
using the composite PET-CT image to geographically identify a 3D boundary of one or more metastatic regions within the PET scan of the composite PET-CT image, the one or metastatic regions including regions corresponding to patient tissue locations outside of the prostate; and
computing a value of the second risk index using the PET scan with the identified 3D boundaries of the one or more metastatic region(s).

49. The system of either of claims 46 or 47, wherein:

the first image subseries comprises one or more composite SPECT-CT image(s), each composite SPECT-CT image comprising a CT scan overlaid with a SPECT scan acquired at substantially the same time;

the second image subseries comprises one or more whole-body scan(s); and

the instructions cause the processor to, at step (b):

automatically analyze each of the one or more composite SPECT-CT images by:

using the composite SPECT-CT image to geographically identify a 3D boundary of a prostate region within the SPECT scan of the composite SPECT-CT image; and

computing a value of the first risk index using the SPECT scan with the identified 3D boundary of the prostate region; and

automatically analyze each of the one or more whole-body scan(s) by:

geographically identifying a boundary of one or more metastatic regions within the whole-body scan, the one or metastatic regions including regions corresponding to patient tissue locations outside of the prostate; and

computing a value of the second risk index using the PET scan with the identified 3D boundaries of the one or more metastatic region(s).

NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS

Cross Reference to Related Applications

[0001] This application claims the benefit of U.S. Provisional Application 62/413,936, filed on October 27, 2016, the content of which is hereby incorporated by reference herein in its entirety.

Technical Field

[0002] This invention relates generally to systems and methods for creation, analysis, and/or presentation of medical image data. More particularly, in certain embodiments, the invention relates to a cloud-based platform and supported GUI decision-making tools for use by medical practitioners and/or their patients, e.g., to aide in the process of making decisions about a course of cancer treatment and/or to track treatment and/or the progress of a disease.

Background

[0003] Targeted image analysis involves the use of radiolabeled small molecules that bind to specific receptors, enzymes and proteins in the body that are altered during the evolution of disease. After administration to a patient, these molecules circulate in the blood until they find their intended target. The bound radiopharmaceutical remains at the site of disease, while the rest of the agent clears from the body. The radioactive portion of the molecule serves as a beacon so that an image may be obtained depicting the disease location and concentration using commonly available nuclear medicine cameras, known as single-photon emission computerized

tomography (SPECT) or positron emission tomography (PET) cameras, found in most hospitals throughout the world. Physicians can then use this information to determine the presence and the extent of disease in a patient. The physician can use this information to provide a recommended course of treatment to the patient and to track the progression of disease.

[0004] There are a variety of software-based analytical techniques available for analysis and enhancement of PET and SPECT images that can be used by a radiologist or physician. There are also a number of radiopharmaceuticals available for imaging particular kinds of cancer. For example, the small molecule diagnostic 1404 targets the extracellular domain of prostate specific membrane antigen (PSMA), a protein amplified on the surface of >95% of prostate cancer cells and a validated target for the detection of primary and metastatic prostate cancer. 1404 is labeled with technetium-99m, a gamma-emitter isotope that is widely available, relatively inexpensive, facilitates efficient preparation, and has spectrum characteristics attractive for nuclear medicine imaging applications.

[0005] Another example radiopharmaceutical is PyL™ (also known as [¹⁸F]DCFPyL), which is a clinical-stage, fluorinated PSMA-targeted PET imaging agent for prostate cancer. A proof-of-concept study published in the April 2015 issue of the Journal of Molecular Imaging and Biology demonstrated that PET imaging with PyL™ showed high levels of PyL™ uptake in sites of putative metastatic disease and primary tumors, suggesting the potential for high sensitivity and specificity in detecting prostate cancer.

[0006] An oncologist may use images from a targeted PET or SPECT study of a patient as input in her assessment of whether the patient has a particular disease, e.g., prostate cancer, what stage of the disease is evident, what the recommended course of treatment (if any) would be, whether surgical intervention is indicated, and likely prognosis. The oncologist may use a

radiologist report in this assessment. A radiologist report is a technical evaluation of the PET or SPECT images prepared by a radiologist for a physician who requested the imaging study and includes, for example, the type of study performed, the clinical history, a comparison between images, the technique used to perform the study, the radiologist's observations and findings, as well as overall impressions and recommendations the radiologist may have based on the imaging study results. A signed radiologist report is sent to the physician ordering the study for the physician's review, followed by a discussion between the physician and patient about the results and recommendations for treatment.

[0007] Thus, the process involves having a radiologist perform an imaging study on the patient, analyzing the images obtained, creating a radiologist report, forwarding the report to the requesting physician, having the physician formulate an assessment and treatment recommendation, and having the physician communicate the results, recommendations, and risks to the patient. The process may also involve repeating the imaging study due to inconclusive results, or ordering further tests based on initial results.

[0008] If an imaging study shows that the patient has a particular disease or condition (e.g., cancer), the physician discusses various treatment options, including surgery, as well as risks of doing nothing or adopting a watchful waiting or active surveillance approach, rather than having surgery.

[0009] There are limitations associated with this process, both from the perspective of the physician and from the perspective of the patient. While the radiologist's report is certainly helpful, the physician must ultimately rely on her experience in formulating an assessment and recommendation for her patient. Furthermore, the patient must place a great deal of trust in his physician. The physician may show the patient his PET/SPECT images and may tell the patient

a numerical risk associated with various treatment options or likelihood of a particular prognosis, but the patient may very well struggle to make sense of this information. Moreover, the patient's family will likely have questions, particularly if cancer is diagnosed but the patient opts not to have surgery. The patient and/or his family members may search online for supplemental information and may become misinformed about risks of the diagnosed condition. A difficult ordeal may become more traumatic.

[0010] Thus, there remains a need for systems and methods for improved analysis of medical imaging studies and communication of those results, diagnoses, prognoses, treatment recommendations, and associated risks to a patient.

Summary of the Invention

[0011] Presented herein is a cloud-based platform and supported graphical user interface (GUI) decision-making tools for use by medical practitioners and/or their patients, e.g., to aide in the process of making decisions about a course of cancer treatment and/or to track treatment and/or the progress of a disease.

[0012] For example, presented herein is a network-based (e.g., cloud-based) support platform allowing multiple users to store, access, analyze, and/or provide feedback regarding a given set of image data for a patient; platform supports software tools for automated analysis of targeted PET/SPECT/or other image(s), generation of radiologist reports, and application of machine learning algorithms to update process by which images are analyzed (e.g. updating segmentation and/or classification routines based on growing image database). In certain embodiments, the targeted PET/SPECT image(s) may be obtained using PyLTM and/or

1404 as the radiopharmaceutical(s). In certain embodiments, multiple (accredited) users can access the information, e.g., to weigh in on data interpretation.

[0013] Also presented herein is a software tool (e.g., mobile app) featuring a graphical user interface (GUI) element with controls for adjusting presentation of a 3D risk image corresponding to a patient organ (and/or other tissue) for comparison with reference images (e.g., for use in communication of results to patient as a decision-making support). For example, the tool may be supported by the network-based support platform above. This tool can provides an easily-understood, user-friendly, interactive, controllable pictorial display to communicate information about a patient's condition to the patient (and/or to the physician, or to the patient's family with the patient's permission). For example, a patient for whom a risk of cancer is detected can display a map indicating areas and/or degrees of risk and can compare this risk map with those of others for whom a given course of treatment is recommended. For instance, this tool can help a patient in his decision whether or not to have surgery (e.g., for a detected risk of prostate cancer). The patient can visually compare his risk map with a map representing a typical risk-level for which surgery would be recommended, below which it may be reasonable to opt not to have surgery and engage in watchful waiting or active surveillance. Thus, a low-risk patient who is told by his physician that he has a non-zero risk of cancer may find comfort in a visual, controllable comparison between his situation and that of someone (e.g., where the reference to which the patient's risk situation is compared can be tuned for age, weight, and/or other risk factors of the patient).

[0014] In one aspect, the invention is directed to a network-based (e.g., cloud based) decision support system comprising: a processor (e.g., of a network or Internet host server); and a memory having instructions stored thereon, wherein the instructions, when executed by the

processor, cause the processor to perform one or more of functions (i) to (v) as follows: (i) receive and store medical images [e.g., comprising one or more of the following: targeted PET images, targeted SPECT images, computed tomography (CT) images, magnetic resonance (MR) images, ultrasound (US) images, gamma camera (i.e. scintillation camera) images, and combinations, fusions, or derivatives of any of the above] in a database [e.g., wherein the targeted PET/SPECT/gamma camera image(s) are obtained using one or more radiopharmaceuticals (e.g., [18F]DCFPyL and/or 1404 and/or a composition comprising technetium 99m, {e.g., technetium 99m methylenediphosphonate (^{99m}Tc MDP)}), and/or wherein the medical images are obtained using non-radioactive agents or no agents], each medical image associated with a particular patient; (ii) access one or more of the medical images and/or related data associated with a particular patient from the database upon user request (e.g., following automated verification that the user is properly credentialed for receiving the requested images and/or data) for transmission to the user for display on a user computing device; (iii) automatically analyze one or more of the medical images [e.g., to generate a risk index (e.g., BSI) and/or a risk map, e.g., a visual representation (e.g., 3D representation) of tissue (e.g., an organ or other part of the body) with graphical denotations (e.g., texture- or color-coding) marking regions of risk of current disease or risk of recurrence of disease, e.g., cancer, e.g., wherein the risk map is displayed as an overlay of the PET/SPECT/CT/MRI/US/combined/derived/fused image of the tissue, or is in place of the image of the tissue]; (iv) generate a radiologist report for a patient according to one or more of the medical images for the patient; and (v) apply a machine learning algorithm to update a process for automatically analyzing one or more of the medical images using accumulated image data in the database [e.g., wherein the automatic analysis of the one or more medical images in (iii)

and/or (v) above comprises any one or more of (a) to (d) as follows: (a) automated fusion of the (e.g., PET, SPECT, CT, MRI, and/or US) image(s) of the tissue; (b) geographic identification of one or more organs, organ structures, sub-organs, organ regions, and/or other regions of the imaged tissue of the patient and production of a 3D image of the geographically identified tissue with PET, SPECT, CT, MRI, and/or US data overlaid; (c) computation of risk information comprising one or more risk indices, a risk field, or a risk map using data from the database, the image(s) of the tissue, and/or the 3D image in (b); and (d) use of the risk information computed in (c) (e.g., and data from the database) to produce a 3D risk picture for the patient].

[0015] In certain embodiments, the medical images in the database comprise a series of medical images of a first patient taken over time (e.g., over the course of multiple visits to one or more doctors), and wherein the instructions cause the processor to determine a value of at least a first risk index for each medical image of the series, thereby tracking determined values of at least the first risk index for the first patient over time.

[0016] In certain embodiments, the medical images comprise a single-photon emission computerized tomography (SPECT) scan of a first patient obtained (e.g., to identify one or more hotspots) following administration to the first patient of an imaging agent comprising ^{140}Tl labeled with $^{99\text{m}}\text{Tc}$, and a computed tomography (CT) scan (e.g., to identify anatomical features) of the first patient, wherein the instructions cause the processor to overlay the SPECT scan with the CT scan to create a composite image (SPECT-CT) of the first patient.

[0017] In certain embodiments, the medical images comprise a positron emission tomography (PET) scan of a first patient obtained (e.g., to identify one or more hotspots) following administration to the first patient of an imaging agent comprising ^{18}F DCFPyL (DCFPyL labeled with ^{18}F), and a CT scan of the first patient, wherein the instructions cause the

processor to overlay the PET scan with the CT scan to create a composite image (PET-CT) of the first patient.

[0018] In certain embodiments, the medical images comprise a whole-body scan (e.g., including anterior and posterior views) of a first patient made with a gamma camera following administration to the first patient of an imaging agent comprising technetium 99m methylenediphosphonate (^{99m}Tc MDP).

[0019] In certain embodiments, the medical images comprise a composite image of a first patient, the composite image comprising a CT scan overlaid with a nuclear medicine image (e.g., a SPECT scan; e.g., a PET scan) obtained at substantially the same time as the CT scan and following administration to the first patient of an imaging agent comprising a Prostate Specific Membrane Antigen (PSMA) binding agent comprising (e.g., labelled with) a radionuclide, and 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 [e.g., organs (e.g., a prostate; e.g., a liver; e.g., lungs or a lung; e.g., lymph nodes), organ structures, sub-organs, organ regions, and/or other regions (e.g., one or more particular bones; e.g., a skeletal region of the patient), e.g., regions of interest] within the nuclear medicine image (e.g., such that portions of the nuclear medicine image falling within and/or outside of the 3D boundaries can be differentiated from each other); and (c) computing (i) a value of each of one or more risk indices and/or (ii) a risk map using the nuclear medicine image with the identified 3D boundaries of the one or more region(s).

[0020] In certain embodiments, the instructions cause the processor to, for at least one risk index of the one or more risk indices, compute the value of the risk index by: determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based

on intensity values of the nuclear medicine image within the 3D boundary of the region (e.g., by identifying within the nuclear medicine image, a plurality of hotspots within the 3D boundary of the region and computing a total number of and/or a total volume of the identified hotspots); and computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.

[0021] In certain embodiments, the nuclear medicine image is a SPECT scan.

[0022] In certain embodiments, the imaging agent comprises a metal chelated to the PSMA binding agent, and wherein the metal is the radionuclide [e.g., wherein the metal is a radioisotope of technetium (Tc) (e.g., wherein the metal is technetium-99m (^{99m}Tc)); e.g., wherein the metal is a radioisotope of rhenium (Re) (e.g., wherein the metal is rhenium-188 (^{188}Re); e.g., wherein the metal is rhenium-186 (^{186}Re)); e.g., wherein the metal is a radioisotope of yttrium (Y) (e.g., wherein the metal is ^{90}Y); e.g., wherein the metal is a radioisotope of lutetium (Lu) (e.g., wherein the metal is ^{177}Lu); e.g., wherein the metal is a radioisotope of gallium (Ga) (e.g., wherein the metal is ^{68}Ga ; e.g., wherein the metal is ^{67}Ga); e.g., wherein the metal is a radioisotope of indium (e.g., ^{111}In); e.g., wherein the metal is a radioisotope of copper (Cu) (e.g., wherein the metal is ^{67}Cu)].

[0023] In certain embodiments, the imaging agent comprises ^{99m}Tc -MIP-1404.

[0024] In certain embodiments, the nuclear medicine image is a PET scan.

[0025] In certain embodiments, the radionuclide is a radioisotope of a halogen [e.g., a radioisotope of fluorine (e.g., ^{18}F); e.g., a radioisotope of iodine (e.g., ^{123}I ; e.g., ^{124}I ; e.g., ^{125}I ; e.g., ^{126}I ; e.g., ^{131}I); e.g., a radioisotope of bromine (e.g., ^{75}Br ; e.g., ^{76}Br ; e.g., ^{77}Br ; e.g., ^{80}Br ; e.g., ^{80m}Br ; e.g., ^{82}Br ; e.g., ^{83}Br); e.g., a radioisotope of astatine (e.g., ^{211}At)].

[0026] In certain embodiments, the imaging agent comprises [18F]DCFPyL (DCFPyL labeled with ¹⁸F).

[0027] In certain embodiments, the radionuclide is a radioisotope of gallium (Ga) (e.g., ⁶⁸Ga).

[0028] In certain embodiments, the medical images comprise a nuclear medicine image (e.g., a whole-body scan made with a gamma camera) of a first patient following administration to the first patient of an imaging agent comprising a radionuclide (e.g., ^{99m}Tc)(e.g., wherein the imaging agent comprises ^{99m}Tc MDP), wherein the instructions cause the processor to automatically analyze the nuclear medicine image by: (a) geographically identifying a boundary (e.g., a 2D boundary; e.g., a 3D boundary) for each of one or more regions of imaged tissue [e.g., organs (e.g., a prostate; e.g., a liver; e.g., lungs or a lung; e.g., lymph nodes), organ structures, sub-organs, organ regions, and/or other regions (e.g., one or more particular bones; e.g., a skeletal region of the patient), e.g., regions of interest] within the nuclear medicine image (e.g., such that portions of the nuclear medicine image falling within and/or outside of the boundaries can be differentiated from each other); and (c) computing (i) a value of each of one or more risk indices and/or (ii) a risk map using the nuclear medicine image with the identified boundaries of the one or more region(s).

[0029] In certain embodiments, the instructions cause the processor to, for at least one risk index of the one or more risk indices, compute the value of the risk index by: determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the boundary of the region (e.g., by identifying within the nuclear medicine image, a plurality of hotspots within the boundary of the region and computing a total number of and/or a total volume of the identified hotspots); and

computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.

[0030] In certain embodiments, the system is a cloud-based system.

[0031] In certain embodiments, the processor is a processor of one or more network or Internet host servers.

[0032] In another aspect, the invention is directed to a method comprising any one or more of (i) to (v) as follows: (i) receiving and storing, by a processor of a server computing device (e.g., received over a network from a client computing device) medical images [e.g., comprising one or more of the following: targeted PET images, targeted SPECT images, computed tomography (CT) images, magnetic resonance (MR) images, ultrasound (US) images, gamma camera (i.e. scintillation camera) images, and combinations, fusions, or derivatives of any of the above] in a database [e.g., wherein the targeted PET/SPECT/gamma camera image(s) are obtained using one or more radiopharmaceuticals, e.g., [18F]DCFPyL and/or 1404 and/or a composition comprising technetium 99m, e.g., technetium 99m methylenediphosphonate (^{99m}Tc MDP), and/or wherein the medical images are obtained using non-radioactive agents or no agents], each medical image associated with a particular patient; (ii) accessing, by the processor, one or more of the medical images and/or related data associated with a particular patient from the database upon user request (e.g., following automated verification that the user is properly credentialed for receiving the requested images and/or data) for transmission to the user for display on a user computing device; (iii) automatically analyzing, by the processor, one or more of the medical images[e.g., to generate a risk map, e.g., a visual representation (e.g., 3D representation) of tissue (e.g., an organ or other part of the body) with graphical denotations (e.g., texture- or color-coding) marking regions of risk of current disease or risk of recurrence of

disease, e.g., cancer, e.g., wherein the risk map is displayed as an overlay of the PET/SPECT/CT/MRI/US/combined/derived/fused image of the tissue, or is in place of the image of the tissue]; (iv) generating, by the processor, a radiologist report for a patient according to one or more of the medical images for the patient; and (v) applying, by the processor, a machine learning algorithm to update a process for automatically analyzing one or more of the medical images using accumulated image data in the database, [e.g., wherein the automatically analyzing the one or more medical images in (iii) and/or (v) above comprises any one or more of (a) to (d) as follows: (a) automatically fusing the (e.g., PET, SPECT, CT, MRI, and/or US) image(s) of the tissue; (b) geographically identifying one or more organs, organ structures, sub-organs, organ regions, and/or other regions of the imaged tissue of the patient and production of a 3D image of the geographically identified tissue with PET, SPECT, CT, MRI, and/or US data overlaid; (c) computing risk information comprising one or more risk indices, a risk field, or a risk map using data from the database, the image(s) of the tissue, and/or the 3D image in (b); and (d) using the risk information computed in (c) (e.g., and data from the database) to produce a 3D risk picture for the patient].

[0033] In certain embodiments, the medical images in the database comprise a series of medical images of a first patient taken over time (e.g., over the course of multiple visits to one or more doctors), and wherein the method comprises determining a value of at least a first risk index for each medical image of the series, thereby tracking determined values of at least the first risk index over time.

[0034] In certain embodiments, the receiving and storing of the medical images comprises repeatedly receiving and storing, over time, a plurality of medical images of the first patient,

each obtained at a different time (e.g., at a different visit to one or more doctors), to obtain the series of medical images of the first patient.

[0035] In certain embodiments, the medical images comprise a single-photon emission computerized tomography (SPECT) scan of a first patient obtained (e.g., to identify one or more hotspots) following administration to the first patient of an imaging agent comprising 1404 labeled with ^{99m}Tc , and a computed tomography (CT) scan (e.g., to identify anatomical features) of the first patient, wherein the method comprises overlaying the SPECT scan with the CT scan to create a composite image (SPECT-CT) of the first patient.

[0036] In certain embodiments, the medical images comprises a positron emission tomography (PET) scan of a first patient obtained following administration to the first patient of an imaging agent comprising $[^{18}\text{F}]\text{DCFPyL}$ (DCFPyL labeled with ^{18}F), and a CT scan of the first patient, wherein the method comprises overlaying the PET scan with the CT scan to create a composite image (PET-CT) of the first patient.

[0037] In certain embodiments, the medical images comprise a whole-body scan (e.g., including anterior and posterior views) of a first patient made with a gamma camera following administration to the first patient of an imaging agent comprising technetium 99m methylenediphosphonate (^{99m}Tc MDP).

[0038] In certain embodiments, the medical images comprise a composite image of a first patient, the composite image comprising a CT scan overlaid with a nuclear medicine image (e.g., a SPECT scan; e.g., a PET scan) acquired at substantially the same time and following administration to the first patient of an imaging agent comprising a Prostate Specific Membrane Antigen (PSMA) binding agent comprising a radionuclide, wherein the method comprises automatically analyzing 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 [e.g., organs (e.g., a prostate; e.g., a liver; e.g., lungs or a lung; e.g., lymph nodes), organ structures, sub-organs, organ regions, and/or other regions (e.g., one or more particular bones; e.g., a skeletal region of the patient), e.g., regions of interest] within the nuclear medicine image (e.g., such that portions of the nuclear medicine image falling within and/or outside of the 3D boundaries can be differentiated from each other); and (c) computing (i) a value of each of one or more risk indices and/or a (ii) risk map using the nuclear medicine image with the identified 3D boundaries of the one or more region(s).

