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Cleveland Medical Devices Inc. 4415 Euclid Ave. Ste. 500 Cleveland, OH 44103			EXAMINER NASSER, ROBERT L	
			ART UNIT	PAPER NUMBER
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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.



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Boston, MA 02110

***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/019,700 .

PATENT UNDER REEXAMINATION 11375921 .

ART UNIT 3992 .

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting Request For Ex Parte Reexamination	Control No. 90/019,700	Patent Under Reexamination 11375921	
	Examiner ROBERT L NASSER	Art Unit 3992	AIA (FITF) Status Yes

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

The request for *ex parte* reexamination filed 10/11/2024 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☐ PTO/SB/08, c) ☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

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cc:Requester (if third party requester)

L Decision on Request

A substantial new question of patentability (SNQ) affecting claims 1-16 of US Patent 11,375,921 (the ‘921 patent) to Kayyali et al is deemed to be raised by the Request For Ex Parte Reexamination (the request), which was filed October 11, 2024.

Prior Art Cited in the Request

US Patent 6,644, 311 to Truit et al, filed December 19, 2001 and issued November 11, 2003 (“Truit”).

US Patent 8,187,209 to Giuffrida, filed March 17, 2005 and issued May 29, 2012 (“Giuffrida”).

US PG PUB 2004/0129838 to Lisy et al, filed January 3, 2003 and published July 8, 2004 (“Lisy”).

US Patent 6,167,258 to Schmidt et al, filed October 9, 1998 and issued December 26, 2000 (“Schmidt”).

US Patent 7,575,005 to Mumford et al, filed May 18, 2005 and issued August 18, 2009 (“Mumford”).

WO 02/078775 to Genger et al, published October 2, 2002 (“Genger”).

US Patent 5,309,921 to Kisner et al, filed February 11, 1992 and issued May 10, 1994 (“Kisner”).

JP 2002-291889 to Toge, published October 8, 2002 (“Toge”).

WO 04/078775 to Burton et al, filed October 9, 2003 and published April 22, 2004 (“Burton”).

Issues Raised By the Request

Issue 1: The request alleges that the technological teachings of the ‘Truitt, Giuffrida, and Lisy, alone or in combination with Burton raise a substantial new question (SNQ) of patentability regarding claims 1-16 of the ‘921 patent, as follows:

A. The request alleges that the technological teachings of Truit, Giuffrida, and Lisy raise an SNQ with respect to claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent (SNQ 1).

B. The request alleges that the technological teachings of Truit, Giuffrida, Lisy, and Burton raise an SNQ with respect to claims 5, 9, and 14 of the '921 patent (SNQ 2).

Truit issued in 2003, which predates the earliest possible filing date of the '921 patent by more than one year. Giuffrida was filed March 17, 2005, which predates earliest possible filing date of the '921 patent. Lisy was published July 8, 2004, which predates the earliest possible filing date of the '921 patent by more than one year. Burton published April 22, 2004, which predates the earliest possible filing date of the '921 patent by more than one year. As such, Truit, Lisy, and Burton qualify as prior art under 35 USC 102(b) and Giuffrida qualifies as prior art at least under 35 USC 102(e).

Issue 2: The request alleges that the technological teachings of the Truit, Schmidt, and Lisy, alone or in combination with Burton raise a substantial new question (SNQ) of patentability regarding claims 1-16 of the '921 patent, as follows:

A. The request alleges that the technological teachings of Truit, Schmidt, and Lisy raise an SNQ with respect to claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent (SNQ 3).

B. The request alleges that the technological teachings of Truit, Schmidt, Lisy, and Burton raise an SNQ with respect to claims 5, 9, and 14 of the '921 patent (SNQ 4).

Schmidt issued in 2000, which predates the earliest possible filing date of the '921 patent by more than one year. As such, Schmidt qualifies as prior art under 35 USC 102(b).

Issue 3: The request alleges that the technological teachings of the Mumford, Genger, and Kisner, alone or in combination with Burton raise a substantial new question (SNQ) of patentability regarding claims 1-16 of the '921 patent, as follows:

A. The request alleges that the technological teachings of Mumford, Genger, and Kisner Lisy raise an SNQ with respect to claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent (SNQ 5).

