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NEW YORK, NY 10036

EXAMINER

NASSER, ROBERT L

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PAPER

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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***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)).

Final Action

This action addresses claims 1-19 of US Patent 11,375,921 (the '921 patent) to Kayyali et al for which a substantial new question of patentability was deemed to be raised by the Request For Ex Parte Reexamination (the request), which was filed October 11, 2024.

This action is being issued following Patent Owner's (PO) response of May 14, 2025, which included 1) claim amendments and 2) arguments. The amendments amend claims 1 and 9 as well as add claims 17-19.

The Examiner notes that the amendment is in improper reexam format. All new claims, i.e. claims 17-19, must be underlined, and the words lined through in claim 9 should be enclosed in single brackets. 37 CFR 1.530. Applicant should file a corrected amendment in response to this office action.

Prior Art

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

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

US PG PUB 2007/0161913 to Farrell et al, filed March 30, 2005 and published July 12, 2007 ("Farrell").

Statutes

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.

Rejections

The rejection below is confined to what has been deemed to be the best available art from the Request. However, prior to conclusion of this reexamination proceeding, claims must be patentable over all prior art cited in the order granting reexamination in order to be considered patentable or confirmed on the reexamination certificate. The references cited in the Request but not utilized in the current office action appear to be largely cumulative to the teachings in the references applied below.

Specifically, the Examiner notes that very similar claim 15 in US Patent 10,076,269 was finally rejected by the Board over Kocinski US PG PUB 20030236450 in view of Farrell WO 2005/096737, Bluetooth (Specification of the Bluetooth System v1.0 B December 1st 1999) and Paradiso (Conference Proceedings of the 34th International IEEE EMBS Special Topic Conference on Information Technology Applications in Biomedicine 2003). Further, the Board has instituted an IPR with several grounds of rejection based on the Toge reference, JP unexamined application 2002-291889A. In the event the current rejection is overcome, the rejections discussed above, in addition to any unaddressed rejections from the request, must be addressed and distinguished as well.

Claims 7-16 are rejected under 35 U.S.C. 103 as being unpatentable over Farrell in view of Giuffrida and Kisner.

7. A sleeping disorder treatment system comprising:

Farrell shows a device for treating sleep disordered breathing (see paragraph [0036]).

a PAP device configured to be a single enclosure, the PAP device comprising:

Farrell discloses a PAP device in figure 1 that has:

a blower having an air output;

a blower 2 that an output of breathing gas which is sent to the tube 8

an airflow sensor internal to the PAP device and adapted for measuring the respiratory airflow of a subject while using the PAP device;

an airflow sensor 4F and pressure sensor 4P, which are internal to the device and monitor the flow and/or pressure of the gas in the breathing circuit 14 (paragraph [0024])¹.

a first processor adapted for generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device;

Farrell has a controller or microprocessor 15, which monitors the output of the sensors 4f and 4p. The output of the sensors is used to determine symptoms of the patient, for example the AHI index mentioned in paragraph [0037] and performs compliance tracking, which tracks the usage of the device (see paragraph [0036]).

a first radio frequency wireless transceiver;

Farrell has a wireless transceiver 10 (see paragraph [0026]).

a mask or a nasal cannula;

¹ As noted in Mumford, US Patent 7,575,005, column 12, lines 42-47, a pressure sensor that senses pressure in the mask cavity, like that of Farrell, can be used to derive the breathing rate. In order to derive breathing rate, the signal must be related to respiratory flow.

Farrell has a mask 6.

wherein the airflow sensor and the first processor are adapted for measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment and further providing for a data related the subject's treatment and the treatment's efficacy;

The airflow sensor and controller 15, i.e. first processor, combine to determine data regarding the severity of the patient's condition, the AHI index. The Examiner notes that by monitoring the patient's condition during treatment, the efficacy of the treatment is determined, i.e. if the index improves the treatment is working. See paragraph [0032].

wherein the blower, and the mask or the nasal cannula are adapted for physically or chemically treating a subject's sleeping disorder symptoms,

The Examiner notes that the blower and the mask/cannula physically treat the patient by supplying air under pressure to physically keep the airway open.

wherein the first processor is configured to adjust or re-adjust the blower using, in part, the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment;

Farrell teaches that the flow and pressure are monitored to determine the symptoms of the patient and the flow is adjusted based on the severity of the symptoms (for example on the number of apneas) (see paragraph [[0032]]).

a software stored on a non-transitory computer readable medium and executable by a second processor, the software adapted to be used with and to display the data related to the subject's treatment and the treatment's efficacy to the subject or a care provider by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display;

Farrell shows a PDA that has its own processor that includes software. Farrell notes that the device can communicate with hand held display devices, like the PDA (see paragraph [0026]).

