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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte YUNLONG ZHANG, JAMES O. GILKERSON,
YONGXING ZHANG, and BOYCE MOON

Appeal 2010-006527
Application 11/208,922
Technology Center 3700

Before LINDA E. HORNER, GAY ANN SPAHN, and
MICHAEL L. HOELTER, *Administrative Patent Judges*.

SPAHN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Yunlong Zhang et al. (Appellants) seek our review under 35 U.S.C. § 134 of the Examiner's rejection of claims 1-12, 14, 16, and 18-31. Appellants cancelled claims 13, 15, and 17. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

The Claimed Subject Matter

The claimed subject matter relates to "implantable medical devices and, in particular, . . . to systems and methods for detecting events related to cardiac activity." Spec. 1, ll. 6-8. Claims 1, 12, 19, 24, and 29 are the independent claims on appeal. Claim 1, reproduced below, with emphasis added, is illustrative of the appealed subject matter.

> 1. A system comprising:
> a medical device including:
> a cardiac cycle sensing circuit, the sensing circuit configured to provide a sensed cardiac cycle;
> an impedance measurement circuit configured to provide an intracardiac impedance signal; and
> a controller circuit coupled to the impedance measurement circuit, the controller circuit configured to detect tachyarrhythmia from the intracardiac impedance signal using at least two of:
> *a cardiac-cycle-to-cardiac-cycle change in a value of a baseline intracardiac impedance value calculated, for a particular cardiac cycle, to represent the baseline intracardiac impedance for that particular cardiac cycle;*
> *a cardiac-cycle-to-cardiac-cycle change in a value of maximum intracardiac impedance value calculated, for a particular cardiac cycle, to represent the maximum intracardiac impedance for that particular cardiac cycle; and*
> *a cardiac-cycle-to-cardiac-cycle change in a slope value of the intracardiac impedance waveform signal, for a particular cardiac cycle, the slope value measured at a time corresponding to one-half of a time interval over which a maximum intracardiac impedance change occurs during that particular cardiac cycle*.

Independent claims 12, 24, and 29 are directed to a method comprising, *inter alia*, the step of "measuring intracardiac impedance

parameters from the waveform including at least two of" the three highlighted parameters as quoted in independent claim 1 *supra*.

Independent claim 19 is directed to a method comprising, *inter alia*, the step of "determining whether the tachyarrhythmia is stable using intracardiac impedance parameters derived from the intracardiac impedance signal wherein the intracardiac impedance parameters include at least two of" the three highlighted parameters as quoted in independent claim 1 *supra*.

The Rejections

The following Examiner's rejections, under 35 U.S.C. § 103(a), are before us for review:

I. claims 1-4, 7-12, 14, 16, and 18-31 as unpatentable over Huvelle (US 6,522,914 B1, issued Feb. 18, 2003); and

II. claims 5 and 6 as unpatentable over Huvelle and Weiss (US 5,179,946, issued Jan. 19, 1993).

OPINION

Rejection I – Obviousness based on Huvelle

The Examiner finds that Huvelle substantially discloses the subject matter of independent claims 1, 12, 19, 24, and 29, "except for said system and method measuring, deriving impedance parameters and/or detecting tacharrhythmia from an intracardiac impedance signal by using at least two of" the highlighted three parameters as quoted in claim 1 *supra*. Ans. 3-5. The Examiner also finds Huvelle discloses:

> that it is known to continuously measure intracardiac impedance values by computing intracardiac impedance derived parameter(s) and/or values (HCA) for each cardiac cycle, in

> which the disclosed HCA values are computed by finding the summation and/or average of the jth impedance signal sample per cardiac cycle of nth samples for m number of cardiac samples in order to provide an averaged or baseline impedance derived parameter per cardiac cycle, and cycle-to-cycle change in a slope value of an intracardiac impedance waveform signal [e.g., (col 4, ln 1-40), (col 9, ln 55-67) & (col 10, ln 1-13)].

Ans. 5 (brackets in original). The Examiner concludes that it would have been obvious to one of ordinary skill in the art "to have incorporated in Huvelle . . . the use of at least two of" the three highlighted parameters as quoted in claim 1 *supra*, "in order to provide the predictable results pertaining to providing intracardiac impedance derived parameters and computed values for each cardiac cycle sampled so as to adjust therapy, such as for the anti-tachycardia pacing used to treat cardiac patients based on the continuous change of the cardiac cycles sampled." Ans. 5-6 (citing Huvelle, col. 4, ll. 1-40).

Appellants note "Huvelle states that it can be observed on 1/HCA curve 1230 . . . that the higher the metabolic demand is, the deeper and the wider the dips are at low pacing rates, and this indicates that the pacing rate is not sufficient." App. Br. 17 (citing Huvelle, col. 10, ll. 1-5). Appellants argue that if the Examiner is "equat[ing] the reference to wider and deeper segments of this inverse area-ratio curve to the slope of the intracardiac impedance waveform signal," then "the derived 1/HCA curve is clearly not the same as an intracardiac impedance waveform signal, and Huvelle clearly does not disclose using a change in a slope value of the intracardiac impedance waveform signal." *Id.* Appellants also argue that "Huvelle uses, (1) a graphical construction involving a decreasing 1/HCA curve, and (2) a V_{rate} plot, to determine a hemodynamic lower rate limit (HLRL)" and

"[t]hus, the cited portions of Huvelle relate to using a decreasing 1/HCA curve to find the HLRL, which is merely used to define a Hemodynamic Pacing Range," but "fails to establish 'detecting tachyarrhythmia using . . . a cardiac-cycle-to-cardiac-cycle change in a slope value of the intracardiac impedance waveform signal . . . .'" *Id.* (quoting claim 1) (emphasis omitted).