[0039] In certain embodiments, step (c) comprises, for at least one risk index of the one or more risk indices, computing the value of the risk index by: determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the 3D boundary of the region (e.g., by identifying within the nuclear medicine image, a plurality of hotspots within the 3D boundary of the region and computing a total number of and/or a total volume of the identified hotspots); and computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.

[0040] In certain embodiments, the nuclear medicine image is a SPECT scan.

[0041] In certain embodiments, the imaging agent comprises a metal chelated to the PSMA binding agent, and wherein the metal is the radionuclide [e.g., wherein the metal is a radioisotope of technetium (Tc) (e.g., wherein the metal is technetium-99m (^{99m}Tc)); e.g., wherein the metal is a radioisotope of rhenium (Re) (e.g., wherein the metal is rhenium-188 (^{188}Re); e.g., wherein the metal is rhenium-186 (^{186}Re)); e.g., wherein the metal is a radioisotope of yttrium (Y) (e.g., wherein the metal is ^{90}Y); e.g., wherein the metal is a radioisotope of lutetium (Lu)(e.g., wherein

the metal is ^{177}Lu); e.g., wherein the metal is a radioisotope of gallium (Ga) (e.g., wherein the metal is ^{68}Ga ; e.g., wherein the metal is ^{67}Ga); e.g., wherein the metal is a radioisotope of indium (e.g., ^{111}In); e.g., wherein the metal is a radioisotope of copper (Cu) (e.g., wherein the metal is ^{67}Cu).

[0042] In certain embodiments, the imaging agent comprises $^{99\text{m}}\text{Tc}$ -MIP-1404.

[0043] In certain embodiments, the nuclear medicine image is a PET scan.

[0044] In certain embodiments, the radionuclide is a radioisotope of a halogen [e.g., a radioisotope of fluorine (e.g., ^{18}F); e.g., a radioisotope of iodine (e.g., ^{123}I ; e.g., ^{124}I ; e.g., ^{125}I ; e.g., ^{126}I ; e.g., ^{131}I); e.g., a radioisotope of bromine (e.g., ^{75}Br ; e.g., ^{76}Br ; e.g., ^{77}Br ; e.g., ^{80}Br ; e.g., $^{80\text{m}}\text{Br}$; e.g., ^{82}Br ; e.g., ^{83}Br), e.g., a radioisotope of astatine (e.g., ^{211}At).

[0045] In certain embodiments, the imaging agent comprises $[^{18}\text{F}]\text{DCFPyL}$ (DCFPyL labeled with ^{18}F).

[0046] In certain embodiments, the radionuclide is a radioisotope of gallium (Ga)(e.g., ^{68}Ga)

[0047] In certain embodiments, the medical images comprise a nuclear medicine image (e.g., a whole-body scan made with a gamma camera) of a first patient obtained following administration to the first patient of an imaging agent comprising a radionuclide (e.g., $^{99\text{m}}\text{Tc}$)(e.g., wherein the imaging agent comprises $^{99\text{m}}\text{Tc}$ MDP), wherein the method comprises automatically analyzing the nuclear medicine image by: (a) geographically identifying a boundary (e.g., a 2D boundary; e.g., a 3D boundary) for each of one or more regions of imaged tissue [e.g., organs (e.g., a prostate; e.g., a liver; e.g., lungs or a lung; e.g., lymph nodes), organ structures, sub-organs, organ regions, and/or other regions (e.g., one or more particular bones; e.g., a skeletal region of the patient), e.g., regions of interest] within the nuclear medicine image (e.g., such that portions of the nuclear medicine image falling within and/or outside of the 3D

boundaries can be differentiated from each other); and (c) computing (i) a value of each of one or more risk indices and/or (ii) a risk map using the nuclear medicine image with the identified boundaries of the one or more region(s).

[0048] In certain embodiments, step (c) comprises, for at least one risk index of the one or more risk indices, computing the value of the risk index by: determining, for each of the one or more regions, a corresponding cancerous tissue level within the region based on intensity values of the nuclear medicine image within the boundary of the region (e.g., by identifying within the nuclear medicine image, a plurality of hotspots within the 3D boundary of the region and computing a total number of and/or a total volume of the identified hotspots); and computing the value of the risk index based on the determined cancerous tissue levels within the one or more regions.

[0049] In certain embodiments, the processor is a processor of a cloud-based system.

[0050] In certain embodiments, the processor is a processor of one or more network or Internet host servers.

[0051] In another aspect, the invention is directed to a system comprising: a processor (e.g., of a network or Internet host server or of a portable computing device); and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to generate and cause display of an interactive graphical user interface (GUI) element (e.g., cause display of the GUI element on a laptop computer or on a remote computing device, e.g., via a mobile app), the GUI element having user-selectable and/or user-adjustable graphical controls (e.g., slider bars, option buttons, text bars, drop-down boxes, windows, animations, and/or any other GUI widget) for selecting and/or adjusting a digital presentation of a 3D risk picture of a patient for comparison with reference images (e.g., for use in communication of

results to patient as a decision-making support) caused to be displayed by the processor(e.g., wherein the reference images displayed to the user or presented for selection by the user are tunable according to one or more predetermined variables associated with the patient, e.g., patient age, time since diagnosis, prior treatment, and/or future treatment).

[0052] In certain embodiments, the interactive GUI element is produced from medical images of the patient [e.g., comprising one or more of the following: targeted PET images, targeted SPECT images, magnetic resonance (MR) images, ultrasound (US) images, gamma camera (i.e. scintillation camera) images, and combinations, fusions, or derivatives of any of the above] and/or other images or information (e.g., other images received and stored in the database of the network-based decision support system of any of the aspects and/or embodiments described herein).

[0053] In another aspect, the invention is directed to a method for tracking prostate cancer progression and treatment efficacy over time, for one or more patient(s), the method comprising: (a) repeatedly receiving and storing in a database, over time, by a processor of a computing device (e.g., a server computing device), a plurality of medical images for each of the one or more patient(s) to obtain, for each of the one or more patient(s), a series of medical images taken over time (e.g., over the course of multiple visits to one or more doctors); (b) for each of the one or more patient(s), automatically analyzing, by the processor, the series of medical images for the patient to determine values of one or more risk indices [e.g., the values of the one or more risk indices corresponding to numeric values indicative of prostate cancer state and/or progression in the patient (e.g., numeric values identifying a particular cancer stage; e.g., numeric values corresponding to a determined overall survival rate for the patient)] for each medical image of the series, thereby tracking determined values of the one or more risk indices

over a course prostate cancer progression and treatment for the patient; and (c) for each of the one or more patient(s), storing, by the processor, the determined values of the one or more risk indices for the patient for further processing and/or causing, by the processor, display of a graphical representation of the determined values of the one or more risk indices for the patient (e.g., causing display of a graph showing variation in the determined values of the one or more risk indices for the patient over time).

[0054] In certain embodiments, the series of medical images for a particular patient of the one or more patient(s) comprises: (i) a first image subseries comprising one or more medical images obtained using a first nuclear imaging modality (e.g., SPECT scans; e.g., composite SPECT-CT images) each following administration to the particular patient of a first radiopharmaceutical (e.g., ^{99m}Tc -MIP-1404) (e.g., wherein the first radiopharmaceutical facilitates imaging of localized disease, e.g., localized prostate cancer); and (ii) a second image subseries comprising one or more medical images obtained using a second nuclear imaging modality (e.g., PET scans; e.g., composite PET-CT images; e.g., whole-body scans) each following administration to the particular patient of a second radiopharmaceutical (e.g., ^{18}F DCFPyL; e.g., ^{99m}Tc MDP) (e.g., wherein the second radiopharmaceutical facilitates imaging of metastatic disease, e.g., metastatic prostate cancer), such that the values of the one or more risk indices determined in step (b) for the particular patient comprise a first subseries of values of a first risk index determined by automated analysis of the first image subseries and a second subseries of values of a second risk index determined by automated analysis of the second image subseries.

[0055] In certain embodiments, the medical images of first image subseries are obtained over a first period of time, when prostate cancer of the particular patient is localized (e.g.,

substantially localized to a prostate of the particular patient), and the medical images of the second image subseries are obtained over a second period of time, when prostate cancer of the particular patient is metastatic (e.g., having spread to regions of the patient outside of the prostate).

[0056] In certain embodiments, the first image subseries comprises one or more composite SPECT-CT image(s), each composite SPECT-CT image comprising a CT scan overlaid with a SPECT scan acquired at substantially the same time; the second image subseries comprises one or more composite PET-CT image(s), each composite PET-CT image comprising a CT scan overlaid with a PET scan acquired at substantially the same time; and step (b) comprises: automatically analyzing each of the one or more composite SPECT-CT images by: using the composite SPECT-CT image to geographically identify a 3D boundary of a prostate region (e.g., corresponding to a prostate of the patient) within the SPECT scan of the composite SPECT-CT image (e.g., such that portions of the nuclear medicine image falling within and/or outside of the 3D boundary of the prostate region can be differentiated from each other); and computing a value of the first risk index using the SPECT scan with the identified 3D boundary of the prostate region (e.g., computed based on a region of the SPECT scan corresponding to the identified 3D boundary of the prostate region); and automatically analyzing each of the one or more composite PET-CT images by: using the composite PET-CT image to geographically identify a 3D boundary of one or more metastatic regions within the PET scan of the composite PET-CT image, the one or metastatic regions including regions corresponding to patient tissue locations outside of the prostate [e.g., organs (e.g., a prostate; e.g., a liver; e.g., lungs or a lung; e.g., lymph nodes), organ structures, sub-organs, organ regions, and/or other regions (e.g., one or more particular bones; e.g., a skeletal region corresponding to the patient's skeleton), e.g.,

regions of interest] (e.g., such that portions of the PET imaging scan falling within and/or outside of the 3D boundaries of the one or more metastatic region(s) can be differentiated from each other); and computing a value of the second risk index using the PET scan with the identified 3D boundaries of the one or more metastatic region(s).

[0057] In certain embodiments, the first image subseries comprises one or more composite SPECT-CT image(s), each composite SPECT-CT image comprising a CT scan overlaid with a SPECT scan acquired at substantially the same time; the second image subseries comprises one or more whole-body scan(s); and step (b) comprises: automatically analyzing each of the one or more composite SPECT-CT images by: using the composite SPECT-CT image to geographically identify a 3D boundary of a prostate region (e.g., corresponding to a prostate of the patient) within the SPECT scan of the composite SPECT-CT image (e.g., such that portions of the nuclear medicine image falling within and/or outside of the 3D boundary of the prostate region can be differentiated from each other); and computing a value of the first risk index using the SPECT scan with the identified 3D boundary of the prostate region (e.g., computed based on a region of the SPECT scan corresponding to the identified 3D boundary of the prostate region); and automatically analyzing each of the one or more whole-body scan(s) by: geographically identifying a boundary of one or more metastatic regions within the whole-body scan, the one or more metastatic regions including regions corresponding to patient tissue locations outside of the prostate [(e.g., one or more particular bones; e.g., a skeletal region corresponding to the patient's skeleton), e.g., regions of interest] (e.g., such that portions of the whole-body scan falling within and/or outside of the boundaries of the one or more metastatic region(s) can be differentiated from each other); and computing a value of the second risk index using the PET scan with the identified 3D boundaries of the one or more metastatic region(s).

[0058] In another aspect, the invention is directed to a system for tracking prostate cancer progression and treatment efficacy over time, for one or more patient(s), the system comprising: a processor (e.g., of a network or Internet host server); and a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to: (a) repeatedly receive and store in a database, over time, a plurality of medical images for each of the one or more patient(s) to obtain, for each of the one or more patient(s), a series of medical images taken over time (e.g., over the course of multiple visits to one or more doctors); (b) for each of the one or more patient(s), automatically analyze the series of medical images for the patient to determine values of one or more risk indices [e.g., the values of the one or more risk indices corresponding to numeric values indicative of prostate cancer state and/or progression in the patient (e.g., numeric values identifying a particular cancer stage; e.g., numeric values corresponding to a determined overall survival rate for the patient)] for each medical image of the series, thereby tracking determined values of the one or more risk indices over a course prostate cancer progression and treatment for the patient; and (c) for each of the one or more patient(s), store the determined values of the one or more risk indices for the patient for further processing and/or cause display of a graphical representation of the determined values of the one or more risk indices for the patient (e.g., causing display of a graph showing variation in the determined values of the one or more risk indices for the patient over time).

[0059] In certain embodiments, the series of medical images for a particular patient of the one or more patient(s) comprises: (i) a first image subseries comprising one or more medical images obtained using a first nuclear imaging modality (e.g., SPECT scans; e.g., composite SPECT-CT images) each following administration to the particular patient of a first radiopharmaceutical (e.g., ^{99m}Tc-MIP-1404) (e.g., wherein the first radiopharmaceutical

facilitates imaging of localized disease, e.g., localized prostate cancer); and (ii) a second image subseries comprising one or more medical images obtained using a second nuclear imaging modality (e.g., PET scans; e.g., composite PET-CT images; e.g., whole-body scans) each following administration to the particular patient of a second radiopharmaceutical (e.g., [18F]DCFPyL; e.g., ^{99m}Tc MDP) (e.g., wherein the second radiopharmaceutical facilitates imaging of metastatic disease, e.g., metastatic prostate cancer), such that the values of the one or more risk indices determined in step (b) for the particular patient comprise a first subseries of values of a first risk index determined by automated analysis of the first image subseries and a second subseries of values of a second risk index determined by automated analysis of the second image subseries.

[0060] In certain embodiments, the medical images of first image subseries are obtained over a first period of time, when prostate cancer of the particular patient is localized (e.g., substantially localized to a prostate of the particular patient), and the medical images of the second image subseries are obtained over a second period of time, when prostate cancer of the particular patient is metastatic (e.g., having spread to regions of the patient outside of the prostate).

[0061] In certain embodiments, the first image subseries comprises one or more composite SPECT-CT image(s), each composite SPECT-CT image comprising a CT scan overlaid with a SPECT scan acquired at substantially the same time; the second image subseries comprises one or more composite PET-CT image(s), each composite PET-CT image comprising a CT scan overlaid with a PET scan acquired at substantially the same time; and the instructions cause the processor to, at step (b): automatically analyze each of the one or more composite SPECT-CT images by: using the composite SPECT-CT image to geographically identify a 3D boundary of a

prostate region (e.g., corresponding to a prostate of the patient) within the SPECT scan of the composite SPECT-CT image (e.g., such that portions of the nuclear medicine image falling within and/or outside of the 3D boundary of the prostate region can be differentiated from each other); and computing a value of the first risk index using the SPECT scan with the identified 3D boundary of the prostate region (e.g., computed based on a region of the SPECT scan corresponding to the identified 3D boundary of the prostate region); and automatically analyze each of the one or more composite PET-CT images by: using the composite PET-CT image to geographically identify a 3D boundary of one or more metastatic regions within the PET scan of the composite PET-CT image, the one or metastatic regions including regions corresponding to patient tissue locations outside of the prostate [e.g., organs (e.g., a prostate; e.g., a liver; e.g., lungs or a lung; e.g., lymph nodes), organ structures, sub-organs, organ regions, and/or other regions (e.g., one or more particular bones; e.g., a skeletal region corresponding to the patient's skeleton), e.g., regions of interest] (e.g., such that portions of the PET imaging scan falling within and/or outside of the 3D boundaries of the one or more metastatic region(s) can be differentiated from each other); and computing a value of the second risk index using the PET scan with the identified 3D boundaries of the one or more metastatic region(s).

[0062] In certain embodiments, the first image subseries comprises one or more composite SPECT-CT image(s), each composite SPECT-CT image comprising a CT scan overlaid with a SPECT scan acquired at substantially the same time; the second image subseries comprises one or more whole-body scan(s); and the instructions cause the processor to, at step (b): automatically analyze each of the one or more composite SPECT-CT images by: using the composite SPECT-CT image to geographically identify a 3D boundary of a prostate region (e.g., corresponding to a prostate of the patient) within the SPECT scan of the composite SPECT-CT

image (e.g., such that portions of the nuclear medicine image falling within and/or outside of the 3D boundary of the prostate region can be differentiated from each other); and computing a value of the first risk index using the SPECT scan with the identified 3D boundary of the prostate region (e.g., computed based on a region of the SPECT scan corresponding to the identified 3D boundary of the prostate region); and automatically analyze each of the one or more whole-body scan(s) by: geographically identifying a boundary of one or more metastatic regions within the whole-body scan, the one or metastatic regions including regions corresponding to patient tissue locations outside of the prostate [(e.g., one or more particular bones; e.g., a skeletal region corresponding to the patient's skeleton), e.g., regions of interest] (e.g., such that portions of the whole-body scan falling within and/or outside of the boundaries of the one or more metastatic region(s) can be differentiated from each other); and computing a value of the second risk index using the PET scan with the identified 3D boundaries of the one or more metastatic region(s).

[0063] Embodiments described with respect to one aspect of the invention may be, applied to another aspect of the invention (e.g., features of embodiments described with respect to one independent claim, e.g., a method claim, are contemplated to be applicable to other embodiments of other independent claims, e.g., a system claim, and vice versa).

Brief Description of the Drawings

[0064] The foregoing and other objects, aspects, features, and advantages of the present disclosure will become more apparent and better understood by referring to the following description taken in conjunction with the accompanying drawings, in which:

[0065] FIG. 1 is a screenshot of a graphical user interface (GUI) showing mobile app icons for three cloud-based services, according to illustrative embodiments.

[0066] FIG. 2 is a schematic showing the relationship between a platform and a computing device (e.g., personal computer or mobile computing device, e.g., smart phone) running an application, according to illustrative embodiments of the invention.

[0067] FIG. 3 is a screenshot of a GUI window in the BSI Cloud application (displayed to a user) that allows a user to enter information about a patient and upload and/or access medical images for the patient, e.g., series of images obtained over a period of time, according to an illustrative embodiment.

[0068] FIG. 4 is a screenshot of a GUI window in the BSI Cloud application showing representative full body gamma camera images showing hotspots automatically identified by the system, with corresponding overall computed BSI values for a particular image set obtained at a given time, according to an illustrative embodiment.

[0069] FIG. 5 is a screenshot of a GUI window in the BSI Cloud application showing an automatically or semi-automatically generated radiologist report, which can be signed and dated by a radiologist, according to an illustrative embodiment.

[0070] FIG. 6 is a block diagram showing a set of functionalities offered by the a cloud-based platform and supported graphical user interface (GUI) decision-making tools described herein, according to an illustrative embodiment.

[0071] FIG. 7 is a block diagram of an exemplary cloud computing environment, used in certain embodiments.

[0072] FIG. 8 is a block diagram of an example computing device and an example mobile computing device used in certain embodiments.

[0073] FIG. 9 is block diagram of an example architecture for implementing the cloud based platform described herein, according to an illustrative embodiment.

[0074] FIG. 10 is a schematic showing stages of prostate cancer progression, along with various therapies and diagnostic imaging modalities appropriate for various disease states, according to an illustrative embodiment.

[0075] FIG. 11 is a block flow diagram of a process for tracking prostate cancer progression and treatment efficacy over time, according to an illustrative embodiment.

[0076] The features and advantages of the present disclosure will become more apparent from the detailed description set forth below when taken in conjunction with the drawings, in which like reference characters identify corresponding elements throughout. In the drawings, like reference numbers generally indicate identical, functionally similar, and/or structurally similar elements.

Detailed Description

[0077] It is contemplated that systems, devices, methods, and processes of the claimed invention encompass variations and adaptations developed using information from the embodiments described herein. Adaptation and/or modification of the systems, devices, methods, and processes described herein may be performed by those of ordinary skill in the relevant art.

[0078] Throughout the description, where articles, devices, and systems are described as having, including, or comprising specific components, or where processes and methods are described as having, including, or comprising specific steps, it is contemplated that, additionally, there are articles, devices, and systems of the present invention that consist essentially of, or consist of, the recited components, and that there are processes and methods according to the present invention that consist essentially of, or consist of, the recited processing steps.

[0079] It should be understood that the order of steps or order for performing certain action is immaterial so long as the invention remains operable. Moreover, two or more steps or actions may be conducted simultaneously.

[0080] The mention herein of any publication, for example, in the Background section, is not an admission that the publication serves as prior art with respect to any of the claims presented herein. The Background section is presented for purposes of clarity and is not meant as a description of prior art with respect to any claim.

[0081] Headers are provided for the convenience of the reader – the presence and/or placement of a header is not intended to limit the scope of the subject matter described herein.

A. Medical Imaging Modalities, Associated Radiopharmaceuticals, and Computed Risk Indices

[0082] FIG. 1 shows mobile app icons 100 for three cloud-based services, according to illustrative embodiments. As described in the following, the cloud-based services of the platform described herein provide for processing and analysis of medical images in a fully automated fashion and/or in combination with a user interaction (e.g., in a semi-automated fashion). The medical images include nuclear medicine images, obtained using a nuclear

imaging modality such as whole-body scans with a gamma camera, Positron Emission Tomography (PET) scans, and Single-Photon Emission Tomography (SPECT) scans.

[0083] In certain embodiments, nuclear medicine images use imaging agents comprising radiopharmaceuticals. Nuclear medicine images are obtained following administration of a radiopharmaceutical to a patient, and provide information regarding the distribution of the radiopharmaceutical within the patient. Radiopharmaceuticals are compounds that comprise a radionuclide.