As such, the PDA displays the data from the PAP device related to treatment and efficacy, where the PDA would have its own wireless transceiver.

and a remote internet site, the remote internet site adapted to receive the data relate to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

Farrell sends data for later analysis to a database through a network. It is not clear that it is an internet site. Giuffrida is a similar medical device that sends data to a remote internet site, for later viewing and analysis by the physician (see column 13, lines 5-36). As such, it would have been obvious to modify Farrell to have the database be part of an internet site, as it is merely the substitution of one known data structure for another. Since both references are from telemedicine devices, the results would be predictable.

wherein the software is further adapted to receive, in whole or part, the data related to the subject's treatment and the treatment's efficacy generated by the PAP device that is first received by then retransmitted from the remote internet site,

As just discussed, the combination retransmits data received at the second remote device to the remote internet site, where the data is received from the first wireless transceiver of the PAP device. Hence, the software at the remote communications station performs this function.

Further, Giuffrida teaches that the remote station can send data to another device and back. The remote station also can send data to the remote internet site. See column 13, lines 5-36. It is the Examiner's position that this combination of teaches suggests that data can be sent from the remote station to the internet site and back. Hence, the combination meets the claim language.

and wherein the sensor data from the sensors is processed by the first processor 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 kernals, and a wavelet analysis.

The combination above does not use any of the recited signal processing techniques. Kisner shows a device for monitoring breathing that uses a wavelet transformation to extract parameters from a breathing signal. Again, while the processing is not exactly the same environment as Farrell, Kisner teaches the use of a known processing technique in an airflow monitoring field. As such, it would have been obvious to modify the combination above to use the processing technique of Kisner, as it is merely the use of a well-known processing technique in the art. This qualifies under rationale C, D, E and F of KSR (see MPEP 2141 III. Since both Farrell and Kisner are air flow measuring devices, the combination would produce predictable results. The Examiner notes that the PTAB used similar logic in issuing a final decision in IPR2023-00565 over the Paradiso reference.

8. The system in claim 7, wherein the PAP device and the remote internet site as well as the remote internet site and the software adapted for the base station, cellular phone or PDA transmit the data related to the subject's treatment and the treatment's efficacy via cell towers or cable.

As noted in column 13, lines 5-36 of Giuffrida, the communication can be via cell towers. Hence, it would have been obvious to modify Farrell to have the wireless communication be performed using cell towers, as it is merely the use of a well-known wireless technique in the art.

9. The system in claim 7, wherein the wherein the index of the subject's symptoms is a respiratory disturbance index.

Farrell determines the apnea/hypopnea index, which is a respiratory distress index (see paragraph [0037]).

10. The system in claim 7, wherein the software adapted for use with the base station, cellular phone or PDA is configured to be reprogrammed or modified remotely.

As to claim 10, since the remote station of Farrell has wireless technology, it is configured to be reprogrammed remotely, such as by wirelessly downloading a program update.

11. The system of claim 7, wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the data related to the subject's treatment and the treatment's efficacy transmitted to the remote internet site.

Giuffrida teaches that the data is sent to the internet site for analysis in column 13. In combination with the teaching of Farrell to adjust the treatment based on the analysis of the data, discussed above, the combination would adjust the treatment from a signal received from the internet site. As such, the combination would have an electronic component to allow adjustment of the PAP device.

12. A sleeping disorder treatment system comprising:

Farrell shows a device for treating sleep disordered breathing (see paragraph [0036]).

a PAP device configured to be a single enclosure, the PAP device comprising:

Farrell discloses a PAP device in figure 1 that has:

a blower having an air output;

a blower 2 that an output of breathing gas which is sent to the tube 8

an airflow sensor internal to the PAP device and adapted for measuring the respiratory airflow of a subject while using the PAP device;

an airflow sensor 4F and pressure sensor 4P, which are internal to the device and monitor the flow and/or pressure of the gas in the breathing circuit 14 (paragraph [0024]).

a first processor adapted for generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device;

Farrell has a controller or microprocessor 15, which monitors the output of the sensors 4f and 4p. The output of the sensors is used to determine symptoms of the patient, for example the AHI index mentioned in paragraph [0037] and performs compliance tracking, which tracks the usage of the device (see paragraph [0036]).