The Examiner responds that Huvelle discloses

> a method of controlling cardiac activities and implantable devices based on an intracardiac impedance-derived parameter, HCA, in which HCA values are computed in order to provide a cycle-to-cycle change in a slope value measured at a time of one-half a time interval over a maximum intracardiac impedance change of an intracardiac waveform [e.g., (col 9, ln 55-67)-(col 10, ln 1-13)] and computed to find the summation and/or average of the jth impedance signal sample per cardiac cycle of nth samples for m number of cardiac samples in order to provide an averaged or baseline impedance derived parameter per cardiac cycle [e.g., (col 4, ln 1-40), (col 9, ln 55-67) & (col 10, ln 1-13)], therefore providing said method and devices with the capability of providing a cycle-to-cycle change in a value of a baseline intracardiac impedance value and a cycle-to-cycle change in a slope value of the intracardiac impedance waveform signal as is instantly claimed.

Ans. 7 (brackets in original). Thus, we understand the Examiner's position to be that either Huvelle teaches the claimed baseline and slope parameters of the three recited parameters or Huvelle suggests and could be modified to have the claimed baseline and slope parameters of the three recited parameters. The Examiner never addresses the claimed maximum peak impedance value Z_{max} parameter.

Appellants' Figure 5A depicts a measured intracardiac impedance waveform 510 with the segment of the impedance waveform 510 between

the vertical bars 525 being the intracardiac impedance over a cardiac cycle. Spec. 8, ll. 18-26. Appellants' Specification indicates that "controller circuit 420 of FIG. 4 derives many intracardiac impedance parameters from intracardiac impedance waveforms 510," namely, baseline impedance value Z_0, area Z_{area} between the impedance signal waveform 510 and the baseline Z_0, maximum peak impedance value Z_{max}, time interval of maximum impedance change $T_{Z0\text{-}Zmax}$, and slope of the intracardiac impedance wave form measured at ½ $T_{Z0\text{-}Zmax}$ 530, or $S_{½TZ0\text{-}Zmax}$. Spec. 8, l. 27 through Spec. 9, l. 21.

Huvelle's Figure 2 depicts an intracardiac impedance waveform 202 corresponding to a single cardiac cycle which is similar to Appellants' measured intracardiac impedance waveform 510. Huvelle, col. 2, ll. 30-32. In contrast to those intracardiac impedance parameters described in Appellants' Specification and mentioned *supra*, Huvelle describes yet another "intracardiac impedance derived parameter, [namely,] Half Cycle Activity (HCA)," and "[r]eferring to FIG. 2, HCA corresponds to the dark-shaded area 204 divided by the sum of the dark-shaded area 204 and the light-shaded area 206 underneath the impedance wave form 202 of a single cardiac cycle." Huvelle, col. 4, ll. 2-4, 24-27. Huvelle also describes numerous experiments performed on an ambulatory dog. Huvelle, col. 7, l. 1 through col. 12, l. 48. The Examiner particularly points to Experiment VI, in which the Hemodynamic Upper Rate Level (HURL) and Hemodynamic Lower Rate Level (HLRL) are determined, as support for Huvelle teaching or suggesting a cycle-to-cycle change in slope value. Ans. 5 and 7 (citing Huvelle, col. 9, ll. 51-53). Huvelle's Figures 12a-12d are discussed in connection with Experiment VI and these figures show overlaid plots of the

changes over time in several cardiac cycles in (a) the treadmill speed, (b) ventricular rate, (c) atrial rate, and (d) 1/HCA value, respectively, in the ambulatory dog engaged in an exercise on a treadmill, demonstrating the HURL and HLRL determination. Huvelle, col. 3, ll. 1-5.

In view of the above-discussed disclosure of Huvelle, we are persuaded by Appellants' arguments that Huvelle does not disclose or suggest a cardiac-cycle-to-cardiac-cycle change in a slope value of the intracardiac impedance waveform signal as suggested by the Examiner. Huvelle's Experiment VI and Figures 12a-12d do not support the Examiner's position that "HCA values are computed in order to provide a cycle-to-cycle change in a slope value." Ans. 7. HCA values are ratios of areas and involve graph variables different from those recited in the claims. We agree with Appellants that the Examiner's reliance on the 1/HCA curve 1230 shown in Figure 12d to establish the slope value is misplaced since it is the intracardiac impedance curve 202 shown in Figure 2 that the Examiner should be relying on to generate the slope values. Even if a slope value could be computed from the 1/HCA curve 1230 shown in Huvelle's Figure 2d, it would be the wrong slope value since it would not be a slope value associated with the intracardiac impedance curve 202 shown in Huvelle's Figure 2. Thus, the Examiner has failed to show that Huvelle meets the claim language of using at least two the three recited parameters because the Examiner has not addressed the maximum peak intracardiac impedance value and has failed to show that the slope value can be computed from Huvelle's HCA parameter.

Accordingly, we do not sustain the Examiner's rejection of claims 1-4, 7-12, 14, 16, and 18-31 under 35 U.S.C. § 103(a) as unpatentable over Huvelle.

Rejection II – Obviousness based on Huvelle and Weiss

The Examiner's rejection relies on the erroneous finding that Huvelle discloses the capability of providing a cycle-to-cycle change in a slope value of the intracardiac impedance waveform. Appellants argue that Weiss fails to cure the deficiency of Huvelle. App. Br. 18. We agree. Accordingly, we do not sustain the Examiner's rejection of claims 5 and 6 under 35 U.S.C. § 103(a) as unpatentable over Huvelle and Weiss.

DECISION

We reverse the Examiner's decision to reject claims 1-12, 14, 16, and 18-31.

REVERSED

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