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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BO OLDE and KRISTIAN SOLEM

Appeal 2018-004375
Application 13/519,067[1]
Technology Center 3700

Before STEFAN STAICOVICI, LEE L. STEPINA, and ARTHUR M. PESLAK, *Administrative Patent Judges*.

STAICOVICI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Bo Olde and Kristian Solem ("Appellants") appeal under 35 U.S.C. § 134(a) from the Examiner's decision in the Final Office Action (dated March 7, 2017, hereinafter "Final Act.") rejecting claims 1–3, 6–10, 12–18, and 38–52.[2] We have jurisdiction under 35 U.S.C. § 6(b).

SUMMARY OF DECISION

We AFFIRM.

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[1] According to Appellants' Appeal Brief (dated Aug. 14, 2017, hereinafter "Appeal Br.") Gambro Lundia AB is the real party in interest. Appeal Br. 2.
[2] Claims 4, 5, 11, and 19–37 are canceled. *Id.*

INVENTION

Appellants' invention relates to a monitoring apparatus for "detection of the onset of rapid (i.e. acute) symptomatic drop in a subject's blood pressure." Spec. 1, ll. 5–7.

Claims 1 and 38 are independent. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A monitoring arrangement for predicting a symptomatic blood pressure decrease in a subject, the monitoring arrangement comprising:
>
> a pulse recording apparatus configured to repeatedly register a pulse shape parameter in a peripheral body part of the subject based on a pulse signal, wherein each registered pulse shape parameter is a sequence of signal values in a respective time window representing a segment in the pulse signal, wherein the pulse recording apparatus comprises a pulse oximetry instrument configured to register the pulse shape parameter based on light response variations in at least one blood vessel of the subject, and
>
> a control unit configured to receive a plurality of pulse shape parameters registered by the pulse recording apparatus, wherein each received pulse shape parameter represents a different sequence of signal values, the control unit comprising a processing unit configured to:
>
> calculate, during a measurement period, a plurality of pulse magnitude measures, each calculated pulse magnitude measure based on a different received pulse shape parameter registered by the pulse recording apparatus,
>
> calculate a statistical dispersion measure from the plurality of calculated pulse magnitude measures,
>
> investigate whether the calculated statistical dispersion measure fulfils a statistical measure decision criterion relative to a reference predetermined statistical dispersion measure, and
>
> generate an output signal indicating a prediction of a symptomatic blood pressure decrease in the subject

based on the calculated statistical dispersion measure fulfilling the decision criterion relative to the reference predetermined statistical dispersion measure, wherein the output signal comprises an alarm triggering signal prompting performance of at least automatic actions, and

wherein the monitoring arrangement is connected to a dialysis machine comprising one or more systems in the dialysis machine configured to be activated by the alarm triggering signal to automatically perform at least one of a plurality of actions to counter-act an occurrence of a hypotension event in response to generation of an output signal indicating a prediction of a symptomatic blood pressure decrease in the subject, wherein the plurality of actions to counter-act an occurrence of a hypotension event comprises adjusting a rate of fluid removal from the subject by reducing and/or stopping a rate of fluid removal, increasing a conductivity in a dialysis fluid, supplying a saline bolus to a blood line connected to the cardiovascular system of the subject, adjusting a position of a controllable structure supporting the subject, and setting a dialysis monitor in bypass.

REJECTIONS

I. Claims 1–3, 6–10, 12–18, and 38–52 are rejected under 35 U.S.C. § 103(a) as unpatentable over Sornmo et al. (US 2009/0272678 A1, pub. Nov. 5, 2009, hereinafter "Sornmo"), Al-Ali et al. (US 2008/0188733 A1, pub. Aug. 7, 2008, hereinafter "Al-Ali"), Mancini et al. (E Mancini, *Short Term Variability of Oxygen Saturation During Hemodialysis is a Warning Parameter for Hypotension Appearance*, Computers in Cardiology, 35:881–883 (2008), hereinafter "Mancini"), Storm (US 2011/0144523 A1, pub. June 16, 2011), and Bassale (Jules Bassale, *Hypotension Prediction Arterial Blood Pressure Variability*, Electrical and Computer Engineering, Portland State University ECE 457: Learning From Data (Spring 2001)).

II. Claims 1–3, 6–10, 12–18, and 38–52 are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1–37 of copending U.S. Application No. 13/519,559.

ANALYSIS

Rejection I

Appellants do not present arguments for the patentability of claims 2, 3, 6–10, 12–18, and 38–52 apart from claim 1. *See* Appeal Br. 6–16. Therefore, in accordance with 37 C.F.R. 41.37(c)(1)(iv), we select claim 1 as the representative claim to decide the appeal, with claims 2, 3, 6–10, 12–18, and 38–52 standing or falling with claim 1.