[0084] As used herein, “radionuclide” refers to a moiety comprising a radioactive isotope of at least one element. Exemplary suitable radionuclides include but are not limited to those described herein. In some embodiments, a radionuclide is one used in positron emission tomography (PET). In some embodiments, a radionuclide is one used in single-photon emission computed tomography (SPECT). In some embodiments, a non-limiting list of radionuclides includes ^{99m}Tc, ¹¹¹In, ⁶⁴Cu, ⁶⁷Ga, ⁶⁸Ga, ¹⁸⁶Re, ¹⁸⁸Re, ¹⁵³Sm, ¹⁷⁷Lu, ⁶⁷Cu, ¹²³I, ¹²⁴I, ¹²⁵I, ¹²⁶I, ¹³¹I, ¹¹C, ¹³N, ¹⁵O, ¹⁸F, ¹⁵³Sm, ¹⁶⁶Ho, ¹⁷⁷Lu, ¹⁴⁹Pm, ⁹⁰Y, ²¹³Bi, ¹⁰³Pd, ¹⁰⁹Pd, ¹⁵⁹Gd, ¹⁴⁰La, ¹⁹⁸Au, ¹⁹⁹Au, ¹⁶⁹Yb, ¹⁷⁵Yb, ¹⁶⁵Dy, ¹⁶⁶Dy, ¹⁰⁵Rh, ¹¹¹Ag, ⁸⁹Zr, ²²⁵Ac, ⁸²Rb, ⁷⁵Br, ⁷⁶Br, ⁷⁷Br, ⁸⁰Br, ^{80m}Br, ⁸²Br, ⁸³Br, ²¹¹At and ¹⁹²Ir.

[0085] As used herein, the term “radiopharmaceutical” refers to a compound comprising a radionuclide. In certain embodiments, radiopharmaceuticals are used for diagnostic and/or therapeutic purposes. In certain embodiments, radiopharmaceuticals include small molecules that are labeled with one or more radionuclide(s), antibodies that are labeled with one or more radionuclide(s), and antigen-binding portions of antibodies that are labeled with one or more radionuclide(s).

[0086] Nuclear medicine images (e.g., PET scans; e.g., SPECT scans; e.g., whole-body scans; e.g. composite PET-CT images; e.g., composite SPECT-CT images) detect radiation emitted from the radionuclides of radiopharmaceuticals to form an image. The distribution of a particular radiopharmaceutical within a patient may be determined by biological mechanisms such as blood flow or perfusion, as well as by specific enzymatic or receptor binding interactions. Different radiopharmaceuticals may be designed to take advantage of different biological mechanisms and/or particular specific enzymatic or receptor binding interactions and thus, when administered to a patient, selectively concentrate within particular types of tissue and/or regions within the patient. Greater amounts of radiation are emitted from regions within the patient that have higher concentrations of radiopharmaceutical than other regions, such that these regions appear brighter in nuclear medicine images. Accordingly, intensity variations within a nuclear medicine image can be used to map the distribution of radiopharmaceutical within the patient. This mapped distribution of radiopharmaceutical within the patient can be used to, for example, infer the presence of cancerous tissue within various regions of the patient's body.

[0087] For example, upon administration to a patient, technetium 99m methylenediphosphonate (^{99m}Tc MDP) selectively accumulates within the skeletal region of the patient, in particular at sites with abnormal osteogenesis associated with malignant bone lesions. The selective concentration of radiopharmaceutical at these sites produces identifiable hotspots – localized regions of high intensity in nuclear medicine images. Accordingly, presence of malignant bone lesions associated with metastatic prostate cancer can be inferred by identifying such hotspots within a whole-body scan of the patient. As described in the following, risk indices that correlate with patient overall survival and other prognostic metrics indicative of

disease state, progression, treatment efficacy, and the like, can be computed based on automated analysis of intensity variations in whole-body scans obtained following administration of ^{99m}Tc MDP to a patient. In certain embodiments, other radiopharmaceuticals can also be used in a similar fashion to ^{99m}Tc MDP.

[0088] In certain embodiments, the particular radiopharmaceutical used depends on the particular nuclear medicine imaging modality used. For example ^{18}F sodium fluoride (NaF) also accumulates in bone lesions, similar to ^{99m}Tc MDP, but can be used with PET imaging. In certain embodiments, PET imaging may also utilize a radioactive form of the vitamin choline, which is readily absorbed by prostate cancer cells.

[0089] In certain embodiments, radiopharmaceuticals that selectively bind to particular proteins or receptors of interest – particularly those whose expression is increased in cancerous tissue may be used. Such proteins or receptors of interest include, but are not limited to tumor antigens, such as CEA, which is expressed in colorectal carcinomas, Her2/neu, which is expressed in multiple cancers, BRCA 1 and BRCA 2, expressed in breast and ovarian cancers; and TRP-1 and -2, expressed in melanoma.

[0090] For example, human prostate-specific membrane antigen (PSMA) is upregulated in prostate cancer, including metastatic disease. PSMA is expressed by virtually all prostate cancers and its expression is further increased in poorly differentiated, metastatic and hormone refractory carcinomas. Accordingly, radiopharmaceuticals corresponding to PSMA binding agents (e.g., compounds that a high affinity to PSMA) labelled with one or more radionuclide(s) can be used to obtain nuclear medicine images of a patient from which the presence and/or state of prostate cancer within a variety of regions (e.g., including, but not limited to skeletal regions) of the patient can be assessed. In certain embodiments, nuclear medicine images obtained using

PSMA binding agents are used to identify the presence of cancerous tissue within the prostate, when the disease is in a localized state. In certain embodiments, nuclear medicine images obtained using radiopharmaceuticals comprising PSMA binding agents are used to identify the presence of cancerous tissue within a variety of regions that include not only the prostate, but also other organs and tissue regions such as lungs, lymph nodes, and bones, as is relevant when the disease is metastatic.

[0091] In particular, upon administration to a patient, radionuclide labelled PSMA binding agents selectively accumulate within cancerous tissue, based on their affinity to PSMA. In a similar manner to that described above with regard to ^{99m}Tc MDP, the selective concentration of radionuclide labelled PSMA binding agents at particular sites within the patient produces detectable hotspots in nuclear medicine images. As PSMA binding agents concentrate within a variety of cancerous tissues and regions of the body expressing PSMA, localized cancer within a prostate of the patient and/or metastatic cancer in various regions of the patient's body can be detected, and evaluated. As described in the following, risk indices that correlate with patient overall survival and other prognostic metrics indicative of disease state, progression, treatment efficacy, and the like, can be computed based on automated analysis of intensity variations in nuclear medicine images obtained following administration of a PSMA binding agent radiopharmaceutical to a patient.

[0092] A variety of radionuclide labelled PSMA binding agents may be used as radiopharmaceutical imaging agents for nuclear medicine imaging to detect and evaluate prostate cancer. In certain embodiments, the particular radionuclide labelled PSMA binding agent that is used depends on factors such as the particular imaging modality (e.g., PET; e.g., SPECT) and the particular regions (e.g., organs) of the patient to be imaged. For example, certain radionuclide

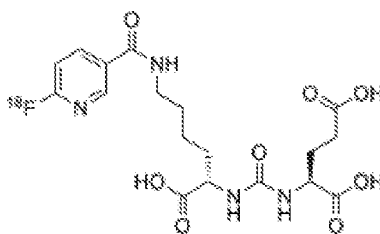
labelled PSMA binding agents are suited for PET imaging, while others are suited for SPECT imaging. For example, certain radionuclide labelled PSMA binding agents facilitate imaging a prostate of the patient, and are used primarily when the disease is localized, while others facilitate imaging organs and regions throughout the patient's body, and are useful for evaluating metastatic prostate cancer.

[0093] A variety of PSMA binding agents and radionuclide labelled versions thereof are described in U.S. Patent Nos. 8,778,305, 8,211,401, and 8,962,799, each of which are incorporated herein by reference in their entireties.

A.i PET Imaging Radionuclide Labelled PSMA Binding Agents

[0094] In certain embodiments, the radionuclide labelled PSMA binding agent is a radionuclide labelled PSMA binding agent appropriate for PET imaging.

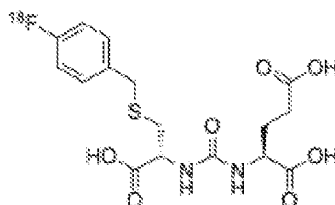
[0095] In certain embodiments, the radionuclide labelled PSMA binding agent comprises [18F]DCFPyL (also referred to as PyLTM; also referred to as DCFPyL-18F):



[18F]DCFPyL,

or a pharmaceutically acceptable salt thereof.

[0096] In certain embodiments, the radionuclide labelled PSMA binding agent comprises [18F]DCFBC:

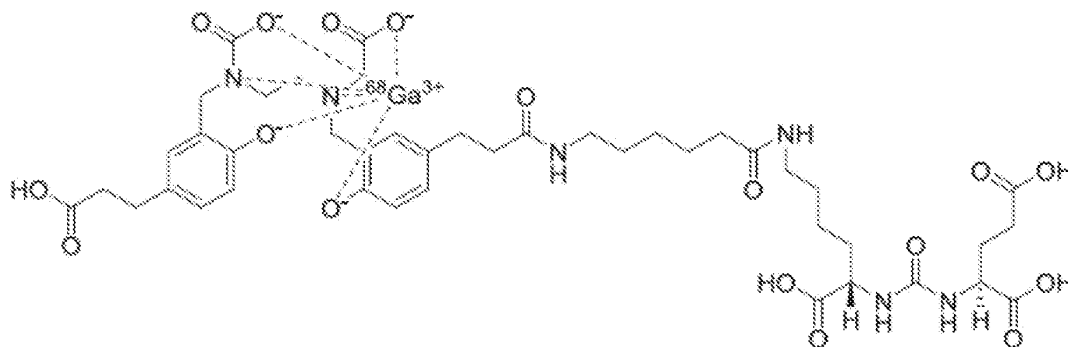


[18F]DCFBC,

or a pharmaceutically acceptable salt thereof.

[0097] In certain embodiments, the radionuclide labelled PSMA binding agent comprises

^{68}Ga -PSMA-HBED-CC (also referred to as ^{68}Ga -PSMA-11):



^{68}Ga -PSMA-HBED-CC,

or a pharmaceutically acceptable salt thereof.

[0098] In certain embodiments, the radionuclide labelled PSMA binding agent comprises

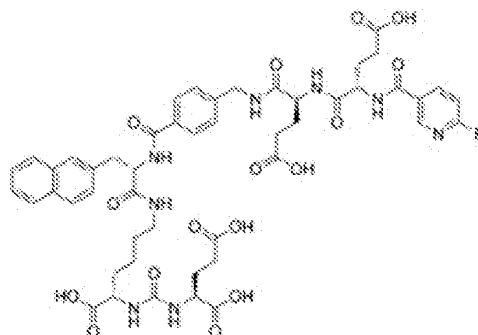
PSMA-617:



[0099] In certain embodiments, the radionuclide labelled PSMA binding agent comprises PSMA-I&T:



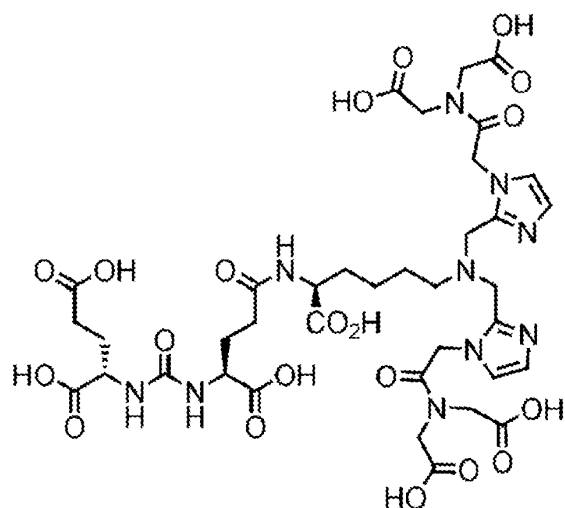
[00101] In certain embodiments, the radionuclide labelled PSMA binding agent comprises PSMA-1007:



[00102] or a pharmaceutically acceptable salt thereof. In certain embodiments, the radionuclide labelled PSMA binding agent comprises ^{18}F -PSMA-1007, which is PSMA-1007 labelled with ^{18}F , or a pharmaceutically acceptable salt thereof.

[00103] In certain embodiments, the radionuclide labelled PSMA binding agent is a radionuclide labelled PSMA binding agent appropriate for SPECT imaging.

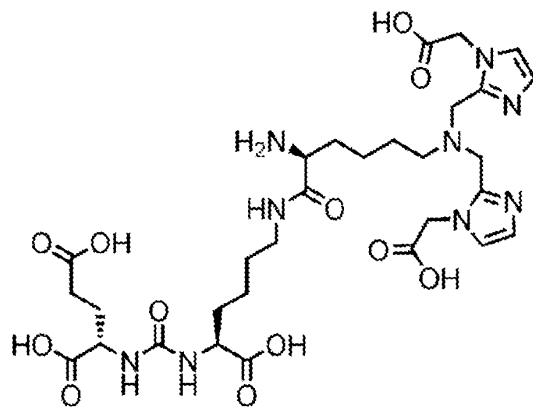
MIM Ex1004



1404,

or a pharmaceutically acceptable salt thereof.

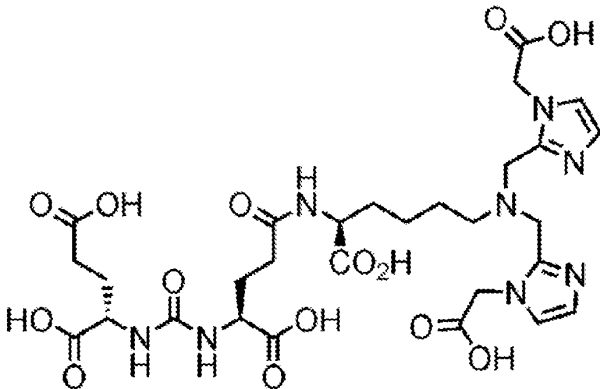
[00105] In certain embodiments, the radionuclide labelled PSMA binding agent comprises 1405 (also referred to as MIP-1405):



1405,

or a pharmaceutically acceptable salt thereof.

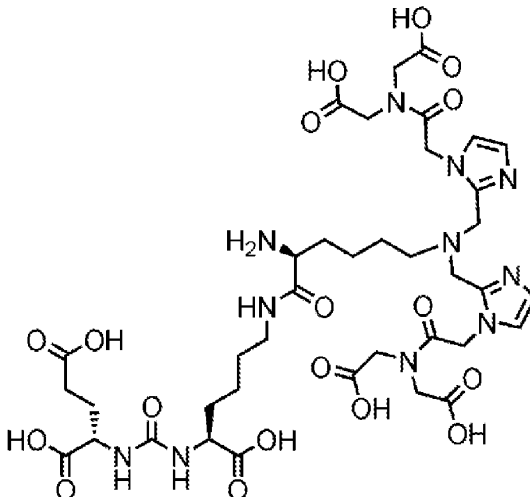
1427 (also referred to as MIP-1427):



1427,

or a pharmaceutically acceptable salt thereof.

1428 (also referred to as MIP-1428):

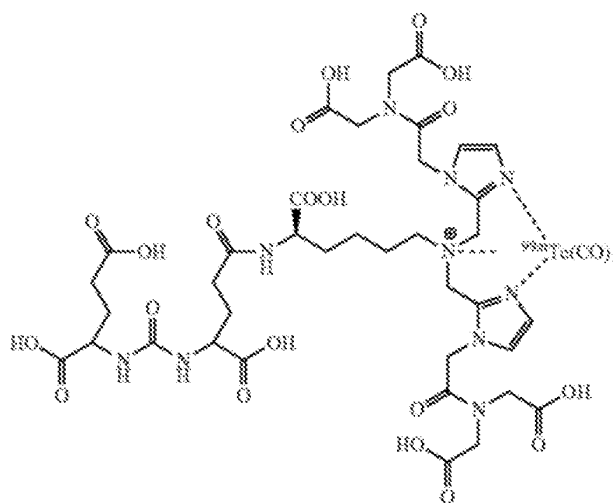


1428,

or a pharmaceutically acceptable salt thereof.

[00108] In certain embodiments, the PSMA binding agent is labelled with a radionuclide by chelating it to a radioisotope of a metal [e.g., a radioisotope of technetium (Tc) (e.g., technetium-99m (^{99m}Tc)); e.g., a radioisotope of rhenium (Re) (e.g., rhenium-188 (^{188}Re); e.g., rhenium-186 (^{186}Re)); e.g., a radioisotope of yttrium (Y) (e.g., ^{90}Y); e.g., a radioisotope of lutetium (Lu) (e.g., ^{177}Lu); e.g., a radioisotope of gallium (Ga) (e.g., ^{68}Ga ; e.g., ^{67}Ga); e.g., a radioisotope of indium (e.g., ^{111}In); e.g., a radioisotope of copper (Cu) (e.g., ^{67}Cu)].

[00109] In certain embodiments, 1404 is labelled with a radionuclide (e.g., chelated to a radioisotope of a metal). In certain embodiments, the radionuclide labelled PSMA binding agent comprises ^{99m}Tc -MIP-1404, which is 1404 labelled with (e.g., chelated to) ^{99m}Tc :

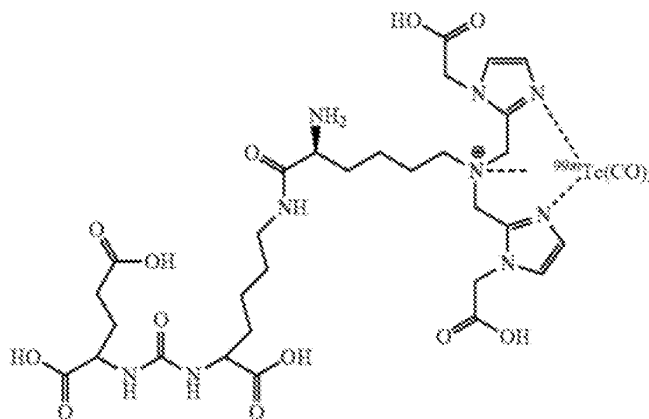


^{99m}Tc -MIP-1404,

or a pharmaceutically acceptable salt thereof. In certain embodiments, 1404 may be chelated to other metal radioisotopes [e.g., a radioisotope of rhenium (Re) (e.g., rhenium-188 (^{188}Re); e.g., rhenium-186 (^{186}Re)); e.g., a radioisotope of yttrium (Y) (e.g., ^{90}Y); e.g., a radioisotope of lutetium (Lu) (e.g., ^{177}Lu); e.g., a radioisotope of gallium (Ga) (e.g., ^{68}Ga ; e.g.,

⁶⁷Ga); e.g., a radioisotope of indium (e.g., ¹¹¹In); e.g., a radioisotope of copper (Cu) (e.g., ⁶⁷Cu)] to form a compound having a structure similar to the structure shown above for ^{99m}Tc-MIP-1404, with the other metal radioisotope substituted for ^{99m}Tc.

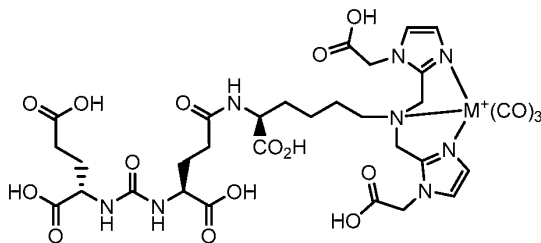
[00110] In certain embodiments, 1405 is labelled with a radionuclide (e.g., chelated to a radioisotope of a metal). In certain embodiments, the radionuclide labelled PSMA binding agent comprises ^{99m}Tc-MIP-1405, which is 1405 labelled with (e.g., chelated to) ^{99m}Tc:



^{99m}Tc-MIP-1405,

or a pharmaceutically acceptable salt thereof. In certain embodiments, 1405 may be chelated to other metal radioisotopes [e.g., a radioisotope of rhenium (Re) (e.g., rhenium-188 (¹⁸⁸Re); e.g., rhenium-186 (¹⁸⁶Re)); e.g., a radioisotope of yttrium (Y) (e.g., ⁹⁰Y); e.g., a radioisotope of lutetium (Lu)(e.g., ¹⁷⁷Lu); e.g., a radioisotope of gallium (Ga) (e.g., ⁶⁸Ga; e.g., ⁶⁷Ga); e.g., a radioisotope of indium (e.g., ¹¹¹In); e.g., a radioisotope of copper (Cu) (e.g., ⁶⁷Cu)] to form a compound having a structure similar to the structure shown above for ^{99m}Tc-MIP-1405, with the other metal radioisotope substituted for ^{99m}Tc.

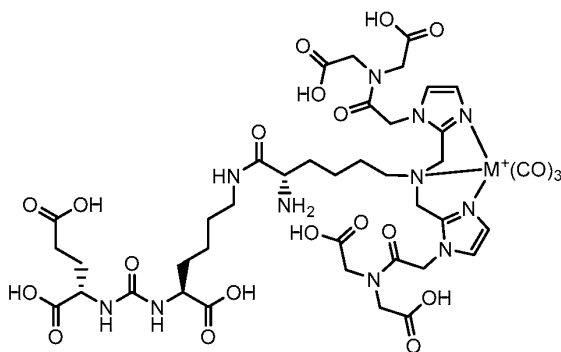
[00111] In certain embodiments, 1427 is labelled with (e.g., chelated to) a radioisotope of a metal, to form a compound according to the formula below:



1427 chelated to a metal,

[00112] or a pharmaceutically acceptable salt thereof, wherein M is a metal radioisotope [e.g., a radioisotope of technetium (Tc) (e.g., technetium-99m (^{99m}Tc)); e.g., a radioisotope of rhenium (Re) (e.g., rhenium-188 (^{188}Re); e.g., rhenium-186 (^{186}Re)); e.g., a radioisotope of yttrium (Y) (e.g., ^{90}Y); e.g., a radioisotope of lutetium (Lu) (e.g., ^{177}Lu); e.g., a radioisotope of gallium (Ga) (e.g., ^{68}Ga ; e.g., ^{67}Ga); e.g., a radioisotope of indium (e.g., ^{111}In); e.g., a radioisotope of copper (Cu) (e.g., ^{67}Cu)] with which 1427 is labelled.

