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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WEI ZONG

Appeal 2016-004910
Application 12/919,819[1]
Technology Center 3700

Before DONALD E. ADAMS, RICHARD J. SMITH, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims 1, 3–7, 9, 10, 12, 14–16, 18–21, and 23 (Final Act.[2] 2). Examiner entered rejections under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

Appellant discloses a: "hemodynamic monitoring instrument" or device, "monitoring method," and non-transitory "computer medium [] storing instructions executable to control a computer and display to perform

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[1] Appellant identifies the real party in interest as "Koninklijke Philips Electronics N.V." (App. Br. 1.)
[2] Examiner's April 2, 2015 Office Action.

[Appellant's] method [and] device" (Spec. 2). Claims 1 and 12 are representative and reproduced below:

1. A hemodynamic monitoring instrument comprising:

a multi-functional patient monitor including:

one or more medical monitoring devices configured to measure

physiological parameters including at least a measured physiological parameter indicative of heart rate and a measured physiological parameter indicative of arterial blood pressure;

a processor arranged to receive the physiological parameter indicative of heart rate and the physiological parameter indicative of arterial blood pressure and configured to compute a vasopressor advisability index (VPAI) correlating with systemic vascular resistance (SVR) using measured physiological parameters consisting only of the measured physiological parameter indicative of heart rate and the measured physiological parameter indicative of arterial blood pressure and not using any other measured physiological parameter, the VPAI quantifying the heuristic "ABP is low AND HR is slightly high or high" OR "ABP is very low" where ABP denotes an arterial blood pressure indicated by the physiological parameter indicative of arterial blood pressure and HR denotes a heart rate indicated by the physiological parameter indicative of heart rate;

a display configured to simultaneously display as a function of time the computed VPAI, the physiological parameter indicative of heart rate, and the physiological parameter indicative of arterial blood pressure; and

an alarm configured to generate a perceptible signal indicating advisability of vasopressor intervention responsive to the computed VPAI satisfying an alarm criterion.

(App. Br. 15–16.)

12. A hemodynamic monitoring method comprising:

using one or more medical monitoring devices, measuring a quantitative heart rate (HR) measure and a quantitative arterial blood pressure (ABP) measure for a patient;

using a processor, computing a vasopressor advisability index (VPAI) that (i) is computed using quantitative patient measures consisting only of the quantitative HR measure and the quantitative ABP measure, and (ii) correlates with the ratio ABP/HR where ABP is the quantitative ABP measure and HR is the quantitative HR measure;

displaying the VPAI;

generating a perceptible signal indicative of an abnormal hemodynamic condition treatable by administration of a vasoconstriction medication conditional upon the VPAI satisfying an alarm criterion.

(*Id.* at 18.)

The claims stand rejected as follows:

I. Claims 1, 3–5, 9, 21, and 23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen,[3] Ardagh,[4] Ceneviva,[5] and Loria.[6]

II. Claims 12, 14, and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen, Ardagh, and Ceneviva.

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[3] Nielsen et al., WO 2007/060559 A2, published May 31, 2007.
[4] Michael W Ardagh et al., *Pulse rate over pressure evaluation (ROPE) is useful in the assessment of compensated haemorrhagic shock*, 13 Emergency Medicine 43–46 (2001).
[5] Gary Ceneviva et al., *Hemodynamic Support in Fluid-refractory Pediatric Septic Shock*, 102 PEDIATRICS 1–6 (1998).
[6] Loria, US 2006/0281724 A1, published Dec. 14, 2006.

III. Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen, Ceneviva, Ardagh, Loria, Becker,[7] and Lynn.[8]

IV. Claim 10 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen, Ceneviva, Ardagh, Loria, and Banet.[9]

V. Claims 15 and 16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen, Ceneviva, Ardagh, Becker, and Lynn.

VI. Claim 19 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen, Ceneviva, Ardagh, and Banet.

VII. Claim 20 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen, Ceneviva, Ardagh, Becker, Lynn, Suizdak,[10] and Griffin.[11]

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Nielsen discloses "a medical monitoring system [that] includes a monitoring station [] operatively connected with a modular biometric monitor rack [that] includes an example heart rate (HR) monitor module []

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[7] Kurt Becker et al., *Fuzzy Logic Approaches to Intelligent Alarms*, IEEE ENGINEERING ON MEDICINE AND BIOLOGY 710–16 (1994).
[8] Lynn et al., US 2007/0191697 A1, published Aug. 16, 2007.
[9] Banet et al., US 2008/0312542 A1, published Dec. 18, 2008.
[10] Siuzdak et al., US 2009/0104605 A1, published Apr. 23, 2009.
[11] Griffin et al., US 2005/0137484 A1, published June 23, 2005.