B. The request alleges that the technological teachings of Mumford, Genger, Kisner, and Burton raise an SNQ with respect to claims 5, 9, and 14 of the '921 patent (SNQ 6).

Mumford was filed May 18, 2005, which predates the earliest possible filing date of the '921 patent. Genger published in 2002, which predates the earliest possible filing date of the '921 patent by more than one year. Kisner issued in 1994, which predates the earliest possible filing date of the '921 patent by more than one year. As such, Mumford qualifies as prior art under 35 USC 102(e) and Genger and Kisner qualify as prior art under 35 USC 102(b).

Issue 4: The request alleges that the technological teachings of the Mumford, Toge, and Kisner, alone or in combination with Burton raise a substantial new question (SNQ) of patentability regarding claims 1-16 of the '921 patent, as follows:

A. The request alleges that the technological teachings of Mumford, Toge, and Kisner Lisy raise an SNQ with respect to claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent (SNQ 5).

B. The request alleges that the technological teachings of Mumford, Toge, Kisner, and Burton raise an SNQ with respect to claims 5, 9, and 14 of the '921 patent (SNQ 6).

Toge published in 2002, which predates the earliest possible filing date of the '921 patent by more than one year. As such, Toge qualifies as prior art under 35 USC 102(b).

Background

Claims 1-16 are the current claims in the Kayyali et al patent (11,375,921) that issued July 5, 2022, from application 16/057963, which was filed August 8, 2018 (the '963 application). The '963 application is a continuation of US application 13/440116, filed April 5, 2012, which is a continuation of US Application 11/266899, filed November 4, 2005

US Patent 11,375,921 is generally system and method for sleep disorder treatment that adjusts PAP treatment based data from an airflow sensor.

Prosecution History

1. The '963 application was filed with claims 1-20.
2. In the first action, dated February 16, 2021, claims 1-20 were rejected under art over art.
3. Prosecution continued until the final rejection of 1/21/2022, which rejected claims 1-17 on art and indicated that claims 18-20 would be allowable. The Examiner included the following reasons for allowance:

As to Claims 18-20, Farrell teaches the subject matter of claims 4-6, as discussed above. However, neither Farrell, Chervin, Tsukashima, nor the prior art of record teaches the sleeping disorder treatment system of base claims 4-6, including the following, in combination with all other limitations of the base claims:

wherein signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis. '963 application, final rejection of 1/21/2022, page 30.

4. In an after final response of 4/20/2022, the Applicant incorporated claims 18, 19, and 20 into the independent claims.

6. On May 23, 2022, the Examiner responded by issuing a Notice of Allowance, repeating the same reasons for allowance as above.

7. As such, it appears from the record that the primary features missing from the prior art at the time of allowance of the claims 1-16 of the '921 patent is that signals from the sensors are processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursive fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

Scope of Reexamination

On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis. In the present instance, an SNQ appears to exist based on the existence of newly uncovered prior art that was not before the Examiner at the time of examination.

35 USC 325(d)

A review of the post grant history for the underlying patent indicates that there have been no other Office post grant challenges made to the patent (Reexamination Proceedings, Inter Partes Reviews, Post Grant Review, or Covered Business Method trials). Accordingly, a discretionary denial of reexamination pursuant to 35 USC 325(d) is not applicable.

Analysis

Issue 1: None of Truit, Giuffrida, and Lisy were of record during prosecution of the '921 patent and are therefore new art. The US version of Burton was of record, but was not applied or discussed. As such, Burton is being viewed in a new light.