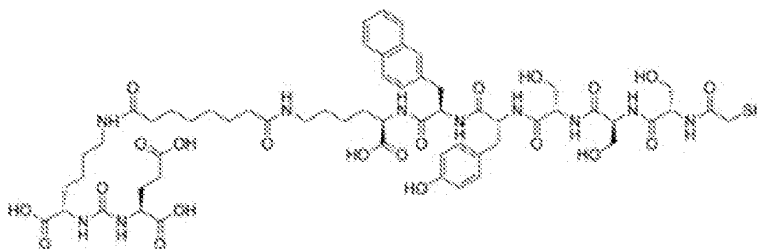
[00113] In certain embodiments, 1428 is labelled with (e.g., chelated to) a radioisotope of a metal, to form a compound according to the formula below:



1428 chelated to a metal,

[00114] or a pharmaceutically acceptable salt thereof, wherein M is a metal radioisotope [e.g., a radioisotope of technetium (Tc) (e.g., technetium-99m (^{99m}Tc)); e.g., a radioisotope of rhenium (Re) (e.g., rhenium-188 (^{188}Re); e.g., rhenium-186 (^{186}Re)); e.g., a radioisotope of yttrium (Y) (e.g., ^{90}Y); e.g., a radioisotope of lutetium (Lu) (e.g., ^{177}Lu); e.g., a radioisotope of gallium (Ga) (e.g., ^{68}Ga ; e.g., ^{67}Ga); e.g., a radioisotope of indium (e.g., ^{111}In); e.g., a radioisotope of copper (Cu) (e.g., ^{67}Cu)] with which 1428 is labelled.

[00115] In certain embodiments, the radionuclide labelled PSMA binding agent comprises PSMA I&S:



PSMA I&S,

[00116] or a pharmaceutically acceptable salt thereof. In certain embodiments, the radionuclide labelled PSMA binding agent comprises ^{99m}Tc -PSMA I&S, which is PSMA I&S labelled with ^{99m}Tc , or a pharmaceutically acceptable salt thereof.

A.iii Whole-Body Bone Scans

[00117] Turning to FIG. 1, BSI Cloud 130 refers to a cloud-based decision support system that implements BSI values. BSI refers to bone scan index, which is a value computed from a method for detecting skeletal lesions from whole-body scanning (and anterior and posterior

views) with a gamma camera following administration of the radionuclide technetium 99m methylenediphosphonate (^{99m}Tc MDP). Further explanation of BSI is provided, for example, in U.S. Patent No. 8,855,387, which is incorporated herein by reference in its entirety, as well as in U.S. Patent Application No. 15/282422, filed September 30, 2016, which is incorporated herein by reference in its entirety.

[00118] In particular, BSI is computed from whole-body scans by segmenting anterior and posterior views of the whole-body scan of the patient to geographically identify boundaries of regions within the views that correspond to various portions of the patient's skeleton. Segmentation of the patient's skeleton can be performed using a variety of approaches, such as the Active Shape Model-based approach and the atlas image registration approach (which registers the anterior and posterior views of a whole body scan with reference anterior and posterior views of a reference whole body scan that have already been segmented (referred to as an atlas image)) described in U.S. Patent No. 8,855,387. Other approaches, based on machine learning techniques (e.g., artificial neural networks (ANNs); e.g., convolutional neural networks (CNNs)) may also be used.

[00119] The BSI value is computed based on the intensity values of whole-body scan within the identified boundaries of the various skeletal regions. As discussed above, hotspots that correspond to localized regions of high intensity within the views (anterior and/or posterior views) of the whole-body scan can be detected. Hotspots may be detected and/or classified as corresponding to cancerous lesions (e.g., metastases) using a variety of approaches, including, as described in U.S. Patent No. 8,855,387, machine learning techniques such as ANNs.

[00120] Hotspots corresponding to cancerous tissue lesions within the patient's skeleton, once detected, can be used to determine a risk index that provides a measure of disease state for the

patient. For example, cancerous tissue levels within one or more regions, such as particular bones and/or the overall skeletal region, can be determined based on features of detected hotspots (e.g., detected hotspots classified as metastases). For example, a cancerous tissue level within a region (e.g., a particular bone; e.g., the overall skeletal region) may be determined based on (e.g., as a function of) a total number of detected hotspots within the region, a total volume of detected hotspots within the region, an average intensity of detected hotspots, a maximal intensity of detected hotspots, and the like, as well as combinations thereof. Properties of the one or more regions, such as their area or volume may also be used. For example, a total number and/or total volume of detected hotspots may be normalized (e.g., divided) by a volume and/or area of the region in which they are detected. A risk index may be determined based on the determined cancerous tissue levels within one or more regions, directly, e.g., as the cancerous tissue level within a single region, or determined from cancerous tissue levels in multiple regions (e.g., as an average; e.g., as a scaled sum; e.g., as a ratio; etc.), or even using machine learning approaches.

[00121] For example, the BSI value is a risk index that is a numeric value that quantifies the fraction of the total skeleton of the patient that is involved by cancerous tissue (e.g., tumors), based on the detected hotspots. The BSI value can be compared between different patients, and used as an objective measure of disease state and risk for a particular patient. Notably, since BSI is computed in an automated fashion, variability due to human factors such as radiologist interpretation of images is avoided.

[00122] Moreover, a variety of actionable information can be obtained from a patient's BSI value. For example, BSI can be correlated with prognostic values that provide a measure of disease state, progression, life expectancy (e.g., overall survival), treatment efficacy, and the like

for the patient. Accordingly, a patient's BSI value can be used and tracked over time (e.g., over the course of multiple visits to one or more doctors) to provide them or their physician with an objective metric of what state their cancer is in, how fast it is progressing, what their outlook is, and whether one or more particular treatments are proving effective.

A.iv Positron Emission Tomography (PET) Scans

[00123] PyL Cloud 120 refers to a cloud-based system that uses medical images obtained with the agent PyLTM, which is DCFPyL labeled with ¹⁸F ([¹⁸F]DCFPyL). The patient, after injection of the imaging agent, receives a positron emission tomography (PET) scan to identify hot spots, and a CT scan. Further information about the PyLTM imaging agent is provided above, and, for example, in U.S. Patent No. 8,778,305, which is incorporated herein by reference in its entirety.

[00124] In certain embodiments, the PET scan and the CT scan are combined as a composite image comprising the CT scan overlaid with the PET scan. As used herein, overlaying one image (e.g., a CT scan) with another (e.g., a PET scan) refers to establishing a mapping between coordinates and/or pixels or voxels of the two images that represent the same physical locations (e.g., within the patient). CT scans provide accurate anatomical information in the form of detailed three-dimensional (3D) images of internal organs, bones, soft tissue, and blood vessels. Accordingly, 3D boundaries of specific regions of imaged tissue can be accurately identified by analysis of CT scans. For example, automated segmentation of CT scans can be performed to identify 3D boundaries of specific organs (e.g., a prostate, lymph nodes, a lung or lungs), sub-organs, organ regions, as well as other regions of imaged tissue, such as particular bones and an overall skeletal region of the patient. Automated segmentation of CT scans can be

accomplished via a variety of approaches, include machine learning techniques [e.g., ANN-based approaches (including, e.g., convolutional neural networks (CNNs))], atlas image registration, and combinations thereof. In certain embodiments, manual segmentation of CT images can also be utilized, alone or in combination with automated segmentation approaches (e.g., to refine 3D boundaries identified via automated segmentation; e.g., to provide an initial starting point for an automated segmentation approach).

[00125] Once the 3D boundaries of various regions are identified within a CT scan of a composite image, by virtue of the mapping between the CT scan and PET scan of the composite image, the identified 3D boundaries can be transferred to the PET image. Accordingly, regions of the PET image falling within and/or outside of the identified 3D boundaries can be accurately identified.

[00126] In certain embodiments, composite images comprising CT scans overlaid with PET scans are obtained using dedicated PET-CT scanner instruments common in many hospitals, and are uploaded as medical images to the cloud-based platform described herein. In certain embodiments, a PET scan and a corresponding CT scan are obtained separately (but at substantially the same time), and uploaded to the cloud-based platform described herein. In such cases, the separately obtained PET and CT scans can be automatically fused to create a composite image.

[00127] In certain embodiments, once the 3D boundaries of the various regions are identified within the PET scan, one or more risk indices can be computed in a similar fashion to that described above with regard to BSI. In particular, in certain embodiments, intensity values of the PET scan in relation to (e.g., within and/or outside of) the 3D boundaries of the identified regions can be used to determine levels of cancerous tissue within the identified regions, e.g.,

based on features of detected hotspots (e.g., detected hotspots corresponding to metastases). Risk indices can then be computed based on the determined cancerous tissue levels. For example, hotspots within the PET scan can be identified, and, based on features such as their size, number, and distribution with respect to the identified regions, used to compute one or more risk indices. As with BSI, risk indices determined from PET scans can be correlated with prognostic values and tracked over time (e.g., over the course of multiple visits to one or more doctors) to provide patients or their physician with an objective metric of what state their cancer is in, how fast it is progressing, what their outlook is, and whether one or more particular treatments are proving effective. The approaches described herein with regard to PET imaging using PyL™ as a radiopharmaceutical can be applied to a variety of other radiopharmaceuticals, such as those described above, including, without limitation NaF, radioisotopes of choline, and any of the PSMA binding agents described in section A.i above.

A.v Single-Photon Emission Computerized Tomography (SPECT) Scans

[00128] 1404 Cloud 130 refers to a cloud-based system that uses medical images obtained with the agent ^{99m}Tc-MIP-1404, which, as described above, is 1404 labeled with Tc^{99m}. After injection of the imaging agent, the patient receives a single-photon emission computerized tomography (SPECT) scan, e.g., to identify hot spots, and a computed tomography (CT) scan, e.g., to identify anatomical features. These images are overlaid to make a composite image (SPECT/CT). Further information about ^{99m}Tc-MIP-1404 imaging agent is provided above, and, for example, in U.S. Patent Nos. 8,211,401 and 8,962,799, both of which are incorporated herein by reference in their entireties.

[00129] SPECT and CT scans can be analyzed in a manner similar to that described above with respect to PET and CT scans, in order to determine one or more risk indices. In particular, as with PET and CT scans, the SPECT scan and the CT scan can be combined in a composite image in which the CT scan is overlaid with the SPECT scan – a composite SPECT-CT image. As with composite PET-CT images, composite SPECT-CT images may be directly received as medical images by the cloud-based platform described herein (e.g., having been obtained via dedicated SPECT-CT imager in a hospital), or may be created by the cloud-based platform following receipt of separate SPECT scans and CT scans.

[00130] Similar to PET-CT images, 3D boundaries of various regions of imaged tissue can be identified within the SPECT image by virtue of the overlay with the CT image of the composite image. Intensity variations within the SPECT image, in relation to the 3D boundaries can be used to compute one or more risk indices. As with the approaches for computing risk indices from composite PET-CT images, this may comprise determine levels of cancerous tissue within the identified regions, for example by detecting hotspots within the 3D boundaries of the identified regions. Such risk indices can be correlated with prognostic values and tracked over time (e.g., over the course of multiple visits to one or more doctors) to provide patients or their physician with an objective metric of what state their cancer is in, how fast it is progressing, what their outlook is, and whether one or more particular treatments are proving effective. The approaches described herein with regard to SPECT imaging using ^{99m}Tc-MIP-1404 as a radiopharmaceutical can be applied to a variety of other radiopharmaceuticals, such as those described above, including, without limitation, any of the PSMA binding agents described in section A.ii above

B. Platform Services and Computing Device Components

[00131] FIG. 2 is a schematic 200 showing the relationship between a platform and a computing device (e.g., personal computer or mobile computing device, e.g., smart phone) running an application, according to illustrative embodiments of the invention. The platform performs various services, for example, user authentication (“Auth”), image and other data storage (“SliceBox), and the like – many more services than those shown may be provided. The applications may have both a platform component and a device component (e.g., native app on the client device).

[00132] FIG. 9 shows an example architecture 900 for implementing the cloud-based platform described herein, and providing various services such as the BSI Cloud, PyL Cloud, and 1404 Cloud services described above. The architecture shown in FIG. 9 can be used to implement the platform described herein on a variety of datacenters, including publicly available datacenters. The datacenter provides infrastructure in the form of servers and networks and provides services for e.g. networking, messaging, authentication, logging and storage. The architecture 900 for the platform uses a series of functional units with limited scope referred to as microservices. Each microservice handles an isolated set of tasks such as image storage, calculation of a risk index, identification of medical image type, and other tasks. Services (e.g., microservices) can communicate with each other using standard protocols such as Hypertext Transfer Protocol (HTTP). Organizing the platform into a network of microservices, as shown in the architecture 900 of FIG. 9, allows for parts of the platform to be scaled individually to meet high demand and to ensure minimal downtime.

[00133] In certain embodiments, such an architecture allows for components to be improved or replaced without affecting other parts of the platform. The example architecture 900 shown

in FIG. 9 includes a set 920 of microservices that are common to two or more applications in the platform. The left 910 and right 930 panels show microservices in two applications. The microservice network shown in the left panel 910 implements a version of the BSI Cloud service, as described above, and provides for calculation of an automated BSI index (aBSI), which is a risk index derived from automated analysis of whole-body scans obtained with a gamma camera. The microservice network shown in the right panel 930 implements a version of the 1404 Cloud service, as described above, and provides for automated calculation of a SPECT index, which is a risk index derived from automated analysis of composite SPECT-CT images.

C. Image Collection, Analysis, and Result Presentation

[00134] FIG. 3 is a GUI window 300 in the BSI Cloud application (displayed to a user) that allows a user to enter information about a patient and upload and/or access medical images for the patient, e.g., series of images obtained over a period of time.

[00135] FIG. 4 is a GUI window 400 in the BSI Cloud application showing representative full body gamma camera images showing hotspots automatically identified by the system, with corresponding overall computed BSI values for a particular image set obtained at a given time. A graph 410 at left shows how the BSI value has changed over time (increase) for this particular patient.

[00136] FIG. 5 is a GUI window in the BSI Cloud application showing an automatically or semi-automatically generated radiologist report 510, which can be signed and dated by a radiologist. In certain embodiments, the automatically identified hotspots may be adjusted by the radiologist (or other medical practitioner attending to the patient), with the change(s) reflected in the report. For example, an identified hotspot may be deactivated by the radiologist,

or a new hotspot may be activated by the radiologist, such changes possibly affecting the computed BSI value, displayed in the report.

[00137] FIG. 6 is a block flow diagram of an illustrative network-based (e.g., cloud based) decision support system, according to an illustrative embodiment of the invention. FIG. 6 shows various functions that may be performed by the cloud based services described herein. These include: (i) receiving and storing sets of medical images in a database; (ii) accessing one or more of the medical images for transmission to the user for display on a user computing device; (iii) automatically analyzing, by the processor, the medical images to compute a risk index (e.g., BSI) and/or to generate a risk map; (iv) generating a radiologist report for a patient according to the patient images and/or risk index/ risk map; and applying a machine learning algorithm to update a process for the automatic analysis of function (iii).

[00138] FIG. 10 is a schematic showing clinical stages 1010 of prostate cancer progression, along with various therapies 1020 and diagnostic imaging modalities 1030 appropriate for various disease states. As shown in the schematic, depending on the clinical state of a patient's prostate cancer, different imaging modalities and/or different radiopharmaceuticals may be appropriate. Similarly, different risk indices computed based on different imaging modalities and/or different radiopharmaceuticals may most appropriate, depending on the state of the patient's prostate cancer.

[00139] For example, in certain embodiments, when a patient either has, or is suspected of having prostate cancer in a localized state, composite SPECT-CT imaging may be used. SPECT scans of composite SPECT-CT images used for evaluation of localized prostate cancer can be obtained following administration of a particular radiopharmaceutical, such as ^{99m}Tc-MIP-1404, that facilitates imaging of localized prostate cancer. Any of the SPECT-CT images themselves,

derivatives thereof, and risk indices computed from the SPECT-CT images can be used, accordingly, to assess risk, disease state, progression, treatment efficacy and the like for localized prostate cancer.

[00140] In certain embodiments, when a patient has or is suspected of having metastatic prostate cancer, that has metastasized outside of the prostate, other imaging techniques may be used. For example, whole-body scans obtained following administration of ^{99m}Tc-MDP can be used to assess tumor burden in a patient's skeleton. As discussed above, BSI values computed from whole-body scans can be used to assess risk, disease state, progression, treatment efficacy and the like when a patient's prostate cancer has metastasized to their skeleton. In certain embodiments, certain imaging modalities and/or radiopharmaceuticals can be used for evaluate of prostate cancer in both localized and metastatic states. For example, as illustrated in FIG. 10, PET-CT imaging can be used for evaluating prostate cancer in both localized and metastatic states. As shown in the figure, such PET-CT images may be obtained using an appropriate radiopharmaceutical, such as PyLTM, that facilitates imaging of both localized and metastatic prostate cancer.

[00141] In certain embodiments, the cloud-based platform facilitates evaluating prostate cancer progression and treatment efficacy over time. For example, as shown in the example process 1100 of the block flow diagram of FIG. 11, in certain embodiments medical images of a particular patient are repeatedly received and stored over time 1110, over the course of multiple visits to one or more doctors and/or clinical specialists (e.g., radiologists) by the patient. In this manner, a series of medical images for the patient are obtained. The series of medical images can be automatically analyzed to determine values of one or more risk indices, so as to track changes in the determined values over time 1120. The determined risk index values may be

stored 1130a (e.g., for further processing). In certain embodiments, the process causes a graphical representation of the determined risk index values, such as a graph, to be displayed (e.g., on a user computing device; e.g., via a web-based portal) 1130b.

[00142] Notably, by virtue of the capability of the cloud-based platform described herein to receive, store, and analyze a variety of different medical image types, such as composite SPECT-CT images, whole-body scans, and composite PET-CT images, the medical images need not be of the same type.

[00143] For example, a first subseries of medical images may be obtained using a first imaging modality and a first radiopharmaceutical, such as SPECT-CT imaging with ^{99m}Tc -MIP-1404, when the patient's prostate cancer is in a localized state. If the patient's prostate cancer progresses to a metastatic state, a second subseries of images may comprise images obtained via a different, second imaging modality and/or a different, second radiopharmaceutical. For example, the second subseries of medical images may be PET-CT images obtained using PyL^{TM} . For example, the second subseries of medical images may be whole-body scans obtained using ^{99m}Tc -MDP.

[00144] Risk indices can be computed for the first image subseries and for the second image subseries to provide a unified picture of the patient's prostate cancer progression and treatment over time. This approach can be performed for multiple patients, not only for decision making purposes with regard to each patient's disease progression and particular course of treatment, but also in the context of clinical trials, for example to compare efficacy of a particular treatment with others or a control.

D. Computer System and Network Environment

[00145] FIG. 7 shows an illustrative network environment 700 for use in the methods and systems described herein. In brief overview, referring now to FIG. 7, a block diagram of an exemplary cloud computing environment 700 is shown and described. The cloud computing environment 700 may include one or more resource providers 702a, 702b, 702c (collectively, 702). Each resource provider 702 may include computing resources. In some implementations, computing resources may include any hardware and/or software used to process data. For example, computing resources may include hardware and/or software capable of executing algorithms, computer programs, and/or computer applications. In some implementations, exemplary computing resources may include application servers and/or databases with storage and retrieval capabilities. Each resource provider 702 may be connected to any other resource provider 702 in the cloud computing environment 700. In some implementations, the resource providers 702 may be connected over a computer network 708. Each resource provider 702 may be connected to one or more computing device 704a, 704b, 704c (collectively, 704), over the computer network 708.

[00146] The cloud computing environment 700 may include a resource manager 706. The resource manager 706 may be connected to the resource providers 702 and the computing devices 704 over the computer network 708. In some implementations, the resource manager 706 may facilitate the provision of computing resources by one or more resource providers 702 to one or more computing devices 704. The resource manager 706 may receive a request for a computing resource from a particular computing device 704. The resource manager 706 may identify one or more resource providers 702 capable of providing the computing resource requested by the computing device 704. The resource manager 706 may select a resource

provider 702 to provide the computing resource. The resource manager 706 may facilitate a connection between the resource provider 702 and a particular computing device 704. In some implementations, the resource manager 706 may establish a connection between a particular resource provider 702 and a particular computing device 704. In some implementations, the resource manager 706 may redirect a particular computing device 704 to a particular resource provider 702 with the requested computing resource.

[00147] FIG. 8 shows an example of a computing device 800 and a mobile computing device 850 that can be used in the methods and systems described in this disclosure. The computing device 800 is intended to represent various forms of digital computers, such as laptops, desktops, workstations, personal digital assistants, servers, blade servers, mainframes, and other appropriate computers. The mobile computing device 850 is intended to represent various forms of mobile devices, such as personal digital assistants, cellular telephones, smart-phones, and other similar computing devices. The components shown here, their connections and relationships, and their functions, are meant to be examples only, and are not meant to be limiting.