configured to monitor patient heart rate [and] an example blood pressure monitor module [] configured to monitor patient blood pressure []" (Nielsen 4: 4–8; *see also id.* at 1: 22–24 ("some medical monitoring systems include derived parameters. For example, various blood pressure parameters such as arterial blood pressure [] can be derived from a continuous blood pressure monitor"); *see* Final Act. 3–4 (Nielsen discloses "a hemodynamic monitoring instrument comprising . . . one or more medical monitoring devices configured to measure physiological parameters including at least a measured physiological parameter indicative of heart rate and a measured physiological parameter indicative of arterial blood pressure []")).

FF 2. Examiner finds that Nielsen's monitoring system comprises, *inter alia*, "a processor arranged to receive the physiological parameter indicative of heart rate and the physiological parameter indicative of arterial blood pressure" (Final Act. 4; *see generally* Nielsen 5: 1 – 6: 24).

FF 3. Examiner finds that Nielsen's processor is "configured to compute an index correlating with systemic vascular resistance (SVR) based on the received physiological parameter indicative of heart rate and the received physiological parameter indicative of arterial blood pressure," wherein "SVR is estimated using heart rate and arterial blood pressure; see [Nielsen's] equation U2 which estimates SVR; because the device *estimates* SVR, the estimate is considered correlated to SVR[]" (Final Act. 4, citing Nielsen 10: 1–15).

FF 4. Nielsen discloses that "an estimate of the SVR to the user-defined biometric parameter U2" is defined by the equation:

"U2=(MABP – CVP)/((K1/MABP)×(ABPsys-ABPdia)×HR),"

"where 'MAPBP' represents the mean arterial blood pressure library function selected from the library functions list[ ], 'CVP' represents the central venous pressure library function selected from the library functions list []," "'HR' represents the heart rate monitored biometric parameter selected from the monitored biometric parameters list[], 'K1' can be a constant factor that is a function of age or disease state," "'ABPsys' represents the systolic arterial blood pressure library function selected from the library functions list [], [and] 'ABPdia' represents the diastolic arterial blood pressure library function selected from the library functions list (Nielsen 10: 5–12 (emphasis added) and 9: 15–21).

FF 5. Nielsen's "library" includes "pre-defmed functions," which "may include general mathematical, statistical, or calculus functions such as logarithm, integral 'Int()', or average 'Avg()'," and "may additionally or alternatively include pre-defmed biometric parameters such as systolic arterial blood pressure (ABPsys) or diastolic arterial blood pressure (ABPdia)," wherein a user of Nielsen's device may "select from a list [] of the functions stored in the library []" (Nielsen 7:6–11).

FF 6. Examiner recognizes that Nielsen does not disclose a SVR determination that uses measured physiological parameters consisting only of the measured physiological parameter indicative of heart rate and the measured physiological parameter indicative of arterial blood pressure and not using any other measured physiological parameter (Ans. 3; *see* FF 3–5; *cf.* App. Br. 15–16).

FF 7. Ardagh discloses:

> The pulse rate over pressure evaluation (ROPE) places the pulse rate (the numerator) over the pulse pressure (systolic blood pressure minus diastolic blood pressure, the

> denominator). This emphasizes the physiological changes of increased heart rate and increased peripheral vascular resistance that occur during compensation [in a patient who is losing blood volume through hemorrhage], and a high ROPE may indicate approaching decompensation. If ROPE proves to be predictive of decompensation, its ease and rapidity of application would make it a useful clinical tool.

(Ardagh 43; *id.* ("ROPE is an easily applied and useful clinical tool [] being predictive of the patient developing decompensated shock"); *see* Ans. 3 ("arterial blood pressure can be described [as] pulse pressure"); Ans. 5 ("Ardagh was used to teach a SVR measurement that uses heart rate and arterial blood pressure as claimed"); Final Act. 6.)

FF 8. Examiner finds that Nielsen fails to disclose a processor configured to compute a vasopressor advisability index (VPAI) correlating with systemic vascular resistance (SVR), as is required by Appellant's claimed invention (Ans. 4; *cf.* App. Br. 15–16).

FF 9. Examiner relies on Ceneviva to "teach[] that [v]asopressor therapy is used to counter low SVR" (Ans. 4; Ceneviva 1 ("When decreased SVR contributes to shock, vasopressor therapy is used to increase SVR"); *see also* Final Act. 5 (Ceneviva discloses "that SVR is a parameter that can be used to indicate the need for vasopressor therapy")).