a first radio frequency wireless transceiver;

Farrell has a wireless transceiver 10 (see paragraph [0026]).

a mask or a nasal cannula;

Farrell has a mask 6.

wherein the airflow sensor and the first processor are adapted for measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment and further providing for a data related the subject's treatment and the treatment's efficacy;

The airflow sensor and controller 15, i.e. first processor, combine to determine data regarding the severity of the patient's condition, the AHI index. The Examiner notes that by monitoring the patient's condition during treatment, the efficacy of the treatment is determined, i.e. if the index improves the treatment is working. See paragraph [0032].

wherein the blower, and the mask or the nasal cannula are adapted for physically or chemically treating a subject's sleeping disorder symptoms,

The Examiner notes that the blower and the mask/cannula physically treat the patient by supplying air under pressure to physically keep the airway open.

wherein the first processor is configured to adjust or re-adjust the blower using, in part, the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment;

Farrell teaches that the flow and pressure are monitored to determine the symptoms of the patient and the flow is adjusted based on the severity of the symptoms (for example on the number of apneas) (see paragraph [[0032]]).

a software stored on a non-transitory computer readable medium and executable by a second processor, the software adapted to be used with and to display the data related to the subject's treatment and the treatment's efficacy to the subject or a care provider by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display;

Farrell shows a PDA that has its own processor that includes software. Farrell notes that the device can communicate with hand held display devices, like the PDA (see paragraph [0026]).

As such, the PDA displays the data from the PAP device related to treatment and efficacy, where the PDA would have its own wireless transceiver.

and a remote internet site, the remote internet site adapted to receive the data relate to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

Farrell sends data for later analysis to a database through a network. It is not clear that it is an internet site. Giuffrida is a similar medical device that sends data to a remote internet site, for later viewing and analysis by the physician (see column 13, lines 5-36). As such, it would have been obvious to modify Farrell to have the database be part of an internet site, as it is merely the substitution of one known data structure for another. Since both references are from telemedicine devices, the results would be predictable.

wherein both the software and the remote internet site independently receive, in whole or part, the data related to the subject's treatment and the treatment's efficacy generated by the PAP device,

Giuffrida teaches in column 13, lines 5-36 that both the internet site and the remote station can receive the data directly from the PAP device. Hence, the combination meets the claim language.

and wherein the sensor data from the sensors is processed by the first processor 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 kernals, and a wavelet analysis.

The combination above does not use any of the recited signal processing techniques. Kisner shows a device for monitoring breathing that uses a wavelet transformation to extract parameters from a breathing signal. Again, while the processing is not exactly the same environment as Farrell, Kisner teaches the use of a known processing technique in an airflow monitoring field. As such, it would have been obvious to modify the combination above to use the processing technique of Kisner, as it is merely the use of a well- known processing technique in the art. This qualifies under rationale C, D, E and F of KSR (see MPEP 2141 III. Since both Farrell and Kisner are air flow measuring devices, the combination would produce predictable results. The Examiner notes that the PTAB used similar logic in issuing a final decision in IPR2023-00565 over the Paradiso reference.

13. The system in claim 12, wherein the first radio frequency wireless transceiver of the PAP device and the software adapted to use second radio frequency wireless transceiver of the base station, cellular phone or PDA to transmit the data related to the subject's treatment and the treatment's efficacy between each other using Bluetooth wireless protocol.

Giuffrida teaches that the data is transmitted wirelessly using blue tooth technology (column 7, lines 25-32 and column 16, line 2, for example). Hence, it would have been obvious to modify Farrell to use blue tooth technology, as it is merely the substitution of one known wireless technology for another.

14. The system in claim 12, wherein the wherein the index of the subject's symptoms is a respiratory disturbance index.

Farrell determines the apnea/hypopnea index, which is a respiratory distress index (see paragraph [0037]).

15. The system in claim 12, wherein the software adapted for use with the base station, cellular phone or PDA is configured to be reprogrammed or modified remotely.

As to claim 15, since the remote station of Farrell has wireless technology, it is configured to be reprogrammed remotely, such as by wirelessly downloading a program update.

16. The system of claim 12, wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the data related to the subject's treatment and the treatment's efficacy treatment transmitted to the remote internet site.

Giuffrida teaches that the data is sent to the internet site for analysis in column 13. In combination with the teaching of Farrell to adjust the treatment based on the analysis of the data, discussed above, the combination would adjust the treatment from a signal received from the internet site. As such, the combination would have an electronic component to allow adjustment of the PAP device.