[00148] The computing device 800 includes a processor 802, a memory 804, a storage device 806, a high-speed interface 808 connecting to the memory 804 and multiple high-speed expansion ports 810, and a low-speed interface 812 connecting to a low-speed expansion port 814 and the storage device 806. Each of the processor 802, the memory 804, the storage device 806, the high-speed interface 808, the high-speed expansion ports 810, and the low-speed interface 812, are interconnected using various busses, and may be mounted on a common motherboard or in other manners as appropriate. The processor 802 can process instructions for execution within the computing device 800, including instructions stored in the memory 804 or

on the storage device 806 to display graphical information for a GUI on an external input/output device, such as a display 816 coupled to the high-speed interface 808. In other implementations, multiple processors and/or multiple buses may be used, as appropriate, along with multiple memories and types of memory. Also, multiple computing devices may be connected, with each device providing portions of the necessary operations (e.g., as a server bank, a group of blade servers, or a multi-processor system). Thus, as the term is used herein, where a plurality of functions are described as being performed by “a processor”, this encompasses embodiments wherein the plurality of functions are performed by any number of processors (one or more) of any number of computing devices (one or more). Furthermore, where a function is described as being performed by “a processor”, this encompasses embodiments wherein the function is performed by any number of processors (one or more) of any number of computing devices (one or more) (e.g., in a distributed computing system).

[00149] The memory 804 stores information within the computing device 800. In some implementations, the memory 804 is a volatile memory unit or units. In some implementations, the memory 804 is a non-volatile memory unit or units. The memory 804 may also be another form of computer-readable medium, such as a magnetic or optical disk.

[00150] The storage device 806 is capable of providing mass storage for the computing device 800. In some implementations, the storage device 806 may be or contain a computer-readable medium, such as a floppy disk device, a hard disk device, an optical disk device, or a tape device, a flash memory or other similar solid state memory device, or an array of devices, including devices in a storage area network or other configurations. Instructions can be stored in an information carrier. The instructions, when executed by one or more processing devices (for example, processor 802), perform one or more methods, such as those described above. The

instructions can also be stored by one or more storage devices such as computer- or machine-readable mediums (for example, the memory 804, the storage device 806, or memory on the processor 802).

[00151] The high-speed interface 808 manages bandwidth-intensive operations for the computing device 800, while the low-speed interface 812 manages lower bandwidth-intensive operations. Such allocation of functions is an example only. In some implementations, the high-speed interface 808 is coupled to the memory 804, the display 816 (e.g., through a graphics processor or accelerator), and to the high-speed expansion ports 810, which may accept various expansion cards (not shown). In the implementation, the low-speed interface 812 is coupled to the storage device 806 and the low-speed expansion port 814. The low-speed expansion port 814, which may include various communication ports (e.g., USB, Bluetooth®, Ethernet, wireless Ethernet) may be coupled to one or more input/output devices, such as a keyboard, a pointing device, a scanner, or a networking device such as a switch or router, e.g., through a network adapter.

[00152] The computing device 800 may be implemented in a number of different forms, as shown in the figure. For example, it may be implemented as a standard server 820, or multiple times in a group of such servers. In addition, it may be implemented in a personal computer such as a laptop computer 822. It may also be implemented as part of a rack server system 824. Alternatively, components from the computing device 800 may be combined with other components in a mobile device (not shown), such as a mobile computing device 850. Each of such devices may contain one or more of the computing device 800 and the mobile computing device 850, and an entire system may be made up of multiple computing devices communicating with each other.

[00153] The mobile computing device 850 includes a processor 852, a memory 864, an input/output device such as a display 854, a communication interface 866, and a transceiver 868, among other components. The mobile computing device 850 may also be provided with a storage device, such as a micro-drive or other device, to provide additional storage. Each of the processor 852, the memory 864, the display 854, the communication interface 866, and the transceiver 868, are interconnected using various buses, and several of the components may be mounted on a common motherboard or in other manners as appropriate.

[00154] The processor 852 can execute instructions within the mobile computing device 850, including instructions stored in the memory 864. The processor 852 may be implemented as a chipset of chips that include separate and multiple analog and digital processors. The processor 852 may provide, for example, for coordination of the other components of the mobile computing device 850, such as control of user interfaces, applications run by the mobile computing device 850, and wireless communication by the mobile computing device 850.

[00155] The processor 852 may communicate with a user through a control interface 858 and a display interface 856 coupled to the display 854. The display 854 may be, for example, a TFT (Thin-Film-Transistor Liquid Crystal Display) display or an OLED (Organic Light Emitting Diode) display, or other appropriate display technology. The display interface 856 may comprise appropriate circuitry for driving the display 854 to present graphical and other information to a user. The control interface 858 may receive commands from a user and convert them for submission to the processor 852. In addition, an external interface 862 may provide communication with the processor 852, so as to enable near area communication of the mobile computing device 850 with other devices. The external interface 862 may provide, for example,

for wired communication in some implementations, or for wireless communication in other implementations, and multiple interfaces may also be used.

[00156] The memory 864 stores information within the mobile computing device 850. The memory 864 can be implemented as one or more of a computer-readable medium or media, a volatile memory unit or units, or a non-volatile memory unit or units. An expansion memory 874 may also be provided and connected to the mobile computing device 850 through an expansion interface 872, which may include, for example, a SIMM (Single In Line Memory Module) card interface. The expansion memory 874 may provide extra storage space for the mobile computing device 850, or may also store applications or other information for the mobile computing device 850. Specifically, the expansion memory 874 may include instructions to carry out or supplement the processes described above, and may include secure information also. Thus, for example, the expansion memory 874 may be provided as a security module for the mobile computing device 850, and may be programmed with instructions that permit secure use of the mobile computing device 850. In addition, secure applications may be provided via the SIMM cards, along with additional information, such as placing identifying information on the SIMM card in a non-hackable manner.

[00157] The memory may include, for example, flash memory and/or NVRAM memory (non-volatile random access memory), as discussed below. In some implementations, instructions are stored in an information carrier and, when executed by one or more processing devices (for example, processor 852), perform one or more methods, such as those described above. The instructions can also be stored by one or more storage devices, such as one or more computer- or machine-readable mediums (for example, the memory 864, the expansion memory 874, or

memory on the processor 852). In some implementations, the instructions can be received in a propagated signal, for example, over the transceiver 868 or the external interface 862.

[00158] The mobile computing device 850 may communicate wirelessly through the communication interface 866, which may include digital signal processing circuitry where necessary. The communication interface 866 may provide for communications under various modes or protocols, such as GSM voice calls (Global System for Mobile communications), SMS (Short Message Service), EMS (Enhanced Messaging Service), or MMS messaging (Multimedia Messaging Service), CDMA (code division multiple access), TDMA (time division multiple access), PDC (Personal Digital Cellular), WCDMA (Wideband Code Division Multiple Access), CDMA2000, or GPRS (General Packet Radio Service), among others. Such communication may occur, for example, through the transceiver 868 using a radio-frequency. In addition, short-range communication may occur, such as using a Bluetooth®, Wi-Fi™, or other such transceiver (not shown). In addition, a GPS (Global Positioning System) receiver module 870 may provide additional navigation- and location-related wireless data to the mobile computing device 850, which may be used as appropriate by applications running on the mobile computing device 850.

[00159] The mobile computing device 850 may also communicate audibly using an audio codec 860, which may receive spoken information from a user and convert it to usable digital information. The audio codec 860 may likewise generate audible sound for a user, such as through a speaker, e.g., in a handset of the mobile computing device 850. Such sound may include sound from voice telephone calls, may include recorded sound (e.g., voice messages, music files, etc.) and may also include sound generated by applications operating on the mobile computing device 850.

[00160] The mobile computing device 850 may be implemented in a number of different forms, as shown in the figure. For example, it may be implemented as a cellular telephone 880. It may also be implemented as part of a smart-phone 882, personal digital assistant, or other similar mobile device.

[00161] Various implementations of the systems and techniques described here can be realized in digital electronic circuitry, integrated circuitry, specially designed ASICs (application specific integrated circuits), computer hardware, firmware, software, and/or combinations thereof. These various implementations can include implementation in one or more computer programs that are executable and/or interpretable on a programmable system including at least one programmable processor, which may be special or general purpose, coupled to receive data and instructions from, and to transmit data and instructions to, a storage system, at least one input device, and at least one output device.

[00162] These computer programs (also known as programs, software, software applications or code) include machine instructions for a programmable processor, and can be implemented in a high-level procedural and/or object-oriented programming language, and/or in assembly/machine language. As used herein, the terms machine-readable medium and computer-readable medium refer to any computer program product, apparatus and/or device (e.g., magnetic discs, optical disks, memory, Programmable Logic Devices (PLDs)) used to provide machine instructions and/or data to a programmable processor, including a machine-readable medium that receives machine instructions as a machine-readable signal. The term machine-readable signal refers to any signal used to provide machine instructions and/or data to a programmable processor.

[00163] To provide for interaction with a user, the systems and techniques described here can be implemented on a computer having a display device (e.g., a CRT (cathode ray tube) or LCD (liquid crystal display) monitor) for displaying information to the user and a keyboard and a pointing device (e.g., a mouse or a trackball) by which the user can provide input to the computer. Other kinds of devices can be used to provide for interaction with a user as well; for example, feedback provided to the user can be any form of sensory feedback (e.g., visual feedback, auditory feedback, or tactile feedback); and input from the user can be received in any form, including acoustic, speech, or tactile input.

[00164] The systems and techniques described here can be implemented in a computing system that includes a back end component (e.g., as a data server), or that includes a middleware component (e.g., an application server), or that includes a front end component (e.g., a client computer having a graphical user interface or a Web browser through which a user can interact with an implementation of the systems and techniques described here), or any combination of such back end, middleware, or front end components. The components of the system can be interconnected by any form or medium of digital data communication (e.g., a communication network). Examples of communication networks include a local area network (LAN), a wide area network (WAN), and the Internet.

[00165] The computing system can include clients and servers. A client and server are generally remote from each other and typically interact through a communication network. The relationship of client and server arises by virtue of computer programs running on the respective computers and having a client-server relationship to each other. In some implementations, the modules and/or services (e.g. cloud based services, such as BSI Cloud 110, PyL Cloud 120, 1404 Cloud 130; e.g., any of the microservices described herein) described herein can be separated,

combined or incorporated into single or combined modules and/or services. The modules and/or services depicted in the figures are not intended to limit the systems described herein to the software architectures shown therein

[00166] While the invention has been particularly shown and described with reference to specific preferred embodiments, it should be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

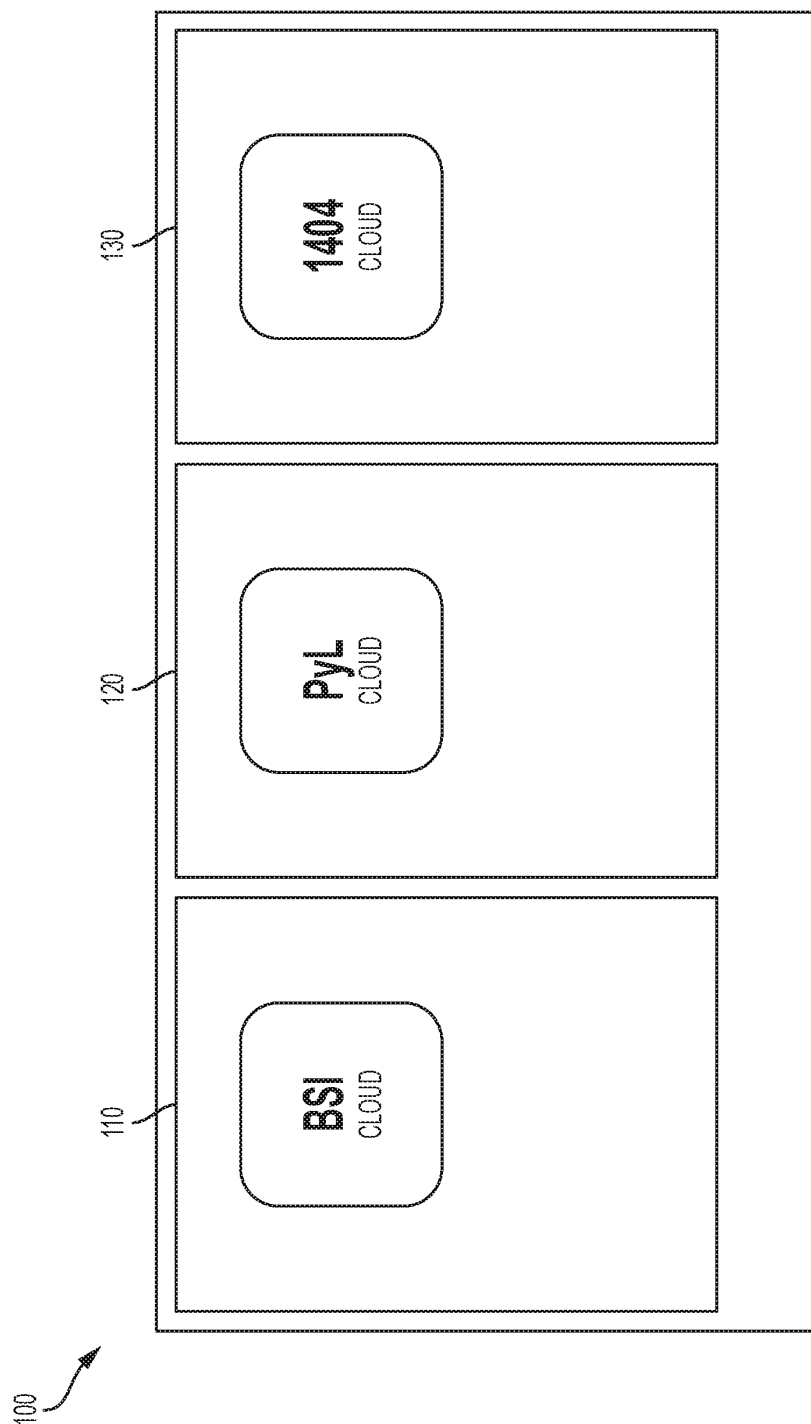


FIG. 1

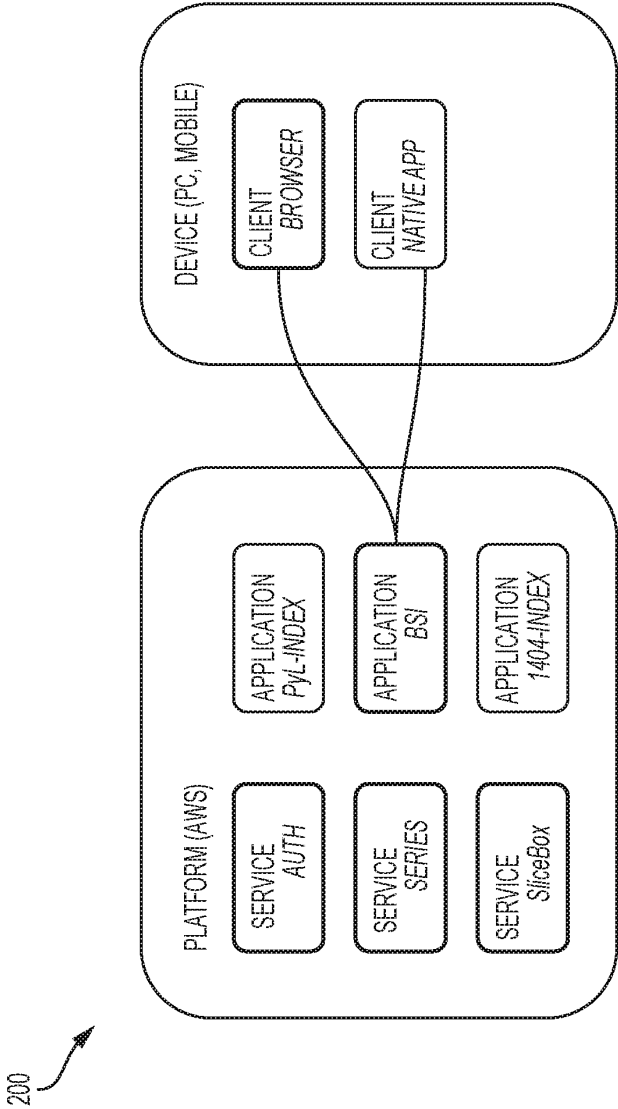


FIG. 2

300

BSI

PATIENTS

SEND INVITATION

SETTINGS

HELP

LOG OUT ANDREAS JÄRUND

Refresh patient list

PATIENT NAME

PATIENT ID

STUDY DATE

Test environment. Do not upload identifiable patient data

John Doe Three Studies

2010-01-19

START PATIENT

SHARE ALL STUDIES WITH

DELETE PATIENT

Name: John Doe Three Studies

Date of birth:

ID: John Doe Three Studies

STUDIES	INFO	SHARE	REPORT
2009-04-09	1	<	
2009-08-24	1	<	
2010-01-19	1	<	

FIG. 3

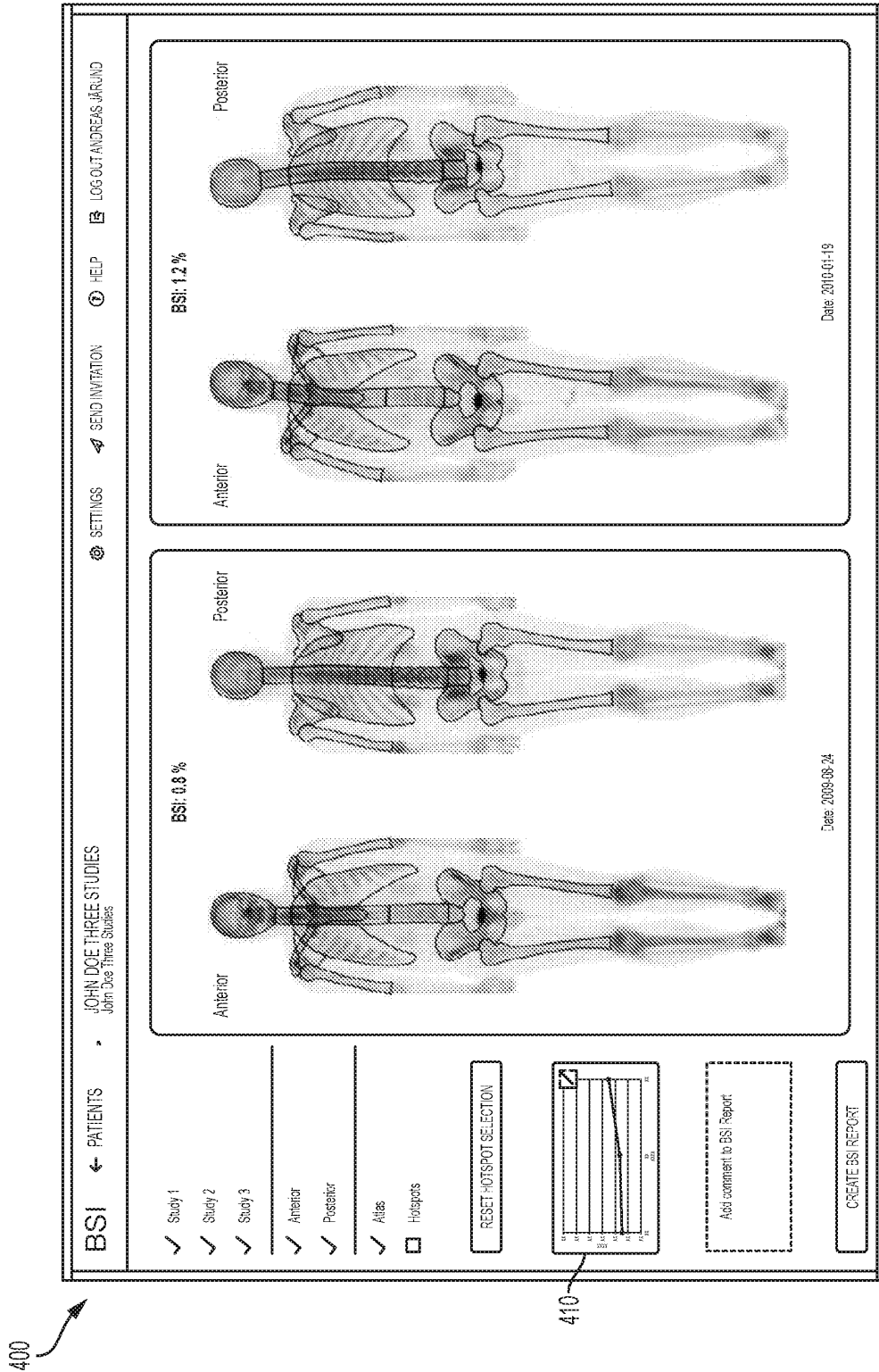


FIG. 4

400

(I) RECEIVING AND STORING SETS OF MEDICAL IMAGES IN A DATABASE

(II) ACCESSING ONE OR MORE OF THE MEDICAL IMAGES FOR TRANSMISSION TO THE USER FOR DISPLAY ON A USER COMPUTING DEVICE

(III) AUTOMATICALLY ANALYZING, BY THE PROCESSOR, THE MEDICAL IMAGES TO COMPUTE A RISK INDEX (E.G., BSI) AND/OR TO GENERATE A RISK MAP

(IV) GENERATING A RADIOLOGIST REPORT FOR A PATIENT ACCORDING TO THE PATIENT IMAGES AND/OR RISK INDEX/RISK MAP

(V) APPLYING A MACHINE LEARNING ALGORITHM TO UPDATE A PROCESS FOR THE AUTOMATIC ANALYSIS OF FUNCTION (III)