FF 10. Examiner finds that Nielsen's device comprises "a display configured to simultaneously display as a function of time the computed index correlating with SVR, the physiological parameter indicative of heart rate, and the physiological parameter indicative of arterial blood pressure" (Final Act. 4, citing Nielsen 5: 13–25).

FF 11. Nielsen's device "[o]ptionally [] includes an alarm, such as a visual alarm light [], an audio alarm speaker [], or so forth" (Nielsen 6: 3–4; Final Act. 5).

FF 12. Examiner finds that Nielsen "does not disclose that the vasopressor advisability index can be used to quantify the heuristics 'ABP is low and HR is slightly high or high' or 'ABP is very low'" and relies on Loria to make up for this deficiency in Nielsen (Final Act. 7).

ANALYSIS

Rejection I:

Based on the combination of Nielsen, Ardagh, Ceneviva, and Loria, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious "to modify Nielsen to use the index correlating with SVR as a vasopressor advisability index based on Ceneviva['s] teachings that low SVR should be treated with vasopressors because this index can be used to treat shock symptoms which can be life threatening" (Final Act. 5–6). Because Appellant's claimed invention uses the open transitional phrase, comprising, Examiner reasons that it would have been prima facie obvious at the time of Appellant's claimed invention to modify the system suggested by the combination of Nielsen and Ceneviva:

> to include a *secondary measure* of vascular resistance that depends only on measurements of HR and BP, as taught by Ardagh, for monitoring patients because Ardagh [] teach[es] that ROPE can be used to conventional signs [sic] of a patient's volume status are unreliable until the patient has decompensated, at which point it may be too late [].

(Final Act. 6 (emphasis added).) In this regard, Examiner reasons that "[a]lthough Ardagh uses pulse pressure as opposed to the claimed arterial

blood pressure, it is notoriously known that arterial blood pressure can be estimated closely using only diastolic and pulse pressure (i.e. a simple substitution of known equivalent factors" (*id.* at 7). Taken together, Examiner concludes that "Ceneviva in combination with Ardagh and Nielsen teaches that a patient's SVR level itself is an indicator of when to administer vasopressor (e.g. Ceneviva demonstrates that a low SVR can be countered using a vasoconstriction medication)" (Ans. 5).

Lastly, Examiner reasons that when "[t]he term heuristic [is] interpreted as criteria" it would have been prima facie obvious at the time of Appellant's claimed invention "to use heuristics such as 'ABP is low and HR is slightly high or high' or 'ABP is very low' in view of Loria's teaching of shock symptoms because such identified conditions require prompt treatment" (*id.* at 7, citing Loria, Abstract and ¶ 15).

Claim 1:

Examiner relies on Ardagh to suggest a SVR using measured physiological parameters consisting only of the measured physiological parameter indicative of heart rate and the measured physiological parameter indicative of arterial blood pressure and not using any other measured physiological parameter as required by Appellant's claimed invention (FF 7). In this regard, Ardagh discloses that the ease and rapidity of [the ROPE] application [] make it a useful clinical tool (*id.*). Therefore, we find no error in Examiner's conclusion that it would have been prima facie obvious to include a secondary measure of vascular resistance that depends only on measurements of HR and BP, as taught by Ardagh, in Nielsen's device (*see* Final Act. 6–7; *see also* FF 7; *cf.* FF 3–6). In addition, Examiner relies on

Ceneviva to suggest that SVR is correlative to VPAI, because SVR can be used as an indicator to treat shock symptoms with vasopressors (*see* FF 9).

Therefore, we are not persuaded by Appellant's contention that "Ardagh [alone] does not fairly suggest calculating a vasopressor advisability index which is used to indicate the advisability of vasopressor intervention," because that contention fails to account for Ceneviva's contribution to the combination of Nielsen, Ardagh, and Ceneviva (App. Br. 10; *see* Reply Br. 2–3 ("simply predicting decompensated shock does not show when an advisability of vasopressor intervention is warranted. In other words, Ardagh does not fairly suggest a vasopressor advisability index which is used to indicate the advisability of vasopressor intervention").) Likewise, we are not persuaded by Appellant's contention that, when viewed in isolation, "Ceneviva is silent with respect to a[] SVR calculated using only HR and ABP" and, thus, "does not add anything that would cure the deficiencies of Nielsen [in combination with] Ardagh" (App. Br. 10; Reply Br. 3). The references must not be read in isolation, but for what they fairly teach together. *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

We are not persuaded by Appellant's contention that "Ardagh gives two specific examples of where ROPE would be ineffective at determining when a vasoconstriction medication should be administered" or that Ceneviva alone "does not fairly suggest administering of vasopressor intervention based on a calculation using only HR and ABP" (App. Br. 10, citing Ardagh 46; *see* Reply Br. 3).