It is agreed that the technological teachings of Truit, Giuffrida, and Lisy raise an SNQ with respect to claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent. Truit shows a conventional CPAP which is applied in the request to show features of the claims that were not the key feature

missing from the claims at the time of allowance. Giuffrida is a wireless medical device that is also applied in the request to show features of the claims that were not the key feature missing from the claims at the time of allowance. Finally, Lisy teaches in paragraph [0040], processing air flow data using signal processing techniques selected from the standard deviation technique, a recursively fit ARMAX system identification model, a short term Fourier Transform technique, and time-frequency signal analysis with a variety of different kernels. As such, appears that the technological teachings of Lisy teach the many of the key features identified above that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent, i.e. processing air flow signals using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursive fit ARMAX system identification model, a short-time fourier transform technique, and a time-frequency signal analysis with a variety of different kernels. Therefore, the combined teachings of Truit, Giuffrida, and Lisy also teach the key feature missing at the time of allowance. Since the teachings of the Truit, Giuffrida, and Lisy directly related to the subject matter considered as the basis for allowability of patent claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent, a reasonable examiner would consider the evaluation Truit, Giuffrida, and Lisy to be important in determining the patentability of claims 1-4, 6-8, 10-13, 15, and 16. As such, the teachings of the Truit, Giuffrida, and Lisy are deemed to raise an SNQ on claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent.

The request applies Burton to dependent claims 5, 9, and 14. Since the teachings of Truit, Giuffrida, and Lisy raise an SNQ on the independent claims, the references also raise an SNQ on the dependent claim. As such, Burton raises an SNQ on claims 5, 9, and 14 through dependency.

Issue 2: None of Truit, Schmidt, and Lisy were of record during prosecution of the '921 patent and are therefore new art. The US version of Burton was of record, but was not applied or discussed. As such, Burton is being viewed in a new light.

It is agreed that the technological teachings of Truit, Schmidt, and Lisy raise an SNQ with respect to claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent. Truit shows a conventional CPAP which is applied in the request to show features of the claims that were not the key feature missing from the claims at the time of allowance. Schmidt is also a wireless medical device is also applied in the request to show features of the claims that were not the key feature missing from the claims at the time of allowance. Finally, Lisy teaches in paragraph [0040], processing air flow data using signal processing techniques selected from the standard deviation technique, a recursively fit ARMAX system identification model, a short term Fourier Transform technique, and time-frequency signal analysis with a variety of different kernels. As such, it appears that the technological teachings Lisy teach the key features identified above that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent, i.e. processing air flow signals using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursive fit ARMAX system identification model, a short-time fourier transform technique, and a time-frequency signal analysis with a variety of different kernels. Therefore, the combined teachings of Truit, Schmidt, and Lisy also teach the key feature missing at the time of allowance. Since the teachings of the Truit, Schmidt, and Lisy directly related to the subject matter considered as the basis for allowability of patent claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent, a reasonable examiner would consider the evaluation Truit, Schmidt, and Lisy to be important in determining the patentability of claims 1-

16. As such, the teachings of the Truit, Schmidt, and Lisy are deemed to raise an SNQ on claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent.

The request applies Burton to dependent claims 5, 9, and 14. Since the teachings of Truit, Schmidt, and Lisy raise an SNQ on the independent claims, the references also raise an SNQ on the dependent claim. As such, Burton raises an SNQ on claims 5, 9, and 14 through dependency.

Issue 3: Neither of Genger, and Kisner were of record during prosecution of the '921 patent and are therefore new art. Mumford was of record during prosecution of the '921 patent, but was never cited or applied. It was also never considered in combination with Genger And Kisner. The US version of Burton was of record, but was not applied or discussed. As such, Mumford and Burton are being viewed in a new light.

It is agreed that the technological teachings of Mumford, Genger, and Kisner raise an SNQ with respect to claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent. Mumford shows a shows a conventional CPAP device 14 that is applied in the request against features of the claims that were not the key features missing from the references at the time of allowance. Genger shows a CPAP device that further discloses wireless communication (page 7, lines 25+, for example) between sensors and uses a cell phone or pda as the monitoring device (page 7, lines 5+), which is also relied upon in the request to teach features of the claims that were not the key features missing from the references at the time of allowance. Kisner further teaches processing breathing signals using a wavelet analysis (see column 13, lines 36-53). As such, it appears that the technological teachings of Kisner show part of the key feature identified above that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the

'921 patent, i.e. processing air flow signals using wavelet analysis. Therefore, the combined teachings of Mumford, Genger, and Kisner also teach the key feature missing at the time of allowance. Since the teachings of the Mumford, Genger, and Kisner directly related to the subject matter considered as the basis for allowability of patent claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent, a reasonable examiner would consider the evaluation Mumford, Genger, and Kisner to be important in determining the patentability of claims 1-16. As such, the teachings of the Mumford, Genger, and Kisner are deemed to raise an SNQ on claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent.