FIG. 6

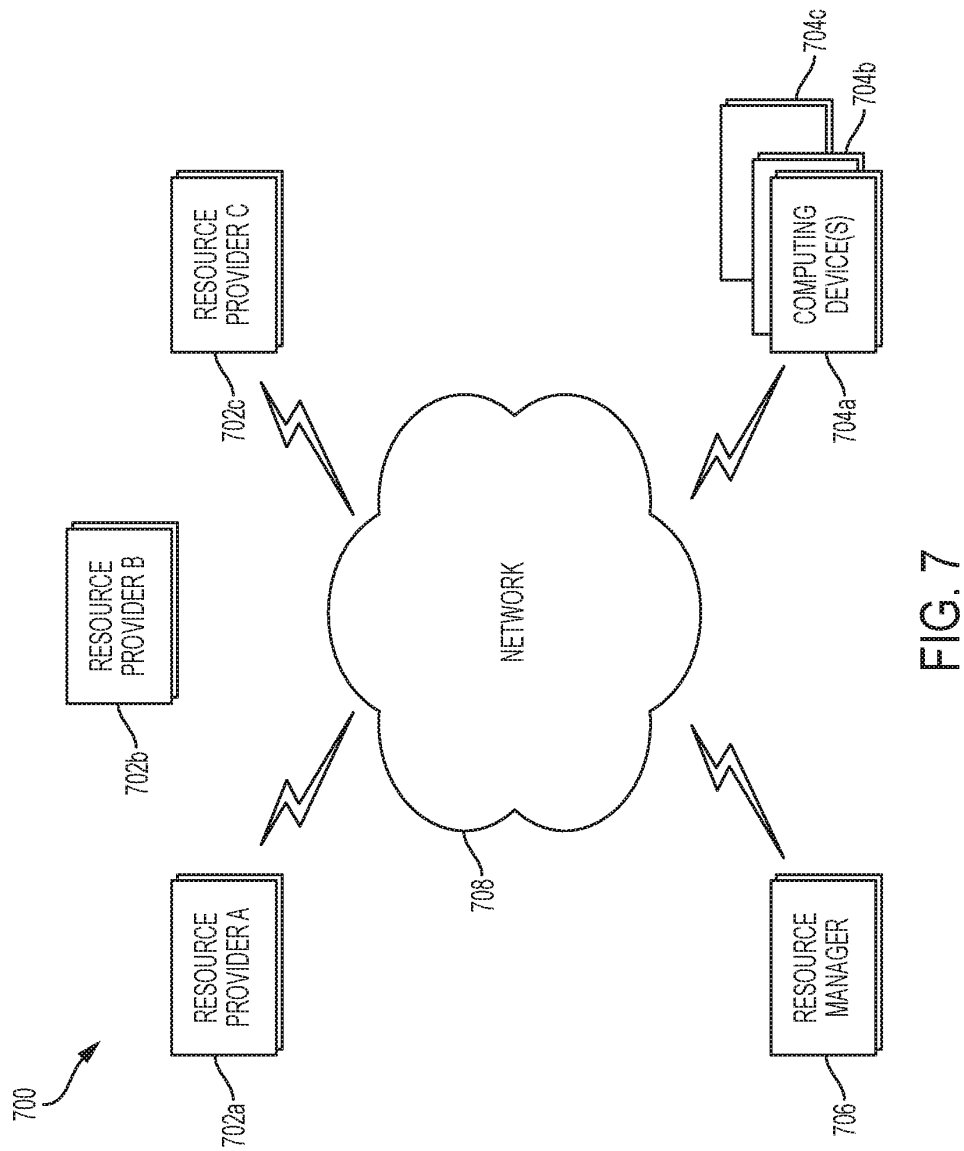


FIG. 7

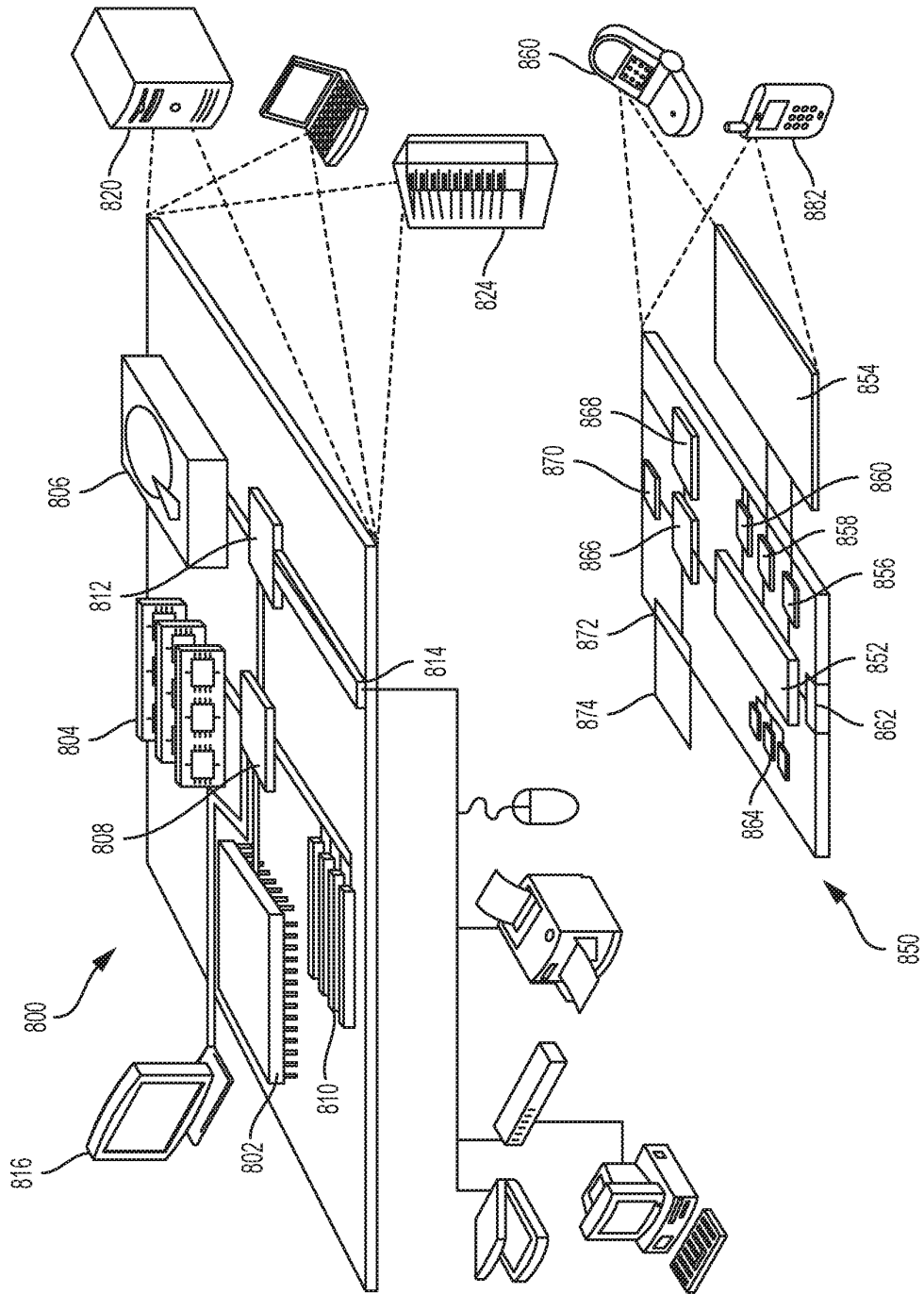


FIG. 8

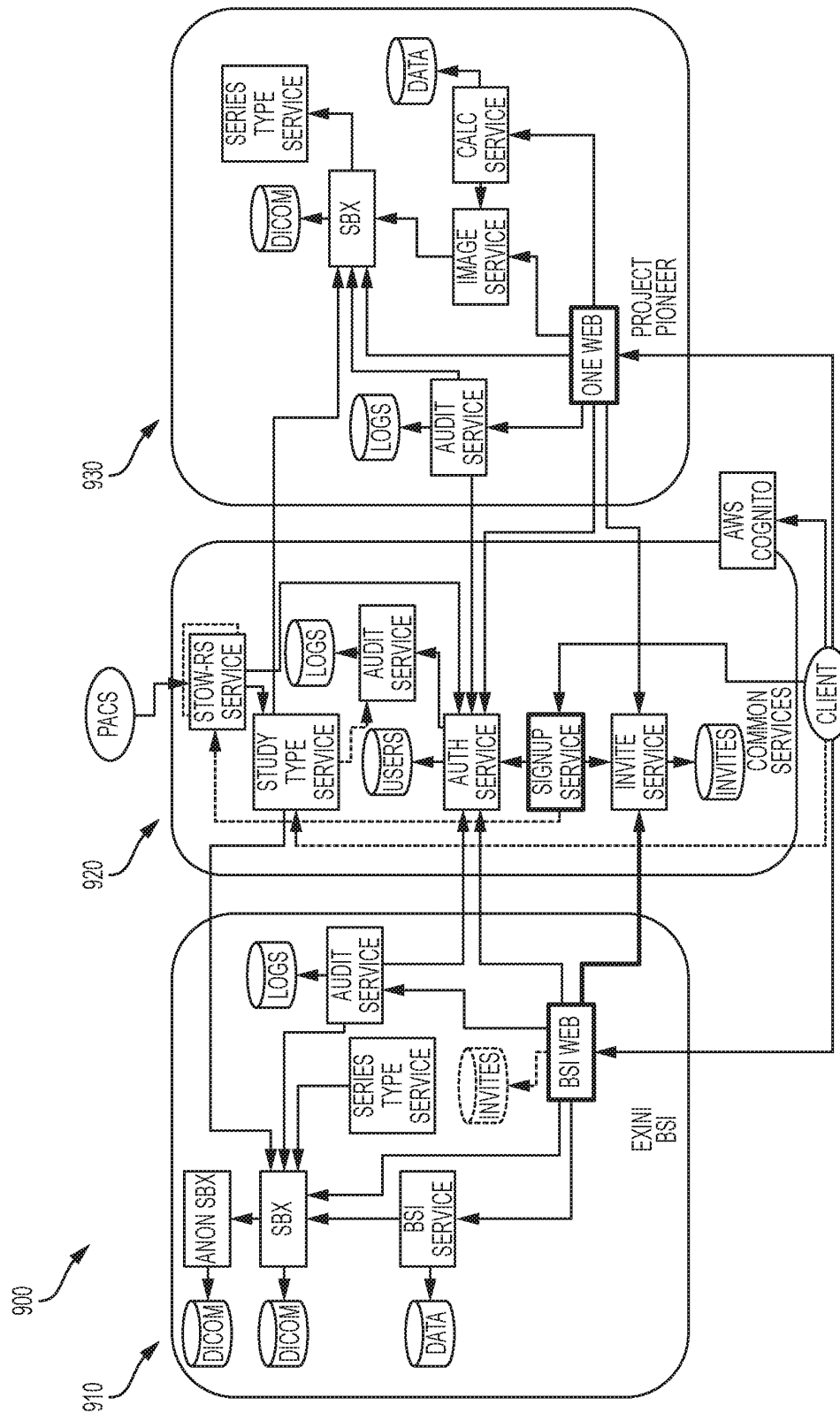


FIG. 9

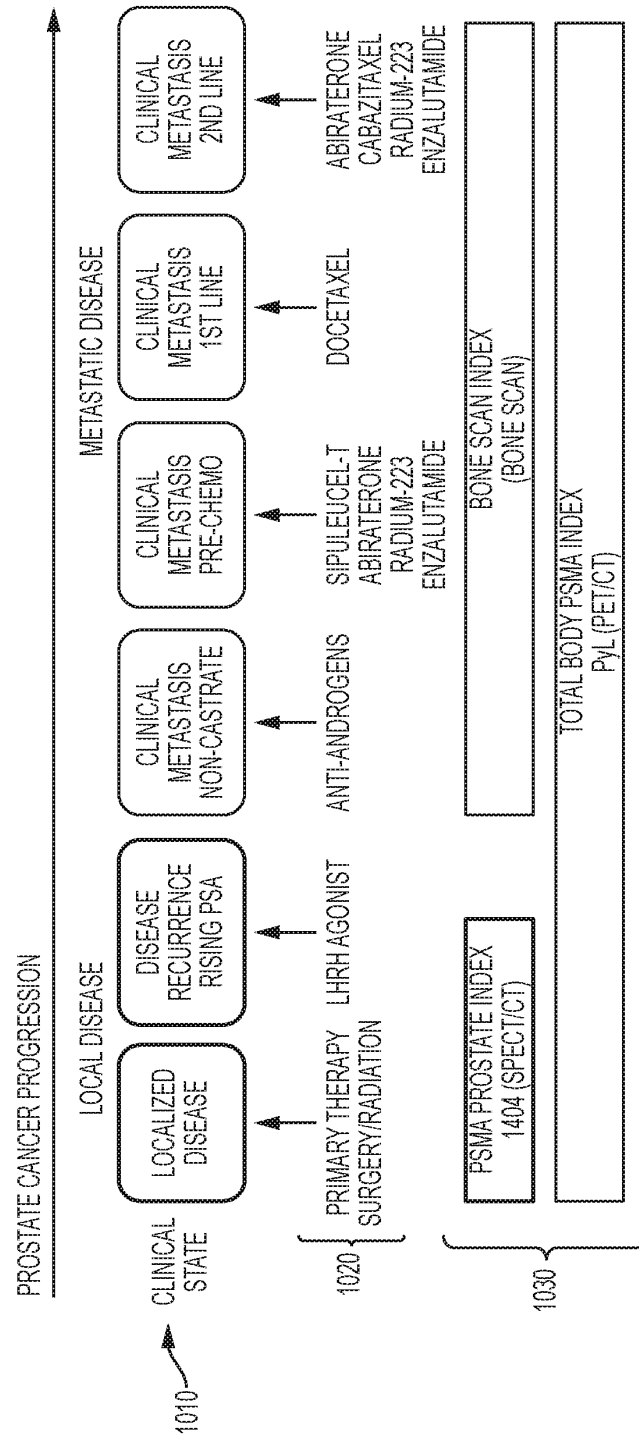


FIG. 10

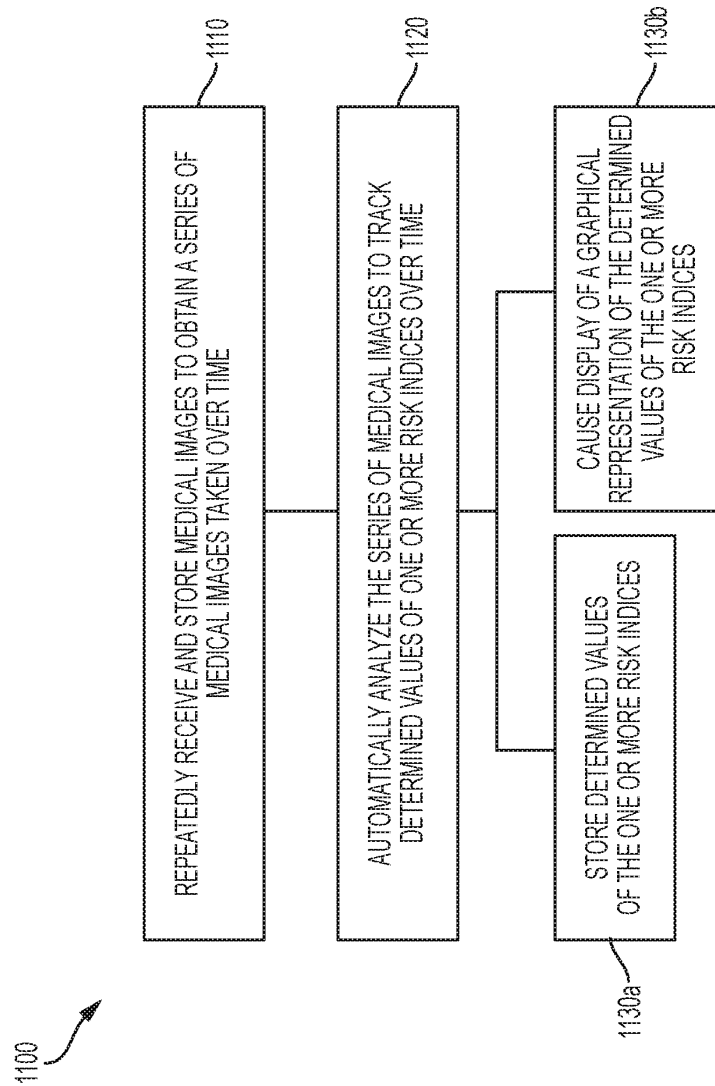


FIG. 11

REMARKS

Status of the Claims

Prior to entry of this Preliminary Amendment, claims 1 - 49 were pending. With entry of this Preliminary Amendment, claim 1 is amended as reflected in the Listing of Claims above, and claims 2 - 49 are cancelled without prejudice or disclaimer. New claims 50 – 63 are added. Support for the amendments and new claims can be found, for example, in original claims 1, 19, 38, and 39 as well as at paragraphs [0013], [0014], [0019], [0032], [0056], [0057], [0061], [0062], [0090], [00120], [00124], and [00137] of the specification as filed . No new matter is added.

Accordingly, after entry of the present Preliminary Amendment, claims 1, and 50 - 63 will be pending for consideration.

Amendment to the Specification

The specification has been amended to update the Cross-Reference to Related Applications paragraph. The amendments to the speciation are fully supported by the specification as originally filed. No new matter is added.

Conclusion

Applicant respectfully requests entry of the present Preliminary Amendment prior to examination. Applicant thanks the Examiner for investing time in consideration of this case. If a telephone conversation would help to clarify any issues, the Examiner is encouraged to contact the undersigned at (617) 248-4814.

Dated: December 18, 2019

Respectfully submitted,

By /Ronen Adato/
Ronen Adato, PhD
Registration No.: 76,341
CHOATE, HALL & STEWART LLP
Two International Place
Boston, Massachusetts 02110
(617) 248-5000
Agent For Applicant

AMENDMENTS TO THE CLAIMS

The Listing Of Claims below will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A network-based ~~decision support~~ 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 ~~perform one or more of functions (i) to (v) as follows:~~

~~—— (i) —— receive and store medical images in a database, each medical image associated with a particular patient;~~

(i[[i]]) access one or more [[of the]]medical images ~~and/or related data~~ associated with a particular patient from [[the]]a database ~~upon user request for transmission to the user for display on a user computing device;~~

(ii[[i]]) perform an analysis of ~~automatically analyze the~~ one or more [[of the]] medical images associated with the particular patient using a machine learning algorithm, to generate the risk map, wherein the risk map comprises a visual representation of tissue overlaid with graphical denotations marking one or more regions of risk of cancer or risk of recurrence of cancer; and

~~—— (iii) ——~~ cause display of the risk map via a graphical user interface (GUI) for presentation and/or review of the risk map by a user.

~~(iv) generate a radiologist report for a patient according to one or more of the medical images for the patient; and~~
~~— (v) apply a machine learning algorithm to update a process for automatically analyzing one or more of the medical images using accumulated image data in the database.~~

2 - 49. (Canceled)

50. (New) The system of claim 1, wherein the one or more medical images comprise one or more magnetic resonance images (MRIs).

51. (New) The system of claim 1, wherein the one or more medical images comprise (i) one or more PET/CT image(s) and/or (ii) one or more SPECT/CT image(s).

52. (New) The system of claim 1, wherein the visual representation of tissue is at least a portion of one of the one or more medical images of the particular patient.

53. (New) The system of claim 1, wherein the cancer is prostate cancer.

54. (New) The system of claim 1, wherein the visual representation of tissue comprises a visual representation of bone.

55. (New) The system of claim 1, wherein the analysis of the one or more medical images comprises geographic identification of one or more specific tissue region(s) within at least one of the one or more medical images.

56. (New) The system of claim 55, wherein the analysis of the one or more medical images further comprises creation of a 3D image of the one or more geographically identified specific tissue region(s) with the one or more medical images overlaid.

57. (New) The system of claim 55, wherein the one or more specific tissue region(s) comprise one or members selected from the group consisting of organs, organ structures, sub-organs, organ regions.

58. (New) The system of claim 55, wherein the one or more specific tissue region(s) comprise one or more particular bones.

59. (New) The system of claim 1, wherein the instructions cause the processor to generate a radiologist report for the particular patient based at least in part on the analysis of the one or more medical images.

60. (New) The system of claim 59, wherein the radiologist report comprises the one or more medical images and/or the risk map.

61. (New) The system of claim 59, wherein the radiologist report comprises one or more reference images and/or reference risk maps.

62. (New) The system of claim 1, wherein the instructions cause the processor to apply a machine learning algorithm to update a process for automatically analyzing the one or more medical images using accumulated image data in the database.

63. (New) A method for generating a disease risk map for use as a decision-making support for evaluating risk of cancer or risk of recurrence of cancer, the method comprising:

- (i) accessing, by the processor, one or more medical images associated with a particular patient from a database;
- (ii) automatically analyzing, by the processor, using a machine learning algorithm, the one or more medical images to generate the risk map, wherein the risk map comprises a visual representation of tissue overlaid with graphical denotations marking one or more regions of risk of cancer or risk of recurrence of cancer;
- (iii) causing, by the processor, display of the risk map via a graphical user interface (GUI) for presentation and/or review of the risk map by a user.

AMENDMENTS TO THE SPECIFICATION

Applicant respectfully requests amendment to the specification by the following change:

Please amend paragraph [0001] under the heading “Cross Reference to Related Applications” as follows:

[0001] This application is a continuation of U.S. Appl. No. 16/418,527, filed May 21, 2019, which is a continuation of U.S. Appl. No. 15/794,220, filed October 26, 2017 (now U.S. Patent No. 10,340,046, issued July 2, 2019), which claims the benefit of U.S. Provisional Application 62/413,936, filed on October 27, 2016, the content of each of which ~~[[is]]~~are hereby incorporated by reference herein in ~~[[its]]~~their entirety.

SCORE Placeholder Sheet for IFW Content

Application Number: 16718839

Document Date: 12/23/2019

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

At the time of document entry (noted above):

- USPTO employees may access SCORE content via DAV or via the SCORE web page.
- External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: March 1, 2019

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Progenics Pharmaceuticals, Inc.

Application No.: 16/718,839

Confirmation No.: 1052

Filed: December 18, 2019

Art Unit: Not yet assigned

For: NETWORK FOR MEDICAL IMAGE
ANALYSIS, DECISION SUPPORT SYSTEM,
AND RELATED GRAPHICAL USER
INTERFACE (GUI) APPLICATIONS

Examiner: Not Yet Assigned

SECOND PRELIMINARY AMENDMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

Amendments to the Drawings begin on page **2** of this paper;

Remarks/Arguments begin on page **3** of this paper.

300

BSI

PATIENTS

SETTINGS

SEND INVITATION

HELP

LOG OUT ANDREAS JÄRUND

Refresh patient list

PATIENT NAME

PATIENT ID

STUDY DATE

Test environment. Do not upload identifiable patient data.

John Doe Three Studies

2010-01-19

Filter list

Name: John Doe Three Studies

Date of birth:

ID: John Doe Three Studies

STUDIES

INFO

SHARE

REPORT

2009-04-09

2009-08-24

2010-01-19

▼

▼

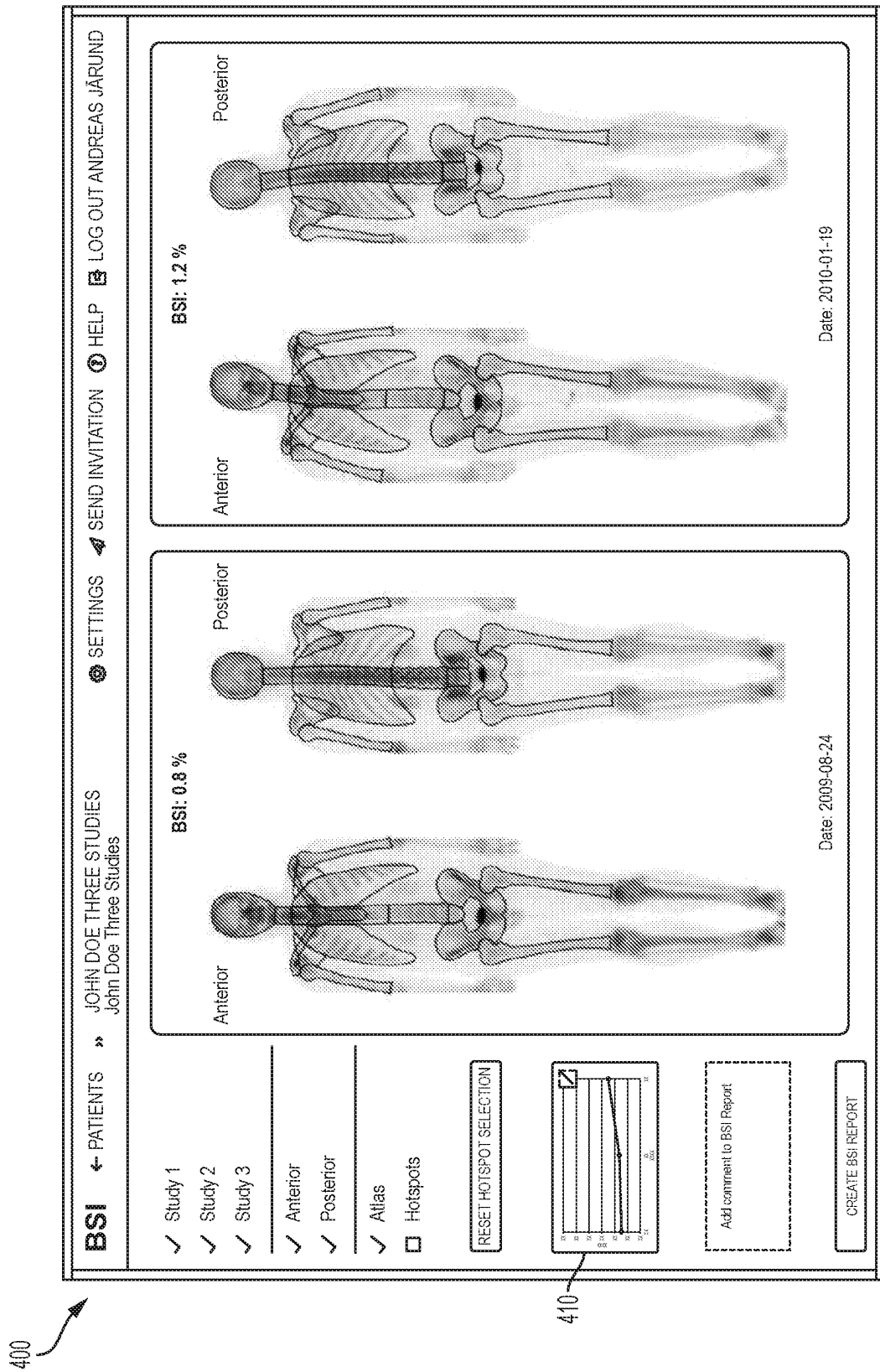
▼

START PATIENT

SHARE ALL STUDIES WITH ▼

DELETE PATIENT

FIG. 3



REPLACEMENT SHEET

5/11

BSI

← PATIENTS »

JOHN DOE THREE STUDIES

Settings

SEND INVITATION

Help

LOG OUT ANDREAS JÄRUND

EXINI BSI Report

PATIENT NAME

John Doe Three Studies

PATIENT ID

John Doe Three Studies

DATE OF BIRTH

2010-01-19

GENDER

M

Study 1

✓

Study 2

✓

Study 3

✓

Anterior

✓

Posterior

✓

Atlas

✓

Hotspots

☐

RESET HOTSPOT SELECTION

10

8

6

4

2

0

10

8

6

4

2

0

10

8

6

4

2

0

Add comment to BSI Report

CREATE BSI REPORT

Anterior

Posterior

1.2%

Study date 2010-01-19

COMMENTS

BS assessment performed according to requirements.

ASSESSMENT

BS assessment performed according to requirements.

SIGNED

ANDREAS JÄRUND

RESEARCHER

EXINI

10/20/2016, 23:41

BSI TABLE

2009-04-09	2009-06-24	2010-01-19
0.7%	0.8%	1.2%

Created with EXINI BSI version v1.0.0-RC2

BSI

Disclaimer - Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, Lorem ipsum dolor sit amet, consectetur adipiscing elit sed.

www.exini.com

CANCEL

SIGN AND SAVE REPORT

Anterior

Posterior

1.2%

Study date 2010-01-19

COMMENTS

BS assessment performed according to requirements.

ASSESSMENT

BS assessment performed according to requirements.

SIGNED

ANDREAS JÄRUND

RESEARCHER

EXINI

10/20/2016, 23:41

BSI TABLE

2009-04-09	2009-06-24	2010-01-19
0.7%	0.8%	1.2%

Created with EXINI BSI version v1.0.0-RC2

BSI

Disclaimer - Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, Lorem ipsum dolor sit amet, consectetur adipiscing elit sed.

www.exini.com

CANCEL

SIGN AND SAVE REPORT

FIG. 5

Page 133 of 196

MIM Ex1004

Electronic Acknowledgement Receipt	
EFS ID:	38116444
Application Number:	16718839
International Application Number:	
Confirmation Number:	1052
Title of Invention:	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS
First Named Inventor/Applicant Name:	Mark R. Baker
Customer Number:	24280
Filer:	Ronen Adato/Logan Moss
Filer Authorized By:	Ronen Adato
Attorney Docket Number:	2010358-0167
Receipt Date:	23-DEC-2019
Filing Date:	
Time Stamp:	10:21:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2010358_0167_PreliminaryAmendment.pdf	125387	yes	3
			fd6a9b705a7fce610a7d6121aa31a4156c9f414f		

Multipart Description/PDF files in .zip description					
Document Description			Start	End	
Preliminary Amendment			1	1	
Drawings-only black and white line drawings			2	2	
Applicant Arguments/Remarks Made in an Amendment			3	3	
Warnings:					
Information:					
2	Drawings-only black and white line drawings	2010358_0167_ReplacementDrawings.pdf	1012895	no	3
			f40d50d8ba8f9d6c5d306bf87c3f834cf12bb eda		
Warnings:					
Information:					
Total Files Size (in bytes):			1138282		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

AMENDMENTS TO THE DRAWINGS

Please replace page 3 (corresponding to FIG. 3), page 4 (corresponding to FIG. 4), and page 5 (corresponding to FIG. 5) of the currently filed drawings with the 3 pages of replacement sheets of drawings filed herewith. The amendments are fully supported by the Specification and Drawings as originally filed, and are solely to enlarge and darken text for reproducibility considerations. No new matter has been added.

REMARKS

Amendments to the Drawings

The drawings are amended via submission of replacement drawings corresponding to revised versions (solely to enlarge and darken text for reproducibility considerations) of certain figures of the originally filed drawings. The amendments to the drawing are fully supported by the specification and drawings as originally filed. No new matter is added.

Conclusion

Applicant respectfully requests entry of the present Preliminary Amendment prior to examination. Applicant thanks the Examiner for investing time in consideration of this case. If a telephone conversation would help to clarify any issues, the Examiner is encouraged to contact the undersigned at (617) 248-4814.

Dated: December 23, 2019

Respectfully submitted,

By /Ronen Adato/
Ronen Adato, PhD
Registration No.: 76,341
CHOATE, HALL & STEWART LLP
Two International Place
Boston, Massachusetts 02110
(617) 248-5000
Agent For Applicant

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 16/718,839				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A				
SEARCH FEE (37 CFR 1.16(k), (j), or (m))	N/A	N/A	N/A	330		N/A				
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	15	minus 20 = *	x 50 =	0.00	OR					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 = *	x 230 =	0.00						
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00						
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL				
				785						
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=	OR	x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=	OR	x	=
	Application Size Fee (37 CFR 1.16(s))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=	OR	x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=	OR	x	=
	Application Size Fee (37 CFR 1.16(s))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.										



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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY DOCKET NO	TOT CLAIMS	IND CLAIMS
16/718,839	12/18/2019		785	2010358-0167	15	2

CONFIRMATION NO. 1052

FILING RECEIPT



0000000113963783

24280

CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

Date Mailed: 01/17/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Mark R. Baker, New York, NY;

Applicant(s)

Progenics Pharmaceuticals, Inc., New York, NY;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 16/418,527 05/21/2019
which is a CON of 15/794,220 10/26/2017 PAT 10340046
which claims benefit of 62/413,936 10/27/2016

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 01/14/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/718,839**

Projected Publication Date: 04/23/2020

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/718,839	12/18/2019	Mark R. Baker	2010358-0167	1052
24280 7590 01/23/2020 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER	
			ART UNIT	PAPER NUMBER
			2667	
			NOTIFICATION DATE	DELIVERY MODE
			01/23/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jnease@choate.com
patentdocket@choate.com

<i>Decision Granting Request for Prioritized Examination (Track I)</i>	Application No. 16/718,839	Applicant(s) Baker, Mark R.	
	Examiner TERRI S JOHNSON	Art Unit OPET	AIA (FITF) Status Yes
1. THE REQUEST FILED <u>19 December 2019</u> IS GRANTED . The above-identified application has met the requirements for prioritized examination A. ☒ for an original nonprovisional application (Track I). B. ☐ for an application undergoing continued examination (RCE). 2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs: A. filing a <u>petition for extension of time</u> to extend the time period for filing a reply; B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u>, or a multiple dependent claim; C. filing a <u>request for continued examination</u> ; D. filing a notice of appeal; E. filing a request for suspension of action; F. mailing of a notice of allowance; G. mailing of a final Office action; H. completion of examination as defined in 37 CFR 41.102; or I. abandonment of the application. Telephone inquiries with regard to this decision should be directed to TERRI JOHNSON at (571)272-2991. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.			
/TERRI S JOHNSON/ Paralegal Specialist, OPET			

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
16/718,839	December 18, 2019

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

24280

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or
Individual Name

Address

City

State

Zip

Country

Telephone

Email

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Progenics Pharmaceuticals, Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature

Date (Optional)

1/9/2020

Name

Patrick Fabbio

Title

Executive Vice President/CFO

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☒ Total of 1 forms are submitted.

ATTORNEY DOCKET NO.: 2010358-0167
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Progenics Pharmaceuticals, Inc.

Application No.: 16/718,839

Confirmation No.: 1052

Filed: December 18, 2019

Art Unit: Not Yet Assigned

For: NETWORK FOR MEDICAL IMAGE
ANALYSIS, DECISION SUPPORT SYSTEM,
AND RELATED GRAPHICAL USER
INTERFACE (GUI) APPLICATIONS

Examiner: Not Yet Assigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

WRITTEN ASSERTION OF SMALL ENTITY STATUS
UNDER 37 CFR § 1.27(a)(2)
SMALL BUSINESS CONCERN

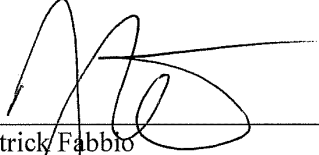
The undersigned hereby asserts entitlement to small entity status as a small business concern under 37 CFR § 1.27(a)(2) on behalf of Progenics Pharmaceuticals, Inc.

This assertion is made on the ground that Progenics Pharmaceuticals, Inc. is a concern:

- (a) whose number of employees, including affiliates, does not exceed 500 persons; and
- (b) that has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license, any rights in the above-referenced patent application to any party who does not qualify for small entity

status either as a person, a small business concern, or a nonprofit organization under 37 CFR § 1.27.

Respectfully submitted,



Name: Patrick Fabbio
Title: Executive Vice President/CFO
On Behalf of Progenics Pharmaceuticals, Inc.

Date: 1/9/2020

Electronic Acknowledgement Receipt	
EFS ID:	38534595
Application Number:	16718839
International Application Number:	
Confirmation Number:	1052
Title of Invention:	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS
First Named Inventor/Applicant Name:	Mark R. Baker
Customer Number:	24280
Filer:	Ronen Adato/Caroline Lawlor
Filer Authorized By:	Ronen Adato
Attorney Docket Number:	2010358-0167
Receipt Date:	10-FEB-2020
Filing Date:	18-DEC-2019
Time Stamp:	13:28:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no				
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	2020-02-10_EXI-005USC2-T1_Power_of_Attorney.PDF	241033 c534db4173144a42c19ae07aa3364a69f780c3b9	no	1
Warnings:					

Information:					
2	Assertion of entitlement to small entity status	2020-02-10_EXI-005USC2-T1_Small_Entity_Statement.PDF	225239	no	2
			df4e6dde9122e49452f15017ba64664c29e58b7e		
Warnings:					
Information:					
Total Files Size (in bytes):			466272		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 2010358-0167
In re Application of: Mark R. Baker Application No.: 16/718,839 Filed: December 18, 2019 For: NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS The applicant, <u>Progenics Pharmaceuticals, Inc.</u>, owner of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent No. <u>10,340,046</u> as the term of said prior patent is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. Check either box 1 or 2 below, if appropriate. 1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee. I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. 2. ☒ The undersigned is an attorney or agent of record. Reg. No. <u>76,341</u> <u>/Ronen Adato/</u> Signature <u>February 10, 2020</u> Date <u>Ronen Adato, PhD</u> Typed or printed name <u>Agent for Applicant</u> Title <u>(617) 248-4814</u> Telephone Number ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.	

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Docket No.: 2010358-0167
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Progenics Pharmaceuticals, Inc.

Application No.: 16/718,839

Confirmation No.: 1052

Filed: December 18, 2019

Art Unit: 2667

For: NETWORK FOR MEDICAL IMAGE
ANALYSIS, DECISION SUPPORT SYSTEM,
AND RELATED GRAPHICAL USER
INTERFACE (GUI) APPLICATIONS

Examiner: S. Azarian

TRANSMITTAL

Dear Commissioner:

Applicant submits herewith a terminal disclaimer over U.S. Patent Number 10,340,046, issued July 2, 2019. Applicant has also filed, on February 10, 2020, a Power of Attorney appointing the Patent Practitioners associated with Customer Number 24280 as attorney or agent for Applicant in the above referenced application.

Applicant submits herewith the Terminal Disclaimer fee in the amount of \$160.00 via the EFS credit card payment system with this filing.

9815546v1

It is Applicant's understanding that all fees due in connection with this submission are being paid. However, if Applicant's understanding is in error, please charge any additional fees that are required to maintain pendency of the present case, or credit any overpayments, to our Deposit Account Number 03-1721, referencing Attorney Docket Number 2010358-0167.

Should the Examiner have any questions or require any additional papers to be filed, the Examiner is requested to contact the undersigned.

Dated: February 10, 2020

Respectfully submitted,
Electronic signature: /Ronen Adato/
Ronen Adato, PhD
Registration No.: 76,341
CHOATE, HALL & STEWART LLP
Two International Place
Boston, Massachusetts 02110
(617) 248-5000
Agent For Applicant

Electronic Patent Application Fee Transmittal				
Application Number:		16718839		
Filing Date:		18-Dec-2019		
Title of Invention:		NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		
First Named Inventor/Applicant Name:		Mark R. Baker		
Filer:		Ronen Adato/Logan Moss		
Attorney Docket Number:		2010358-0167		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	160	160

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				160

Electronic Acknowledgement Receipt	
EFS ID:	38544048
Application Number:	16718839
International Application Number:	
Confirmation Number:	1052
Title of Invention:	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS
First Named Inventor/Applicant Name:	Mark R. Baker
Customer Number:	24280
Filer:	Ronen Adato/Logan Moss
Filer Authorized By:	Ronen Adato
Attorney Docket Number:	2010358-0167
Receipt Date:	10-FEB-2020
Filing Date:	18-DEC-2019
Time Stamp:	17:53:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$160
RAM confirmation Number	E202020H54482352
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	TerminalDisclaimer.pdf	156397	no	2
			59801acaaa26194eccc41b96cf9807bdfb20d49f		
Warnings:					
Information:					
2	Transmittal Letter	TerminalDisclaimerTransmittal.pdf	96070	no	2
			d18f79195e26fedf9aded3830212f0b7daf4f15f		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30673	no	2
			563c3042b35260ab64eadd2c143883d559d14b44		
Warnings:					
Information:					
Total Files Size (in bytes):			283140		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Application Number * 16/718,839 *	Application/Control No. 16/718,839	Applicant(s)/Patent under Reexamination Baker, Mark R.	
	Examiner AZARIAN, SEYED H	Art Unit 2667	
Document Code - DISQ		Internal Document - DO NOT MAIL	

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed: <u>10 February 2020</u>	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
/FELICIA D ROBERTS/ Technology Center: OPLC Telephone: (571)272-0550 10,340,046



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/718,839	12/18/2019	Mark R. Baker	2010358-0167

24280
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

CONFIRMATION NO. 1052
POA ACCEPTANCE LETTER



Date Mailed: 02/13/2020

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/10/2020.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/dgela/



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

24280 7590 02/21/2020
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER

AZARIAN, SEYED H

ART UNIT

PAPER NUMBER

2667

DATE MAILED: 02/21/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/718,839	12/18/2019	Mark R. Baker	2010358-0167	1052

TITLE OF INVENTION: NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	05/21/2020

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24280 7590 02/21/2020
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

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16/718,839	12/18/2019	Mark R. Baker	2010358-0167	1052

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nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	05/21/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
AZARIAN, SEYED H	2667	382-128000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

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16/718,839	12/18/2019	Mark R. Baker	2010358-0167	1052
24280 7590 02/21/2020 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER AZARIAN, SEYED H	
			ART UNIT 2667	PAPER NUMBER
DATE MAILED: 02/21/2020				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/718,839	Applicant(s) Baker, Mark R.	
	Examiner SEYED H AZARIAN	Art Unit 2667	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/18/2019, also telephone interview on 2/7/2020.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1,50-54 and 57-63. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____.	

/SEYED H AZARIAN/ Primary Examiner, Art Unit 2667	
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Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Amendment

Drawings

1. The drawing filed on 12/23/2019 is accepted by the Examiner.
2. The terminal disclaimer filed on 2/10/2020 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of (U.S. Patent No. 10,340,046) has been reviewed and is accepted. The terminal disclaimer has been recorded.
3. Based on telephone interview on February 7, 2020, with respect to cancellation of claims 2-49, 55-56, and amended claims 1, 51, 57-58, 60-61 and 63, also review of prior art of record, all have been fully considered and are persuasive.

The claims 1, 50-54 and 57-63 now renumbered as 1-13 are allowed.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicants Attorney (Ronen Adato, Reg No. 76,341), on February 7, 2020, without traverse.

The amended claims 1, 51, 57, 58, 60, 61 and 63 as follows:

Cancel claims 2-49 and 55-56.