Claim 3:

Appellant's claim 3 depends from and further limits Appellant's claim 1 to require "a memory for storing a patient age" and a "processor configured to compute the VPAI further using the stored patient age" (App. Br. 16). In this regard, we note that Appellant's claimed invention is open to include multiple SVR calculations, which correlate with VPAI, including an SVR calculation that accounts for patient age such as disclosed by Nielsen (*see* FF 4). Thus, the combination of Nielsen, Ardagh, Ceneviva, and Loria makes obvious a device comprising memory for storing a patient's age and a processor configured to compute VPAI using the stored patient age.

Further, Appellant's claim 3 does not require that the device or any of a plurality of methods for calculating VPAI, used by the device's processor, to compute VPAI is effective for all age groups, but instead simply requires that patient age be stored in the memory of the device and that the device's processor be configured to compute the VPAI using the stored patient age (*see* App. Br. 16). Therefore, we are not persuaded by Appellant's contention that one method (ROPE), among a plurality (*see* Nielsen), of computing VPAI "may not climb in elderly people prior to decompensation; thus, ROPE is an ineffective predictor of decompensation for this group of people" (App. Br. 12; *see* Reply Br. 4).

Claim 9:

Appellant's claim 9 depends from and further limits Appellant's claim 1 to require that "the processor is configured to increase HR by AF_{HR} where AF_{HR} denotes a correction term based on patient age" (App. Br. 18).

As discussed above the combination of Nielsen, Ardagh, Ceneviva, and Loria makes obvious a devices comprising a processor configured to compute VPAI using the stored patient age. In this regard, Nielsen discloses a SVR calculation, which correlates with VPAI, that includes the variable K1, thereby, accounting for a patient's age (FF 4).

Therefore, we are not persuaded by Appellant's contention that the combination of Nielsen, Ardagh, Ceneviva, and Loria fail to make obvious Appellant's claimed invention (App. Br. 12; *see* Reply Br. 4–5).

Rejection II:

Examiner relies on Nielsen, Ardagh, and Ceneviva as discussed above (*see* Final Act. 12). Examiner recognizes, however, that the combination of Nielsen, Ardagh, and Ceneviva suggests an SVR calculation, ROPE, that is HR/ABP, which is the inverse of the calculation required by Appellant's claimed invention: ABP/HR (*id.*). Nevertheless, Examiner reasons that the use of "an inverse of a known ratio fails to make the teachings unobvious to one of ordinary skill in the art at the time of the invention" (*id.*).

Claim 12:

Appellant does not dispute Examiner's rationale regarding the use of an inverse relationship (*see* App. Br. 11). Rather, Appellant contends that the combination of Nielsen, Ardagh, and Ceneviva fails to "'comput[e] a vasopressor advisability index (VPAI) that (i) is computed using quantitative patient measures consisting only of the quantitative HR measure and the quantitative ABP measure' . . . for similar reasons discussed above with

respect to claim 1" (*id.*). Having found no error in Examiner's rejection of claim 1, we are not persuaded.

Claim 18:

Appellant's claim 18 depends from and further limits the method of Appellant's claim 12 to require that the VPAI computation "further comprises increasing the quantitative HR measure by AF_{HR} where AF_{HR} denotes a correction term based on patient age" (App. Br. 20.)

Having found no deficiency in Examiner's rejection of claim 9, we are not persuaded by Appellant's contention that "[c]laim 18 is patentable over the applied references for similar reasons discussed with respect to claim 9" (App. Br. 13; *see* Reply Br. 5).

Rejections III–VII:

ANALYSIS

If a ground of rejection stated by the examiner is not addressed in Appellant's Brief, that ground of rejection will be summarily sustained by the Board. *See* Manual of Patent Examining Procedure § 1205.02. Appellant does not address Rejections III–VII; therefore, they are summarily affirmed.

CONCLUSION OF LAW

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness.

Rejection I: The rejection of claims 1, 3, and 9 under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen, Ardagh,

Ceneviva, and Loria is affirmed. Claims 4, 5, 21, and 23 are not separately argued and fall with claim 1.

Rejection II: The rejection of claims 12 and 18 under 35 U.S.C. § 103(a) as unpatentable over the combination of Nielsen, Ardagh, and Ceneviva is affirmed. Claim 14 is not separately argued and falls with claim 12.

Rejections III–VII are summarily affirmed.

TIME PERIOD FOR RESPONSE

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

AFFIRMED