The request applies Burton to dependent claims 5, 9, and 14. Since the teachings of Mumford, Genger, and Kisner raise an SNQ on the independent claims, the references also raise an SNQ on the dependent claim. As such, Burton raises an SNQ on claims 5, 9, and 14 through dependency.

Issue 4: Neither of Toge and Kisner were of record during prosecution of the '921 patent and are therefore new art. Mumford was of record during prosecution of the '921 patent, but was never cited or applied. It was also never considered in combination with Toge and Lisy. The US version of Burton was of record, but was not applied or discussed. As such, Mumford and Burton are being viewed in a new light.

It is agreed that the technological teachings of Mumford, Toge, and Kisner raise an SNQ with respect to claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent. Mumford shows a conventional CPAP device 14 that is applied in the request against features that were not the key features missing from the references at the time of allowance. Toge is also a wireless medical device is also applied in the request to show features of the claims that were not the key feature

missing from the claims at the time of allowance. Kisner further teaches processing breathing signals using a wavelet analysis (see column 13, lines 36-53). As such, it appears that the technological teachings of Kisner teach the key features identified above that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent, i.e. processing air flow signals using wavelet analysis. Therefore, the combined teachings of Mumford, Toge, and Kisner also teach the key feature missing at the time of allowance. Since the teachings of the Mumford, Toge, and Kisner directly related to the subject matter considered as the basis for allowability of patent claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent, a reasonable examiner would consider the evaluation Mumford, Toge, and Kisner to be important in determining the patentability of claims 1-16. As such, the teachings of the Mumford, Toge, and Kisner are deemed to raise an SNQ on claims 1-4, 6-8, 10-13, 15, and 16 of the '921 patent.

The request applies Burton to dependent claims 5, 9, and 14. Since the teachings of Mumford, Toge, and Kisner raise an SNQ on the independent claims, the references also raise an SNQ on the dependent claim. As such, Burton raises an SNQ on claims 5, 9, and 14 through dependency.

Service of Papers

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550(f).

Waiver of Right to File Patent Owner Statement

In a reexamination proceeding, Patent Owner may waive the right under 37 C.F.R. 1.530 to file a Patent Owner Statement. The document needs to contain a statement that Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement and proof of service in the manner provided by 37 C.F.R. 1.248, if the request for reexamination was made by a third party requester, see 37 C.F.R. 1.550(f). The Patent Owner may consider using the following statement in a document waiving the right to file a Patent Owner Statement:

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Amendment in Reexamination Proceedings

Patent Owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c). See MPEP § 2250(IV) for examples to assist in the preparation of proper proposed amendments in reexamination proceedings.

Submissions

In order to ensure full consideration of any amendments, affidavits or declarations or other documents as evidence of patentability, such documents must be submitted in response to the first Office action on the merits (which does not result in a close of prosecution).

Submissions after the second Office action on the merits, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, after final rejection and by 37 CFR 41.33 after appeal, which will be strictly enforced.

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a), to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 11,375,921 throughout the course of this reexamination proceeding. Likewise, if present, the third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

All correspondence relating to this ex parte reexamination proceeding should be directed:

Electronically: Registered users may submit via Patent Center at <https://patentcenter.uspto.gov/>.

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For Patent Center transmissions, 37 CFR 1.8(a)(1)(i)(C) and (ii) states that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if (a) it is transmitted via the USPTO patent electronic filing system in accordance with 37 CFR 1.6(a)(4), and (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

Any inquiry concerning this communication or earlier communications from Examiner, or as to the status of this proceeding, should be directed to the Examiner at (571) 272-4731 or his supervisor, Alexander Kosowski at (571) 272-4731. General Inquiries should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

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