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.
18/431,566	02/02/2024	Robert S Bunn	9354.08	1023

23308 7590 05/10/2024
Steven Colby
Rimon Law, P.C.
1655 W Fairview Ave, Suite 102
Boise, ID 83702

EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3798	

NOTIFICATION DATE	DELIVERY MODE
05/10/2024	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):

PV-PatentDoc@rimonlaw.com
docketing.rimonlaw@clarivate.com
eofficeaction@appcoll.com

PTOL-90A (Rev. 04/07)

Office Action Summary	**Application No.** 18/431,566	**Applicant(s)** Bunn, Robert S	
	Examiner JOEL F BRUTUS	**Art Unit** 3798	**AIA (FITF) Status** Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 2/2/24.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-16 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
6) ☐ Claim(s) _____ is/are allowed.
7) ☑ Claim(s) 1-16 is/are rejected.
8) ☐ Claim(s) _____ is/are objected to.
9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, 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.**

Application Papers

10)☐ The specification is objected to by the Examiner.
11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ 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)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ______.
3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ______.
4) ☐ Other: ______.

DETAILED ACTION

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.

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

1. Claim(s) 1-2, 4-7, 9, 11, 13, 15-16 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Srivastava et al (Pub. No.: US 2016/0071266).

Regarding claim 1, Srivastava et al disclose a system configured to make a medical determination, the system comprising:

an image storage storing images of a body part of a patient [see 0024-0026, fig 2];

image analysis logic comprising a trained neural network in communication with the image storage and configured to provide a determination regarding the patient's clinical or lab value, based on the stored images [see 0015-0016, 0018, 0023-0026, 0036-0037, fig 1] by disclosing it will be appreciated that a clinical parameter, as used herein, can be a categorical parameter, representing a specific disorder or a clinical treatment that is likely to be useful for the region of interest, or a continuous parameter, such as a metric representing a likelihood that a given treatment will be successful [see 0018];

a user interface configured to provide the determination to a user [see 0034];

a microprocessor configured to execute at least the image analysis logic [see 0036-0037 and fig 1].

Regarding claim 2, Srivastava et al disclose analyze the stored images to determine a present clinical or lab value at the time the stored images were acquired [see 0026].

Regarding claim 4, Srivastava et al disclose employ a regression algorithm to provide the determination as a range [see 0019, fig 1] by disclosing the outcome class can represent a predicted range of outcomes for the patient given the application of the therapeutic procedure. This can range from a binary “good” and “bad” to a plurality of graduations of expected success [see 0019].

Regarding claim 5, Srivastava et al disclose a classification algorithm to provide the determination as one of a plurality of categories [see 0019, 0022].

Regarding claim 6, Srivastava et al disclose provide the determination based additionally on a clinical data set. [see 0018, 0024, fig 1] by disclosing It will be appreciated that a clinical parameter, as used herein, can be a categorical parameter, representing a specific disorder or a clinical treatment that is likely to be useful for the region of interest, or a continuous parameter, such as a metric representing a likelihood that a given treatment will be successful [see 0018].

Regarding claim 7, Srivastava et al disclose to acquire images, some of the images becoming the stored images [see 0015-0016, 0025-0026, fig 1].

Regarding claim 9, Srivastava et al disclose a method for training a neural network to make a medical determination, the method comprising:

receiving a set of images of body parts of a plurality of patients, the images tagged (by assigning clinical parameters to the images, 0033) with information concerning the current or future lab values [see 0015-0016, 0018, 0023-0026, 0033, 0036-0037, claims 1-2 and fig 2] by disclosing it will be appreciated that a clinical parameter, as used herein, can be a categorical parameter, representing a specific disorder or a clinical treatment that is likely to be useful for the region of interest, or a continuous parameter, such as a metric representing a likelihood that a given treatment will be successful [see 0018];

dividing the set of images into a training set (a plurality of training images) and a validation set (associated confidence value) [see 0019, 0022];

providing the images of the training set (a plurality of training images), and their tags (assigned parameters) to a neural network to train the neural network to determine a current or future lab or clinical values based on images of the body parts [see 0017-0019, 0032];

providing images of a single patient from the validation set to the neural network to make a determination and comparing the determination to the tag associated with the images [see 0020].

Regarding claim 11, Srivastava et al disclose classifying the images before providing the images of the training set to the neural network [see 0017, 0019].

Regarding claim 13, Srivastava et al disclose method for making a medical determination, the method comprising:

generating an image of a body part of a patient;

providing the image to a neural network that has been trained to determine the patient's current or future clinical or lab values from the image of the body part [see 0015-0016, 0018, 0023-0026, 0036-0037, fig 1] by disclosing it will be appreciated that a clinical parameter, as used herein, can be a categorical parameter, representing a specific disorder or a clinical treatment that is likely to be useful for the region of interest, or a continuous parameter, such as a metric representing a likelihood that a given treatment will be successful [see 0018];

receiving the determination of the clinical or lab value [see 0018, 0024].