The Examiner finds that Sornmo discloses a monitoring apparatus for "predicting rapid symptomatic blood pressure decrease in a subject" including, *inter alia*, a processing unit configured to calculate a plurality of pulse magnitude measures that are used to generate an output signal indicating the prediction of asymptomatic blood pressure decrease in the subject. Final Act. 3–4 (emphasis omitted). However, the Examiner finds that Sornmo does not "calculate a statistical dispersion measure from plurality of calculated pulse magnitude measures," [3] as recited by claim 1, to generate the output signal. *Id.* at 5. Thus, the Examiner turns to Al-Ali, which, the Examiner finds, discloses "calculate[ing] a statistical dispersion measure from pulse plurality of calculated pulse magnitude measures from a

[3] Appellants' Specification describes a *statistical dispersion measure* as "any measure that represents a variability or spread of a sequence of values," such as "standard deviation (σ), variance (σ^2), coefficient of variation (σ/μ) and variance-to-mean (σ^2/μ)," and may also include "normalized and/or weighted variants." Spec. 17, ll. 1–5, 14.

pulse oximeter . . . for the purpose [of] generating an output signal indicating a prediction of the physiological condition of a patient." *Id.* at 5. The Examiner further employs Bassale, Storm, and Mancini as evidence that calculating a statistical dispersion measure is well known. *Id.* at 6. Hence, the Examiner concludes that it would have been obvious to a person of ordinary skill in the art to modify the apparatus of Sornmo to calculate a statistical dispersion from the plurality of calculated pulse magnitude measures, as taught by Al-Ali, to generate an output signal indicating a prediction of a symptomatic blood pressure decrease in the patient. *Id.* According to the Examiner, the modification is "for the predictable purpose of generating an output signal indicating a prediction of the physiological condition of a patient based on the calculated statistical dispersion measure." *Id.*

Appellants argue that Al-Ali's broad disclosure of a statistical dispersion is insufficient to establish that "a statistical dispersion of a plurality of calculated pulse magnitude measures would *necessarily* result in being able to predict a symptomatic blood pressure decrease," and, thus, Al-Ali is deficient in supporting the Examiner's modification for the following reasons. Appeal Br. 9–10. First, Appellants argue that Al-Ali provides "an early warning of a *slowly* deteriorating patient condition," whereas Sornmo detects "the *rapid* onset of symptomatic blood pressure decrease." *Id.* at 10. Second, Appellants contend that Al-Ali "only uses blood pressure (BP) as an *input* parameter," but does not predict symptomatic blood pressure decrease. *Id.* Third, Appellants assert that Al-Ali does not use a pulse magnitude

measure[4], but rather uses "multiple types of parameters (e.g., SpO_2 and pulse rate) to predict patient condition instead." *Id.* Appellants' fourth argument is that Al-Ali does not use pulse shape parameters[5] as an input. *Id.* As to the disclosures of Bassale, Storm, and Mancini, Appellants argue that they do not remedy the shortcomings of Sornmo and Al-Ali because these references do not disclose "a calculated statistical dispersion measure (which is calculated from the plurality of pulse magnitude measures) in the prediction of a symptomatic blood pressure decrease in a subject." *Id.* at 10–11.

We are not persuaded by Appellants' arguments because Appellants cannot show nonobviousness by attacking Sornmo, Al-Ali, Bassale, Storm, and Mancini individually when the rejection as articulated by the Examiner is based on a combination of these references. *See In re Merck & Co. Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). In this case, Sornmo discloses "predict[ing] rapid symptomatic blood pressure decrease in the subject P based on an initial pulse magnitude measure PM1 calculated from a pulse shape parameter p_{PS}." Sornmo, para. 40; *see also* Examiner Answer (dated Jan. 25, 2018, hereinafter "Ans.") at 2. Al-Ali discloses that physiological parameters, such as "pulse rate," are used as inputs to generate outputs including "alarms, diagnostics and controls," and that the data is "normalized" and used to "calculate averages, variances, and/or other analytical measures of various physiological parameters over time." Al-Ali,

[4] "[T]he pulse magnitude measure PM represents the magnitude of the signal values in the signal segment." Spec. 9, ll. 23–24.
[5] "[A] 'pulse shape parameter p_{PS}' refers to a signal segment in, or derived from, the pulse signal S, i.e. a sequence of signal values within a time window." Spec. 9, ll. 16–17.

paras. 7, 53, 67, and 84; *see also* Ans. 2–3. As the data in Al-Ali is "normalized" and used to "calculate averages, variances, and/or other analytical measures," a person of ordinary skill in the art would readily appreciate that Al-Ali discloses calculating a statistical dispersion measure.[6] *See e.g.*, *In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962). Bassale, Storm, and Mancini disclose that calculating a statistical dispersion measure and generating an output signal based on the calculated statistical dispersion measure are well known. *See* Ans. 3 (citing Bassale, Abstract; Storm, para. 27; Mancini, p. 882).