Allowable Subject Matter

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

Claims 1-6 and 17-19 are patentable as amended. Specifically, independent claim 1 and dependent claims 18 and 19 now recite predicting the subject's symptoms prior to onset. None of the art of record has this feature. As such, the claims are patentable.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Answer to Arguments

With respect to the rejections based on Farrell, PO has made 3 observations regarding the Examiner's findings in a child application to the '921 patent, application 12/213775. Specifically, PO has asserted that the previous Examiner found that Farrell does not teach at least the following limitations:

an airflow sensor being any type of sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP device and outputting airflow sensor data,

a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating the one or more measures of the treatment efficacy comprising:

- i) the data of a severity of the sleep disorder symptoms of the subject,
- ii) the data of usage of the PAP device by the subject, and/or
- iii) the index based in whole or in part on either 1) or 11) or both 1) and 11),

a remote internet site, the remote internet site adapted for receiving the PAP data or data based on the at least one of the one or more treatment efficacy measures, related to the subject's treatment and the treatment's efficacy in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.

As to the first element, the Examiner notes that since the enclosure in the claims includes the mask, then a sensor in the mask is in the enclosure. As such, the sensors of Farrell are in the enclosure. In addition, as to whether the sensor measures respiratory airflow, the Examiner notes that Mumford, US Patent 7,575,005 teaches that a pressure sensor sensing pressure in the cavity of the mask, like that in Farrell, can be used to detect the breathing rate of the wearer, from which apneas and hypopneas can be determined. Breathing rate is related to respiratory flow. Hence, the sensor senses a signal related to respiratory flow. As such, the Examiner disagrees with the previous Examiner's findings in the '775 application.

As to the second element, the current claims do not recite that the second processor calculate one or more of the recited measures. Rather, the second processor need only receive the measures from the CPAP device. At present, Farrell teaches measuring the AHI in paragraph [0037] which is an index of the severity of symptoms.

As to the third limitation, Farrell and Giuffrida as discussed above, teach a remote internet site that receives the AHI index, which is a measure of treatment efficacy.

PO presented no other arguments regarding the Farrell based rejection. The Examiner wishes to make several additional points. First, with respect to the Kisner reference, the Examiner notes that the PTAB used similar logic to that applied above to issue a final decision rejecting the claims, using the Paradiso reference, in IPR2023-00565. As such, the rejection based on Kisner stands.

Second, to the extent that PO argued that Giuffrida does the processing at the remote site, the Examiner notes that Giuffrida states that the sensor signals are sent to the remote site for

analysis by the physician. This is not processing, but rather observation by the physician. The combination of Farrell and Giuffrida would send the AHI to the remote site for observation.

Hence, the Farrell based rejection stands.

Conclusion

THIS ACTION IS MADE FINAL.

A shortened statutory period for response to this action is set to expire two months from the mailing date of this action.

Extensions of time under 37 CFR 1.136(a) do not apply in reexamination proceedings. The provisions of 37 CFR 1.136 apply only to “an applicant” and not to parties in a reexamination proceeding. Further, in 35 U.S.C. 305 and in 37 CFR 1.550(a), it is required that reexamination proceedings “will be conducted with special dispatch within the Office.”

Extensions of time in reexamination proceedings are provided for in 37 CFR 1.550(c). A request for extension of time must specify the requested period of extension and it must be accompanied by the petition fee set forth in 37 CFR 1.17(g)(1). Any request for an extension in a third party requested ex parte reexamination must be filed on or before the day on which action by the patent owner is due, and the mere filing of a request will not affect any extension of time. A request for an extension of time in a third party requested ex parte reexamination will be granted only for sufficient cause, and for a reasonable time specified. Any request for extension in a patent owner requested ex parte reexamination (including reexamination ordered under 35 U.S.C. 257) for up to two months from the time period set in the Office action must be filed no later than two months from the expiration of the time period set in the Office action. A request for an extension in a patent owner requested ex parte reexamination

for more than two months from the time period set in the Office action must be filed on or before the day on which action by the patent owner is due, and the mere filing of a request for an extension for more than two months will not affect the extension. The time for taking action in a patent owner requested ex parte reexamination will not be extended for more than two months from the time period set in the Office action in the absence of sufficient cause or for more than a reasonable time.

The filing of a timely first response to this final rejection will be construed as including a request to extend the shortened statutory period for an additional two months. In no event, however, will the statutory period for response expire later than SIX MONTHS from the mailing date of the final action. See MPEP § 2265.

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).

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. 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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