Claim 1. (Currently Amended) A network-based system for generating a disease risk map for use as a decision-making support for evaluating risk of cancer or risk of recurrence of cancer, the system comprising:

a processor; and

a memory having instructions stored thereon, wherein the instructions, when executed by the processor, cause the processor to:

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

(ii)perform an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map, wherein the risk map comprises a visual representation of tissue overlaid with graphical denotations marking one or more regions of risk of cancer or risk of recurrence of cancer; and

(iii)cause display of the risk map via a graphical user interface (GUI) for presentation [[and/]]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.

Claims 2-49 (Canceled)

Claim 51. (Currently Amended) The system of claim 1, wherein the one or more medical images comprise (i) one or more PET/CT image(s) [[and/]]or (ii) one or more SPECT/CT image(s).

Claims 55-56. (Canceled)

Claim 57. (Currently Amended) The system of claim 1[[55]], wherein the one or more specific tissue region(s) comprise one or more members selected from the group consisting of organs, organ structures, sub-organs, and organ regions.

Claim 58. (Currently Amended) The system of claim 1[[55]], wherein the one or more specific tissue region(s) comprise one or more particular bones.

Claim 60. (Currently Amended) The system of claim 59, wherein the radiologist report comprises the one or more medical images and[[/or]] the risk map.

Claim 61. (Currently Amended) The system of claim 59, wherein the radiologist report comprises one or more reference images [[and/]]or reference risk maps.

Claim 63. (Currently Amended) A method for generating a disease risk map for use as a decision-making support for evaluating risk of cancer or risk of recurrence of cancer, the method comprising:

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

(ii)automatically analyzing, by the processor, using a machine learning algorithm, the one or more medical images to generate the risk map, wherein the risk map comprises a visual representation of tissue overlaid with graphical denotations marking one or more regions of risk of cancer or risk of recurrence of cancer; and

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

wherein step (ii) comprises creation of a 3D image of the one or more regions of risk of cancer or risk of recurrence of cancer overlaid on the one or more medical images, and wherein

the 3D image comprises geographic identification of one or more specific tissue region(s) overlaid on the one or more medical images.

REASONS FOR ALLOWANCE

5. The following is an examiner's statement of reasons for allowance.

This invention relates generally, to systems and methods for creation, analysis, and/or presentation of medical image data. More particularly, in certain embodiments, the invention relates to a cloud-based platform and supported GUI decision-making tools for use by medical practitioners and/or their patients.

Based on applicant's amendment, with respect to claim 1, representative of claim 63, the closest prior art of record (WU), reference is directed to image processing systems. More particularly, embodiments of the invention relate to cloud-based medical image processing systems with tracking capability, but does not teach or suggest, among other things, "perform an analysis of the one or more medical images associated with the particular patient using a "machine learning algorithm", to generate the risk map, wherein the risk map comprises a visual representation of tissue overlaid with graphical denotations marking one or more regions of risk of cancer or risk of recurrence of cancer; and display of the risk map via a graphical user interface (GUI) for presentation or review of the risk map by a user, wherein the medical images comprises creation of a 3D image of the one or more regions of risk of cancer or risk of recurrence of cancer "overlaid" on the one or more medical images, and wherein the 3D image comprises geographic identification of one or more "specific tissue" region(s) overlaid on the one or more medical images".

These key features in combination with the other features of the claimed invention are neither taught nor suggested by (WU) prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (571) 272-7443. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella, can be reached at (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Status information about the PAIR system, see [http:// pair-direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SEYED H AZARIAN/
Primary Examiner, Art Unit 2667
February 9, 2020

<i>Notice of References Cited</i>	Application/Control No. 16/718,839		Applicant(s)/Patent Under Reexamination Baker, Mark R.	
	Examiner SEYED H AZARIAN		Art Unit 2667	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20160335395-A1	11-2016	WU; Junnan	G06F19/321	1/1
*	B	US-20170083682-A1	03-2017	McNutt; Todd	G16H50/30	1/1
*	C	US-20150331995-A1	11-2015	Zhao; Tiecheng	G16Z99/00	705/2
*	D	US-9002081-B2	04-2015	Brown; Matthew Sherman	G06T7/0014	382/128
*	E	US-20060062425-A1	03-2006	Shen; Hong	G06T15/08	382/100
*	F	US-20070081712-A1	04-2007	Huang; Xiaolei	G06T7/38	382/128
*	G	US-20160203263-A1	07-2016	Maier; Cynthia F.	G16H50/30	705/2
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office
PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20200209

<i>Search Notes</i> 	Application/Control No. 16/718,839	Applicant(s)/Patent Under Reexamination Baker, Mark R.
	Examiner SEYED H AZARIAN	Art Unit 2667

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner
G06K 9/00	2/5/2020	S.A
G06Q 10/00	2/5/2020	S.A

US Classification - Searched*			
Class	Subclass	Date	Examiner
382	100,103,128-134,154-158,162,168,173,181,206,209,220,224,232,254,286-295,305,312.	2/5/2020	S.A
705	2	2/5/2020	S.A
1	1	2/6/2020	S.A

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
INVENTOR SEARCH; EAST SEARCH	2/5/2020	S.A

/SEYED H AZARIAN/ Primary Examiner, Art Unit 2667	
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<i>Search Notes</i> 	Application/Control No. 16/718,839	Applicant(s)/Patent Under Reexamination Baker, Mark R.
	Examiner SEYED H AZARIAN	Art Unit 2667

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
US-PGPUB	See Interference Search History Print Out.	2/5/2020	S.A
382	295	2/8/2020	S.A
705	2	2/8/2020	S.A

/SEYED H AZARIAN/ Primary Examiner, Art Unit 2667	
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Issue Classification 	Application/Control No. 16/718,839	Applicant(s)/Patent Under Reexamination Baker, Mark R.
	Examiner SEYED H AZARIAN	Art Unit 2667

CPC						
Symbol					Type	Version
G16H	/	50	/	20	F	2018-01-01
G16H	/	30	/	20	I	2018-01-01
G16H	/	30	/	40	I	2018-01-01
G16H	/	50	/	70	I	2018-01-01
G16H	/	50	/	30	I	2018-01-01
G16H	/	15	/	00	I	2018-01-01
G01N	/	33	/	57434	I	2013-01-01

CPC Combination Sets					
Symbol				Type	Set
	/		/		

NONE (Assistant Examiner)		Total Claims Allowed: 13	
/SEYED H AZARIAN/ Primary Examiner, Art Unit 2667 (Primary Examiner)		O.G. Print Claim(s) 1	O.G. Print Figure 5

U.S. Patent and Trademark Office

Part of Paper No.: 20200209

Issue Classification 	Application/Control No. 16/718,839	Applicant(s)/Patent Under Reexamination Baker, Mark R.
	Examiner SEYED H AZARIAN	Art Unit 2667

INTERNATIONAL CLASSIFICATION			
CLAIMED			
G06Q		10	00
G06K		9	00
NON-CLAIMED			

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
382	128

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					
382	295					
705	2					

NONE (Assistant Examiner)		Total Claims Allowed: 13	
/SEYED H AZARIAN/ Primary Examiner, Art Unit 2667 (Primary Examiner)		11 February 2020 (Date)	O.G. Print Claim(s) 1
			O.G. Print Figure 5

U.S. Patent and Trademark Office

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	Examiner SEYED H AZARIAN	Art Unit 2667

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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-	2	-	11	-	20	-	29	-	38	-	47	-	56		
-	3	-	12	-	21	-	30	-	39	-	48	7	57		
-	4	-	13	-	22	-	31	-	40	-	49	8	58		
-	5	-	14	-	23	-	32	-	41	2	50	9	59		
-	6	-	15	-	24	-	33	-	42	3	51	10	60		
-	7	-	16	-	25	-	34	-	43	4	52	11	61		
-	8	-	17	-	26	-	35	-	44	5	53	12	62		
-	9	-	18	-	27	-	36	-	45	6	54	13	63		

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 13	
/SEYED H AZARIAN/ Primary Examiner, Art Unit 2667 (Primary Examiner) _____ (Date) 11 February 2020		O.G. Print Claim(s) 1	O.G. Print Figure 5

U.S. Patent and Trademark Office

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<i>Index of Claims</i> 	Application/Control No. 16/718,839	Applicant(s)/Patent Under Reexamination Baker, Mark R.
	Examiner SEYED H AZARIAN	Art Unit 2667

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47										
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<i>Index of Claims</i> 	Application/Control No. 16/718,839	Applicant(s)/Patent Under Reexamination Baker, Mark R.
	Examiner SEYED H AZARIAN	Art Unit 2667

CLAIM		DATE								
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EAST Search History**EAST Search History (Prior Art)**

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L2	562961	cancer\$3	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:49
L3	9598	2 and (machin\$3 near5 learn\$4)	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:50
L4	1734	3 and radiolog\$5	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:50
L5	540	4 and ((graphic\$4 with user\$2 with interfac\$4) or (gui))	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:51
L6	526	5 and display\$4	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:52
L7	398	6 and (medical\$4 with imag\$3)	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:52
L8	347	7 and evaluat\$5	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:53
L9	260	8 and updat\$4	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:53
L10	235	9 and (mri\$2 or tomograp\$5 or pet or ct or spect)	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:54
L11	75	10 and ((bon\$3 or prostat\$4) with (cancer\$2))	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:55
L12	44	11 and overla\$5	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:55

2/ 5/ 2020 6:55:53 PM

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	"20160335395"	US-PGPUB; USPAT	OR	OFF	2020/02/05 18:46

2/ 5/ 2020 6:48:05 PM

Used in Lieu of PTO/SB/08A/B
(Based on PTO 10-07 version)

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Mark R. Baker
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	5	Attorney Docket Number	2010358-0167

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Additional Information
		Number-Kind Code ² (if known)			
	A1*	US-2003/0215120-A1	11-20-2003	Uppaluri et al.	
	A2*	US-2006/0062425-A1	03-23-2006	Shen et al.	
	A3*	US-2007/0081712-A1	04-12-2007	Huang et al.	
	A4*	US-2007/0081713-A1	04-12-2007	Jerebko	
	A5*	US-2007/0100225-A1	05-03-2007	Maschke	
	A6*	US-7,450,747-B2	11-11-2008	Jabri et al.	
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	A11*	US-8,778,305	07-15-2014	Pomper et al.	
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	A14*	US-9,002,081-B2	04-07-2015	Brown	
	A15*	US-2015/0110716-A1	04-23-2015	ARMOR	
	A16*	US-2015/0331995-A1	11-19-2015	Zhao et al.	
	A17*	US-2016/0203263-A1	07-14-2016	Maier et al.	
	A18*	US-2016/0335395-A1	11-17-2016	WU et al.	
	A19*	US-2018/0144828-A1	05-24-2018	Baker	
	A20*	US-RE47609-E	09-17-2019	Hamadeh et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Additional Information	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	B1**	WO-9905503-A2	02-04-1999	Arch Development Corporation		
	B2**	EP-1426903-A2	06-09-2004	GE Medical Systems Global Technology Company LLC		
	B3**	EP-1508872-A1	02-23-2005	Semeion		
	B4**	WO-2007/062135-A2	05-31-2007	Shiraishi, Junji		
	B5**	WO-2009/084995-A1	07-09-2009	Exini Diagnostics AB		
	B6**	WO-2018/081354-A1	05-03-2018	Progenics Pharmaceuticals, Inc		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ** CITE NO.: Those document(s) which are marked with a double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/SEYED H AZARIAN/	Date Considered	02/11/2020
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.H.A/ EXL005USC2-T1

Used in Lieu of PTO/SB/08A/B
(Based on PTO 10-07 version)

Substitute for form 1449/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	Not Yet Assigned
			Filing Date	Concurrently Herewith
			First Named Inventor	Mark R. Baker
			Art Unit	Not Yet Assigned
			Examiner Name	Not Yet Assigned
			Attorney Docket Number	2010358-0167
Sheet	2	of	5	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1**	ANAND, A. et al., Analytic Validation of the Automated Bone Scan Index as an Imaging Biomarker to Standardize Quantitative Changes in Bone Scans of Patients with Metastatic Prostate Cancer, J. Nucl. Med., 57(1):41-45 (2016).	
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Examiner Signature	/SEYED H AZARIAN/	Date Considered	02/19/2020
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EXL005USC2-T1

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	Not Yet Assigned
			Filing Date	Concurrently Herewith
			First Named Inventor	Mark R. Baker
			Art Unit	Not Yet Assigned
			Examiner Name	Not Yet Assigned
			Attorney Docket Number	2010358-0167
Sheet	3	of	5	

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Examiner Signature	/SEYED H AZARIAN/	Date Considered	02/19/2020
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			Art Unit	Not Yet Assigned
			Examiner Name	Not Yet Assigned
			Attorney Docket Number	2010358-0167
Sheet	4	of	5	

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Examiner Signature	/SEYED H AZARIAN/	Date Considered	02/19/2020
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9531340v1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.H.A/

EXL005USC2-T1

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				First Named Inventor	Mark R. Baker
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	5	of	5	Attorney Docket Number	2010358-0167

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C58**	TIAN, Z. et al., A fully automatic multi-atlas based segmentation method for prostate MR images, Proc SPIE Int Soc Opt Eng. Author manuscript, 12 pages (2015).	
C59**	TIAN, Z. et al., A supervoxel-based segmentation method for prostate MR images, Med. Phys., 44(2):558-569 (2017).	
C60**	TIAN, Z. et al., Deep convolutional neural network for prostate MR segmentation, Proc. of SPIE 10135:101351L-1-101351L-6 (2017).	
C61**	TIAN, Z., et al., Superpixel-based Segmentation for 3D Prostate MR Images, IEEE Trans Med Imaging, Author manuscript, 32 pages, (2016).	
C62**	ULMERT, D. et al., A Novel Automated Platform for Quantifying the Extent of Skeletal Tumour Involvement in Prostate Cancer Patients Using the Bone Scan Index, European Urology, 62(1):78-84 (2012).	
C63**	WRANGSJO, A. et al., Non-rigid Registration Using Morphons, Proceedings of the 14th Scandinavian Conference on Image Analysis (SCIA '05), pages 501-510 (2005).	
C64**	Written Opinion, International Application No. PCT/US2017/058418 (NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS, filed October 26, 2017), issued by ISA/European Patent Office, 9 pages, February 27, 2018.	
C65**	YIN, T.-K., A Computer-Aided Diagnosis for Locating Abnormalities in Bone Scintigraphy by a Fuzzy System With a Three-Step Minimization Approach, IEEE Transactions on Medical Imaging, 23(5):639-654 (2004).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/SEYED H AZARIAN/	Date Considered	02/19/2020
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9531340v1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.H.A/

EXL005USC2-T1



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 Alexandria, Virginia 22313-1450
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BIB DATA SHEET

CONFIRMATION NO. 1052

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
16/718,839	12/18/2019 RULE	382	2667	2010358-0167		
APPLICANTS Progenics Pharmaceuticals, Inc., New York, NY; INVENTORS Mark R. Baker, New York, NY; ** CONTINUING DATA ***** This application is a CON of 16/418,527 05/21/2019 which is a CON of 15/794,220 10/26/2017 PAT 10340046 which claims benefit of 62/413,936 10/27/2016 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** * SMALL ENTITY ** 01/14/2020						
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and Acknowledged <u>/SEYED H AZARIAN/</u> Examiner's Signature		☐ Met after Allowance S.A. Initials	STATE OR COUNTRY NY	SHEETS DRAWINGS 11	TOTAL CLAIMS 15	INDEPENDENT CLAIMS 2
ADDRESS CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110 UNITED STATES						
TITLE NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS						
FILING FEE RECEIVED 785	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit			

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1360	(MARK WITH BAKER)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/05 17:26
L2	35	1 AND ((GRAPHIC\$4 WITH USER\$2 WITH INTERFAC\$3)OR (GUI))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/02/05 17:27

2/ 5/ 2020 5:28:15 PM

Docket No.: 2010358-0167
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Progenics Pharmaceuticals, Inc.

Application No.: 16/718,839

Confirmation No.: 1052

Filed: December 18, 2019

Art Unit: 2667

For: NETWORK FOR MEDICAL IMAGE
ANALYSIS, DECISION SUPPORT SYSTEM,
AND RELATED GRAPHICAL USER
INTERFACE (GUI) APPLICATIONS

Examiner: Seyed H. Azarian

STATEMENT OF SUBSTANCE OF TELEPHONE INTERVIEW AND
COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE
UNDER 37 C.F.R. § 1.104(e)

MS Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Applicant thanks the Examiner for the telephonic interview of February 7, 2020 with Applicant's representative in which entry of an Examiner's Amendment was discussed. The substance of the interview is summarized in the Examiner-Initiated Interview Summary dated February 21, 2020.

Applicant has received the Notice of Allowance and Allowability, mailed February 21, 2020, which includes an Examiner's Amendment and the Examiner's Statement of Reasons for Allowance ("Reasons for Allowance"). Entry of the Statement into the record should not be construed as any agreement with or acquiescence in the reasoning stated by the Examiner. Each of the claims stands on its own merits and is patentable because of the combination it recites and not because of the presence or absence of any one particular element.

9695936v1

The Examiner's Statement was not prepared by Applicant and only contains the Examiner's stated positions in one or more reasons for allowability. Thus, any interpretation with respect to the Examiner's Statement of Reasons for Allowance should not be imputed to the Applicant. Nor does Applicant necessarily agree with or acquiesce in any other characterization of any claim term or rejection of any claim that the Examiner may have made during the pendency of the present patent application. Applicant preserves the rights to pursue broader claims and accepts the Examiner's Amendment in the interest of expediency, not as an acknowledgement that Applicant agrees with the Examiner

Applicant notes that the Examiner's Amendment section of the Notice of Allowance and Allowability refers to Ronen Adato as "Attorney" and wishes to clarify that Ronen Adato is a Patent Agent, as indicated in the below and in, for example, Applicant's Preliminary Amendment, dated December 23, 2019.

Applicant is submitting herewith payment of the Issue Fees in this application. It is Applicant's understanding that no additional fees are due at this time. If Applicant is mistaken, please charge any fees that may be required for the processing of this statement to our Deposit Account No. 03-1721 referencing docket no. 2010358-0167.

Dated: April 17, 2020

Respectfully submitted,

/Ronen Adato/
Ronen Adato, PhD
Registration No.: 76,341
CHOATE, HALL & STEWART LLP
Two International Place
Boston, Massachusetts 02110
(617) 248-4814
Agent for Applicant

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24280 7590 02/21/2020
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/718,839	12/18/2019	Mark R. Baker	2010358-0167	1052

TITLE OF INVENTION: NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	05/21/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
AZARIAN, SEYED H	2667	382-128000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

- 1 Ronen Adato
2 William R. Haulbrook
3 Choate, Hall and Stewart LLP

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Progenics Pharmaceuticals, Inc.

New York, NY

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 03-1721

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Ronen Adato/

Date April 17, 2020

Typed or printed name Ronen Adato, PhD

Registration No. 76,341

Electronic Patent Application Fee Transmittal				
Application Number:		16718839		
Filing Date:		18-Dec-2019		
Title of Invention:		NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS		
First Named Inventor/Applicant Name:		Mark R. Baker		
Filer:		Ronen Adato/Peter Rouvalis		
Attorney Docket Number:		2010358-0167		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	500	500

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				500

Electronic Acknowledgement Receipt	
EFS ID:	39189462
Application Number:	16718839
International Application Number:	
Confirmation Number:	1052
Title of Invention:	NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS
First Named Inventor/Applicant Name:	Mark R. Baker
Customer Number:	24280
Filer:	Ronen Adato/Peter Rouvalis
Filer Authorized By:	Ronen Adato
Attorney Docket Number:	2010358-0167
Receipt Date:	17-APR-2020
Filing Date:	18-DEC-2019
Time Stamp:	14:31:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 500
RAM confirmation Number	E20204GE32444707
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	Comments_on_Statement_of_Reasons_for_Allowance.pdf	98989	no	2
			5d32fbccfcd09f2ea4f62d3d1ed4d5a4fa4423a		
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	Issue_Fee_Transmittal.pdf	89387	no	1
			c189c6ee887c2660636186679353ee6beb0a0d0cc		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30600	no	2
			0a4d7c664f5f6291b2fe05cf58a2bc80d1fbd301		
Warnings:					
Information:					
Total Files Size (in bytes):			218976		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/718,839	12/18/2019	Mark R. Baker	2010358-0167

CONFIRMATION NO. 1052

24280
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

PUBLICATION NOTICE



OC000000116475100

Title:NETWORK FOR MEDICAL IMAGE ANALYSIS, DECISION SUPPORT SYSTEM, AND RELATED GRAPHICAL USER INTERFACE (GUI) APPLICATIONS

Publication No.US-2020-0126666-A1

Publication Date:04/23/2020

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publicly available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <https://portal.uspto.gov/pair/PublicPair>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/718,839	05/26/2020	10665346	2010358-0167	1052

24280 7590 05/06/2020
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Mark R. Baker, New York, NY;
Progenics Pharmaceuticals, Inc., New York, NY;

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IR103 (Rev. 10/09)



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY.DOCKET NO./TITLE	REQUEST ID
16/718,839	12/18/2019	Mark R. Baker	2010358-0167	160838

Acknowledgement of Loss of Entitlement to Entity Status Discount

The entity status change request below filed through Private PAIR on 03/09/2022 has been accepted.

CERTIFICATIONS:

Change of Entity Status:

☒ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be notification of loss of entitlement to small or micro entity status, as applicable.

This portion must be completed by the signatory or signatories making the entity status change in accordance with 37 CFR 1.4(d)(4).

Signature:	/Ronen Adato/
Name:	Ronen Adato, PhD.
Registration Number:	76341