As such, Sornmo uses pulse magnitude measures to predict symptomatic blood pressure decrease, Al-Ali calculates a statistical dispersion measure using normalized or averaged pulse rate data to generate outputs including "alarms, diagnostics and controls," and Bassale, Storm, and Mancini disclose calculating a statistical dispersion measure and generating an output signal based on the calculated statistical dispersion. Therefore, the Examiner has a sound basis for determining that a skilled artisan would use Sornmo's pulse magnitude measures to calculate a statistical dispersion measure, as taught by Al-Ali, in order to modify Sornmo's output signal to indicate a prediction of symptomatic blood pressure decrease in a patient. *See* Ans. 4. Accordingly, the Examiner is on solid footing to shift the burden to Appellants to show that Sornmo's pulse

[6] Similarly, Appellants' Specification describes a statistical dispersion measure as "any measure that represents a variability or spread of a sequence of values," such as "*standard deviation* (σ), *variance* (σ^2), coefficient of variation (σ/μ) and variance-to-mean (σ^2/μ)," and may also include "*normalized* and/or weighted variants." Spec. 17, ll. 1–5, 14 (emphasis added).

magnitude data when subjected to Al-Ali's statistical dispersion is incapable of predicting a physiological condition, such as, symptomatic blood pressure decrease, in a patient. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

Furthermore, we note that the Examiner's modification is an improvement to Sornmo's data analysis to *normalize* the data in the same way as taught by Al-Ali, that is, to decrease incidence of false alarms and/or more effectively determine the wellness of the patient (*see* Al-Ali, paras. 46, 49) which leads to a predictable result, and the modification is well within the skill of a person of ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

Appellants further argue that "the Examiner has **not** provided a clear, evidence-supported account of the ***contemplated workings*** of the proposed combination of Sornmo, Al-Ali, Bassale, Storm, and Mancini to support the conclusions of motivation and a reasonable expectation of success." Appeal Br. 14. According to Appellants, the Examiner's rejection would not have motivated a person of ordinary skill to arrive at the pending claims and that one of ordinary skill would not have expected success. *Id.* at 15. Appellants contend that although Al-Ali calculates "analytical measures of various physiological parameters over time . . . Al-Ali does not describe using the calculated variances to indicate a prediction of a physiological condition," and specifically does not predict a symptomatic blood pressure decrease in the subject based on the calculated statistical dispersion measure as claimed. Reply Brief (filed Mar. 21, 2018, hereinafter "Reply Br.") at 2.

Appellants' arguments are not persuasive, because, as the Examiner correctly notes, Sornmo already discloses predicting a symptomatic blood pressure decrease in a patient based on a pulse magnitude measure. *See* Ans. 7. Here, in the rejection, the Examiner is merely applying Al-Ali's statistical dispersion measure to the data that Sornmo already measures. As such, the Examiner is correct that a person of ordinary skill in the art would readily appreciate that using normalized data, that is, data that has been subject to statistical dispersion, as taught by Al-Ali, in Sornmo's monitoring apparatus, would predict a symptomatic blood pressure decrease in a patient. S*ee* Ans. 8. Absolute predictability of predicting a symptomatic blood pressure decrease is not required; all that is required is a reasonable expectation of success. *See In re O'Farrell*, 853 F.2d 894, 903–904 (Fed. Cir. 1988). In addition, Al-Ali discloses that signals from sensors "may be sampled, normalized, and/or analyzed" and that "normalization of sensor signals" provides "benefits, such as decreased incidence of false alarms and/or more effective determination of the wellness of the patient." Al-Ali, paras. 42, 81. As such, modifying Sornmo's monitoring apparatus, according to Al-Ali, provides the added benefit of decreased false alarms.

In conclusion, for the foregoing reasons, we sustain the rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over Sornmo, Al-Ali, Mancini, Storm and Bassale. Claims 2, 3, 6–10, 12–18, and 38–52 fall with claim 1.

Rejection II

As Appellants do not present any arguments with respect to the provisional rejection of claims 1–3, 6–10, 12–18, and 38–52 on the ground

of non-statutory double patenting as unpatentable over claims 1–37 of copending U.S. Application No. 13/519,559, we summarily sustain this rejection as well. *See* Appeal Br. 6.

DECISION

The Examiner's decision to reject claims 1–3, 6–10, 12–18, and 38–52 under 35 U.S.C. § 103(a) as unpatentable over Sornmo, Al-Ali, Mancini, Storm, and Bassale is affirmed.

The Examiner's decision to reject claims 1–3, 6–10, 12–18, and 38–52 on the ground of non-statutory double patenting over claims 1–37 of copending U.S. Application No. 13/519,559 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED