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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ECKHARD ALT

Appeal 2012-002089
Application 10/622,184
Technology Center 3700

Before DEMETRA J. MILLS, MELANIE L. McCOLLUM, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of early detection and monitoring of congestive heart failure. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Appellant's invention relates to body-implantable devices adapted to detect and monitor congestive heart failure in a patient, and includes a circuit module coupled to plural surface electrodes of the device arranged and adapted, when the device is implanted, for contacting tissue in a portion of the patient's body generally occupied by the lungs, to monitor changes in local impedance of said body portion, and to detect the patient's EKG.
(Spec., Abst.)

Claims 31 and 33 – 36 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R.

§ 41.37(c)(1)(vii). Independent claim 31 reads as follows:

31. An implantable device-implemented method of early detection and monitoring of congestive heart failure in a patient, which comprises the steps of:

measuring local impedance of a portion of the patient's body generally occupied by the lungs solely through surface mounted electrodes on the device with the device implanted subcutaneously in the patient's body,

determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema,

detecting the patient's heart rate/activity pattern through said electrodes while concurrently monitoring said local impedance measurements to evaluate cardiopulmonary status of the patient, and

evaluating a trend of the heart rate/activity pattern and said concurrent local impedance measurements *against one another* over a selected period of time, as an additional indicia of congestive heart failure.

The claims stand rejected as follows:

- I. Claims 31 and 33-36 under 35 U.S.C. § 102(b) as being anticipated by Riff (US 5,876,353, issued Mar. 2, 1999).
- II. Claims 31 and 33-36 under 35 U.S.C. § 102(b) as being anticipated by Combs et al (US 5,957,861, issued Sep. 28, 1999).

I.

Issue

The Examiner has rejected claims 31 and 33-36 under 35 U.S.C. § 102(b) as being anticipated by Riff. The Examiner finds that Riff teaches a device having all elements of claim 31. (Ans. 4-5 and 6-9.)

Appellant contends that Riff “does not show, disclose or suggest multiple elements of claim[] 31.” (App. Br. 11.) Specifically, Appellant contends that Riff fails to disclose:

- “means for determining congestive heart failure on the basis of factors other than the existence of edema” (*id.*);
- “detecting the patient’s heart rate/activity pattern and evaluating the trend of the heart rate/activity pattern and lung impedance measurements against one another over a selected period of time as an indicia of congestive heart failure” (*id.*);
- “surface-mounted electrodes on a subcutaneous device that both measure local impedance and detect the patient's heart rate/activity pattern” (*id.*).

The issue presented is:

Does the evidence of record support the Examiner’s findings that Riff anticipates claim 31?

Findings of Fact

The following findings of fact (“FF”) are supported by a preponderance of the evidence of record.

FF1. Riff discloses “[a]n impedance monitor for discerning edema through evaluation of respiratory rate” (Riff, Abst.), where edema is a sign of heart failure (*see e.g.*, Riff col. 1, ll. 44-60).

FF2. The devices of Riff are implantable in the chest (*see e.g., id.* at col. 1, ll. 44-60, and col. 8, ll. 26-28).

FF3. Riff discloses

an implantable apparatus for production of impedance measurement in a subcutaneous region of the living body having *at least two electrically isolated electrodes*, preferably but not necessarily on the *outer surface of its housing* and having within the housing an energy pulse delivery mechanism to deliver electrical pulses to living body and means for receiving electrical impulses on the surface of the housing *so as to determine the impedance of the body between the two preferred or less preferred pair of electrodes*

(*see e.g., id.* at col. 3, ll. 16-25) (emphasis added).

FF4. The devices of Riff may “use the respiratory rate as an indicator of edema or lung water,” which “can be monitored *long term* like the DC impedance signal, but instead of filtering out the respiration signals as noise, we would for these devices use the *respiration varied impedance measures to determine breath rate.*” (*Id.* at col. 13, ll. 59-64.) (Emphasis added.)

FF5. Riff discloses that the

the electrode configuration for impedance measurement may include a cardiac electrode tip in the heart and an electrode on the surface of a pacemaker housing for one measure of

impedance and an additional pair of electrodes both located on the housing would enable the use of two different measures of impedance and facilitate the use of comparisons between the resultant signals to refine the signal and provide additional information.

(*Id.* at col. 3, ll. 40-48.)

