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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ILLAPHA GUSTAV LARS CUBA GYLLENSTEN, ROHAN JOSHI, and HERMAN JAN TER HORST

Appeal 2019-003879
Application 15/284,575
Technology Center 3700

Before JILL D. HILL, LEE L. STEPINA, and ARTHUR M. PESLAK, *Administrative Patent Judges.*

HILL, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1–18. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Koninklijke Philips Electronics N.V. Appeal Br. 2.

BACKGROUND

Appellant's invention relates to a system and method for predicting heart failure decompensation. Claim 1, reproduced below, illustrates the claimed invention with certain limitations italicized:

> 1. A system configured to predict decompensation in a subject with heart failure, the system comprising:
>
> one or more hardware processors configured by machine-readable instructions to:
>
> determine baseline information for the subject based on physiological data of other patients with heart failure, the physiological data of the other patients corresponding to a period of time when the other patients have stable physiological parameters that precedes heart failure;
>
> receive weight information that includes a weight of the subject generated by one or more weight sensors;
>
> receive blood pressure information that includes a blood pressure of the subject generated by one or more blood pressure sensors;
>
> receive heart rate information that includes a heart rate of the subject generated by one or more heart rate sensors;
>
> determine one or more weight parameters associated with a change in the weight of the subject based on the weight information with respect to the baseline information;
>
> determine one or more blood pressure parameters associated with a change in the blood pressure of the subject based on the blood pressure information with respect to the baseline information;
>
> determine one or more heart rate parameters associated with a change in the heart rate of the subject based on the heart rate information with respect to the baseline information;
>
> determine individual weight, blood pressure, and heart rate parameters with higher predictive strength for predicting decompensation relative to other weight, blood pressure, and heart rate parameters with lower predictive strength, the individual weight, blood pressure, and heart rate parameters with higher predictive strength comprising at least one predictive weight parameter, at least one predictive blood

> pressure parameter, and at least one predictive heart rate parameter; and
>
> *predict decompensation in the subject based on the at least one weight parameter, the at least one blood pressure parameter, and the at least one heart rate parameter with higher predictive strength for predicting decompensation relative to the other weight, blood pressure, and heart rate parameters with lower predictive strength*.

REJECTIONS

I. Claims 1–7 and 10–18 stand rejected under 35 U.S.C. § 102(a)(1) as being anticipated by Sarkar (US 2012/0253207 A1, pub. Oct. 4, 2012). Final Act. 7.

II. Claims 8 and 9 stand rejected under 35 U.S.C. § 103 as unpatentable over Sarkar. Final Act. 10.

OPINION

Rejection I – Anticipation by Sarkar

Appellant argues that Sarkar's determination of "the heart failure risk level based on all patient metrics … is not the same as predicting decompensation based on parameters with higher predictive strength." Appeal Br. 14. According to Appellant, Sarkar "does not describe which parameters might be more predictive and which parameters might be less predictive." *Id.* at 15. Appellant thus contends that Sarkar does not predict decompensation based on "the at least one weight parameter, [the] at least one blood pressure parameter, and the at least one heart rate parameter with higher predictive strength for predicting decompensation relative to the other weight, blood pressure, and heart rate parameters with lower predictive strength," as required by the independent claims. *Id.*

The Examiner responds that Sarkar relates the risk of worsening heart failure to decompensation and "discloses weighting different patient metrics to produce a risk level for the patient." Ans. 7 (citing Sarkar ¶¶ 46, 50–51). The Examiner notes that, although intrathoracic impedance is used as an example of a parameter having higher predictive strength, Sarkar also discloses weight, blood pressure, and heart rate as parameters. Ans. 8.

Appellant replies that Sarkar's disclosure that "some factors may be weighted differently than others … is not the same as describing the presently claimed algorithm for predicting heart failure decompensation" based on "determining individual weight, blood pressure, and heart rate parameters with higher predictive strength." Reply Br. 2–3. According to Appellant, Sarkar "does not describe predicting decompensation in the subject based on at least one weight parameter, at least one blood pressure parameter, and at least one heart rate parameter with higher predictive strength for predicting decompensation relative to other weight, blood pressure, and heart rate parameters with lower predictive strength." *Id.* at 3. For the following reasons, Appellant's arguments are persuasive.