Regarding claim 15, Srivastava et al disclose a regression algorithm and receiving the determination includes receiving a range [see 0019, fig 1] by disclosing the outcome class can represent a predicted range of outcomes for the patient given the application of the therapeutic procedure. This can range from a binary "good" and "bad" to a plurality of graduations of expected success [see 0019].

Regarding claim 16, Srivastava et al disclose wherein the neural network employs a classification algorithm and receiving the determination includes receiving one of a plurality of categories [see 0019, 0022].

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim(s) 3, 10, 14 are rejected under 35 U.S.C. 103 as being unpatentable over Srivastava et al (Pub. No.: US 2016/0071266) in view of Samec et al (Pub. No.: US 2017/0000683)

Regarding claim 3, Srivastava et al don't disclose second logic configured to determine a future or lab value within a timeframe.

Nonetheless, Samec et al disclose determine a future or lab value within a timeframe [see 1752, 1607, 1609].

Therefore, it is obvious to one skilled in the art at the time the invention was filed and would have been motivated to combine Srivastava et al and Samec et al by determining a future or lab value within a timeframe; to monitor the effectiveness of treatment for diagnosed ocular hypertension [see 1752].

Regarding claims 10, 14, Srivastava et al don't disclose wherein the image is an ultrasound image.

Nonetheless, Samec et al disclose wherein the image is an ultrasound image [see 0450, 0909].

Therefore, it is obvious to one skilled in the art at the time the invention was filed and would have been motivated to combine Srivastava et al and Samec et al by using ultrasound image; offer valuable insight into the best treatment or medical procedures to effectively tackle various health conditions, making it an essential tool. Ultrasound techniques differ from other imaging procedures, as no radiation is used. As a result, any adverse patient response usually caused by radiation exposure is avoided. Other imaging tests often need substances known as contrast agents. These contrast agents help to emphasize specific areas in the body with issues during diagnostic imaging. Patients are usually administered the agents by oral medications or injection in blood circulation pathways. Many people suffer allergic reactions to these substances. Similar contrast agents for ultrasound imaging are not required in most cases, thus ensuring patient safety. Diagnostic ultrasound methods are generally painless. After all, they do not need injections, incisions, or needles. As a result, patients avoid postoperative chronic pain or operative complications.

3. Claim(s) 8 is rejected under 35 U.S.C. 103 as being unpatentable over Srivastava et al (Pub. No.: US 2016/0071266) in view of Herickhoff et al (Pub. No.: US 2018/0153504)

Regarding claims 8, Srivastava et al don't disclose feedback logic configured to guide a user of the image generator in acquiring the images.

Nonetheless, Herickhoff et al disclose feedback logic configured to guide a user of the image generator in acquiring the images [see 0113] by disclosing external device 98 can have a display for displaying and interacting with the 3D volume. The external device 98 display can also function as a user interface to guide and/or facilitate user acquisition of data (e.g., prompts, instructions, configuration selections, modes, etc.) External device 98 can also have memory to store data or information, which can be used for any of post-acquisition 3D image volume generation (processing and reconstruction), visualization, and analysis [see 0113].

Therefore, it is obvious to one skilled in the art at the time the invention was filed and would have been motivated to combine Srivastava et al and Herickhoff et al by using a feedback logic configured to guide a user of the image generator in acquiring the images; to guide and/or facilitate user acquisition of data (e.g., prompts, instructions, configuration selections, modes, etc.) [see 0113].

4. Claim(s) 12 are rejected under 35 U.S.C. 103 as being unpatentable over Srivastava et al (Pub. No.: US 2016/0071266) in view of Abolmaesumi et al (Pub. US 2020/0069292).

Regarding claims 12, Srivastava et al don't disclose resizing the images before providing the images of the training set to the neural network.

Nonetheless, Abolmaesumi et al disclose resizing the images before providing the images of the training set to the neural network [see 0070] by analyzer processor 100 to crop the raw frames down to include only the ultrasound beam, the boundaries of which may be adjustable by the user. The cropped data may be resized down to 120x120 to match input dimensions of the neural network implemented by the analyzer 14 [see 0070].

Therefore, it is obvious to one skilled in the art at the time the invention was filed and would have been motivated to combine Srivastava et al and Abolmaesumi et al by resizing the images before providing the images of the training set to the neural network; to match input dimensions of the neural network [see 0070].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached Mon-Fri, 10:00 AM to 7:00 PM.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Jeff Hoekstra** can be reached on 571-272-7232. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JOEL F BRUTUS/
Primary Examiner, Art Unit 3798

Notice of References Cited	Application/Control No. 18/431,566	Applicant(s)/Patent Under Reexamination Bunn, Robert S	
	Examiner JOEL F BRUTUS	Art Unit 3798	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20160071266-A1	2016-03-10	Srivastava; Sunil K.	G06T7/0016	382/130
*	B	US-20170000683-A1	2017-01-05	Samec; Nicole Elizabeth	A61B3/066	
*	C	US-20180153504-A1	2018-06-07	HERICKHOFF; Carl Dean	A61B8/4472	1/1
*	D	US-20200069292-A1	2020-03-05	Abolmaesumi; Purang	A61B8/5207	1/1
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	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 YYYY-MM-DD 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. 20240506