FF6. Riff discloses “[r]ecording of Long Term Average and Short Term Average values for secondary edema measure based on DC signal level.” (*Id.* at Abst.; *see also id.* at col. 1, ll. 6-10, col. 2, ll. 38-51, col. 3, ll. 51-57, col. 14, ll. 53-55, and col. 17, ll. 23-25.)

FF7. Riff discloses

[i]t is already known in the art to have and use implantable sensors to monitor and record data including activity sensed, *heart rate, heart rate variability, respiration, minute ventilation and variability of, arrhythmia frequency and duration, averages of these values over long term, pressure at various sensor locations, O2 saturation at various sensor locations, time located patient activated data records for holding various pieces of these data sets around a temporal marker set by a patient activated signaling device (which could be incorporated into a device such as WD, or some other convenient unit) for diagnosing patient symptoms, and so on. However, the use of an impedance sensor dedicated to generate data specific to edema conditions and history has not heretofore been seen. Combining these edema measurements with any of these other signal data provides an enhanced diagnostic and patient management efficacy to all the devices.*

(Riff, col. 13, ll. 9-25) (emphasis added).

FF8. Riff discloses

For additional beneficial data generation purposes other sensors may be included in the implanted device and data therefrom temporally matched with edema data to provide additionally beneficial diagnostic data. Each sensor can be thought of as a system for providing an indication of patient

condition, either *when it's output is taken alone or combined in manners known to those in the art to determine patient condition*. Such included sensor systems or subsystems could include, for example, diurnal cycle indicators, position or posture indicators, resting indicators, *heart beat cycle indicators*, breathing indicators, movement indicators, and so forth, each providing a signal value that could be stored or used to trigger an activity of the implanted device.

(Riff, col. 5, ll. 32-45).

Principles of Law

Anticipation requires that every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001).

Analysis

We find that the preponderance of evidence on this record supports the Examiner's findings that Riff anticipates claim 31. As noted by the Examiner, the "current claim language does not explicitly limit the exact same surface mounted electrodes to perform both the impedance measurement and the heart rate/activity measurement" (Ans. 8; *see also* App. Br. 12-13).

Riff discloses an implantable device for use in the monitoring of edema, a sign of congestive heart failure (FF1). The device may be implanted subcutaneously in the patient's body (FF2) and includes surface mounted electrodes (FF3). The device of Riff involves using respiration varied impedance measures to determine breath rate, which may be indicative of congestive heart failure (FF4). Riff also discloses detecting the patient's heart rate or activity pattern (FF7). Riff discloses evaluating a trend of impedance measurements (FF4, FF6 and FF7) and also the heart

rate or activity pattern (FF7), which are compared to provide diagnostic and patient management efficacy (FF8). We are therefore not persuaded by Appellant's arguments that these elements are not disclosed by Riff. (*See e.g.*, App. Br. 11 and Reply Br. 6.)

We are also not persuaded by Appellant's arguments that using respiratory rate as a surrogate marker for edema for assessing congestive heart failure, as disclosed by Riff, is different from a means for "determining congestive heart failure on the basis of factors other than the existence of edema," as required by claim 31. The Specification describes such a means as measuring a patient's ventilation, "represented by the measured changes in local impedance" (Spec. 5, ll. 3-5), where ventilation is the "product of tidal volume and respiratory rate" (Spec. 3, l. 8). Thus, we find that the "respiratory rate" disclosed by Riff to be encompassed by the claim element "factors other than the existence of edema."

Conclusion of Law

We conclude that the preponderance of the evidence of record supports the Examiner's conclusion that Riff discloses each limitation of claim 31. Claims 33-36 fall with claim 31. 37 C.F.R. § 41.37(c)(1)(vii).

II.

As explained by the Examiner, "Combs et al share the same specification with that of Riff." (Ans. 9.) The facts and analysis of the Examiner's rejection over Comb is substantially the same as the Examiner's rejection over Riff, discussed in Section I above. (*Id.* at 5-6.) Appellant's arguments with respect to Comb are substantially identical to Appellant's arguments made with respect to Riff. (App. Br. 14-16.) We thus affirm the

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Examiner's rejection under 35 U.S.C. § 102(b) over Comb for reasons explained above with regard to Riff.

SUMMARY

We affirm all rejections on appeal for the reasons of record.

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

cdc