Appellant defines "decompensation" as "a period of worsening heart failure symptoms until [the patients] eventually require hospitalization." Spec. ¶ 20. Sarkar discloses that "a relatively rapid worsening of the patient's condition, e.g., a decompensation, precipitates hospitalization and, in some cases, death." Sarkar ¶ 27; *see also* Ans. 7. As such, we agree with the Examiner that Sarkar discloses decompensation as claimed. Sarkar also discloses that "lower resolution diagnostic information based on the patient metrics may be transmitted to the user, which may be used to determine a risk level of the patient being re-admitted to the hospital due to heart

failure." *Id.* ¶ 6. Sarkar discloses that "patient metrics may include, as examples, therapy use statistics (e.g., pacing or shocks), thoracic impedance, *heart rate*, heart rate variability, patient activity, and a percentage of time receiving cardiac resynchronization therapy. Other example patient metrics include *weight*, *blood pressure*, [and] respiration rate." *Id.* ¶ 30; *see also* Ans. 7. Sakar discloses that "external electrodes or other sensors may be used by IMD 16 to … sense and detect patient metrics used to generate the high and lower resolution diagnostic information, e.g., a heart failure risk level." *Id.* ¶ 76. Thus, Sarkar discloses determining weight, blood pressure, and heart rate using sensors.

Appellant uses sensed information to determine weight, blood pressure, and heart rate parameters based on a change with respect to baseline information. Specifically, the Specification discloses determining a change in weight, blood pressure, and heart rate over time, or "window size." Spec. ¶ 31. Sarkar discloses that "metric-specific thresholds may be rate of change thresholds or relative change thresholds." Sarkar ¶ 61; *see also* Final Act. 8. Thus, we agree with the Examiner that Sarkar determines weight, blood pressure and heart rate parameters, as recited.

However, although Sarkar discloses that "some states or metrics may be more indicative of the risk of re-hospitalization" and "may provide a greater contribution to the determined risk level" (Sarkar ¶ 51), Sarkar is comparing one patient metric to a different patient metric to determine the risk level. Sarkar discloses, for example, that "intrathoracic impedance may be a greater risk factor to the patient than patient inactivity." Sarkar ¶ 51. In Sarkar, "the risk level may be determined by the sum, average, or other combination of weighted scores for each of the patient metrics." *Id.* Claim

1, by contrast, requires a comparison of parameters with higher predictive strength for predicting decompensation relative to the same parameters with lower predictive strength. *See* Spec. ¶ 34 ("prediction component 24 is configured to identify and/or predict decompensation for subject 12 based on individual parameters with higher predictive strength relative to individual parameters with lower predictive strength.").

Figure 5 assists us in ascertaining the meaning of higher and lower "predictive strength," by showing various parameters having different predictive strengths ("predictive strength of the classifier was evaluated by calculating the area under the curve (AUC)). Spec. ¶ 63. For example, a change in blood pressure over a two day window has a higher predictive strength, i.e., a larger area under the curve than a change in blood pressure over an eight day window. As claimed, each of weight, blood pressure and heart rate parameters are compared to other weight, blood pressure, and heart rate parameters to predict decompensation. In Sarkar, "the risk level may be determined based on a predetermined number of patient metrics exceeding their representative thresholds," not based on relative predictive strengths of parameters. Because Sarkar does not predict decompensation based on higher predictive strength parameters relative to the same parameters with lower predictive strength, the Examiner erred in finding that Sarkar is able to predict decompensation in the subject based on the at least one weight parameter, the at least one blood pressure parameter, and the at least one heart rate parameter with higher predictive strength for predicting decompensation relative to the other weight, blood pressure, and heart rate parameters with lower predictive strength. We, therefore, do not sustain the rejection of independent claims 1, 6, and 11 based on Sarkar. Claims 2–5, 7,

10, and 12–18 depend directly or indirectly from claim 1, claim 6, or claim 11, and include the limitations thereof. Independent claims 6 and 11 contain substantially the same limitations as claim 1. We, therefore, do not sustain Rejection I.

Rejection II – Obviousness of Claims 8 and 9 Based on Sarkar

Claims 8 and 9 depend from claim 6. The Examiner does not conclude that it would have been obvious to one skilled in the art to predict decompensation in the subject based on the at least one weight parameter, the at least one blood pressure parameter, and the at least one heart rate parameter with higher predictive strength for predicting decompensation relative to the other weight, blood pressure, and heart rate parameters with lower predictive strength. We therefore do not sustain the rejection of claims 8 and 9 as unpatentable over Sarkar.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1–7, 10–18	102(a)(1)	Sarkar		1–7, 10–18
8, 9	103	Sarkar		8, 9
Overall Outcome				1–18

REVERSED