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D E C I S I O N
of 7 April 2005

Case Number: T 1029/03 - 3.2.2

Application Number: 95944683.2

Publication Number: 0874584

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Language of the proceedings: EN

Title of invention:

Non-invasive monitoring and treatment of subjects on cardiac arrest using ECG parameters predictive of outcome

Applicant:

THE OHIO STATE UNIVERSITY RESEARCH FOUNDATION

Opponent:

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Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 54

Keyword:

"Novelty - (no) "

Decisions cited:

-

Catchword:

-



Case Number: T 1029/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 7 April 2005

Appellant: THE OHIO STATE UNIVERSITY RESEARCH FOUNDATION
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 10 April 2003
refusing European application No. 95944683.2
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: S. S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 10 April 2003 to refuse European patent application No. 95 944 683.2.

The application was refused on the grounds that the subject-matter of claim 1 was not novel in view of D1 (WO-A-91/19452).

On 10 June 2003 the appellant lodged an appeal against the decision having already paid the prescribed fee on 5 June 2003. On 15 August 2003 a statement of grounds of appeal was filed.

- II. Oral proceedings were held on 7 April 2005 in the absence of the appellant's representative, who had written to say that he would not be attending the oral proceedings.
- III. The appellant requested, in the written proceedings, that the decision under appeal be set aside and that the application proceed to grant on the basis of claims 1 to 18 filed with the grounds of appeal, or on the basis of claims 1 to 18 filed with the letter dated 4 March 2005 as an auxiliary request, or on the basis of claim 1 filed with the letter dated 23 March 2005 as a second auxiliary request. The appellant also requested a reimbursement of the appeal fee.

IV. Claim 1 of the requests read as follows:

Main request

"Apparatus for indicating the condition of a heart in ventricular fibrillation or asystole, the apparatus including an analyser (104) arranged to receive samples representative of a time-domain sampled electrocardiogram of a heart under test, to transform the samples to a frequency-domain power spectrum and to determine a frequency parameter from the power spectrum; the apparatus being characterised by a processor (106, 206) arranged to resolve the frequency parameter determined by the analyser into a characteristic that is predictive of a clinically relevant cardiac arrest outcome for the subject; wherein the processor is arranged such that, in operation, the characteristic is predictive of a successful outcome if the frequency parameter exceeds a threshold value."

First auxiliary request

The feature "the frequency parameter comprising at least one of the centroid frequency (F_c) and the peak power frequency (F_p) of the power spectrum;" is added to claim 1 of the main request as the first characterising feature of the claim.

Second auxiliary request

"Apparatus for predicting the ability of a heart in ventricular fibrillation or asystole to be converted to a pulsatile rhythm following countershock, the apparatus including an analyser (104) arranged to

receive samples representative of a time-domain sampled electrocardiogram of a heart under test, to transform the samples to a frequency-domain power spectrum and to determine a frequency parameter from the power spectrum, the frequency parameter comprising at least one of the centroid frequency (Fc) and the peak power frequency (Fp) of the power spectrum and a processor (106, 206) arranged to provide a positive prediction of said ability when the frequency parameter exceeds a threshold value."

V. The appellant argued as follows:

D1 did not disclose determining from the power spectrum a parameter which was predictive of a clinically relevant cardiac arrest outcome. D1 was directed toward a method for detecting and evaluating heart disorders and for delivering an automatic shock whose size was determined by the FFT's peak energy, and also disclosed detecting the effects of drug toxicity. In neither case was the parameter being measured predictive of a clinically relevant cardiac arrest outcome.

D1 did not relate to a device including a processor and an analyser but instead could be carried out by merely visually examining the output of a spectrum analyser. It was unreasonable to construe a passage which said "the patient exhibiting VF which is difficult to revert with shock will have and FFT with peak energy at a relatively high frequency" as indicating that the presence of the high frequency was predictive of a successful outcome.

The appellant had argued in its letter dated 16 August 2002 against the novelty objection of the examining division, based on the fact that D1 did not disclose a step of determining from the power spectrum a parameter which was predictive of a clinically relevant cardiac arrest outcome and introduced a clarifying example. This represented a bona-fide attempt at overcoming the objections and changed the points at issue. Moreover, in its decision the examining division relied on the argument that a method step cannot be considered in assessing novelty, which ground of rejection the appellant had not had an opportunity to comment upon. Therefore, the requested reimbursement of the appeal fee was justified.

Reasons for the Decision

The appeal is admissible.

1. *Main request*

1.1 Interpretation of claim 1

The application appears to define three different objects on page 2, lines 14 to 21 of WO-A-97/24062, and corresponding apparatus or methods, of which only the second object (It is additionally desirable to more accurately predict whether attempts to countershock the subject will result in conversion of the heart to an organized, pulsatile rhythm, in order to avoid the application of unnecessary and potentially harmful counter shocks) is pertinent to the claimed invention. This aspect of the application is described as "one

aspect" on page 3, lines 1 to 7 and line 28 to page 4, line 7 and in detail on page 5, line 9 to page 6, line 27. The remainder of the description deals with the other objects and aspects of the application.

According to claim 1 the apparatus is characterised by a processor arranged to resolve the frequency parameter determined by the analyser into a characteristic that is predictive of a clinically relevant cardiac arrest outcome for the subject. It is not clear from the description that the frequency parameter determined by the analyser is in fact resolved into a characteristic predictive of a clinically relevant cardiac arrest outcome for the subject, rather the frequency parameter itself appears to be predictive of a clinically relevant cardiac arrest outcome for the subject.

This is stated clearly on page 2, lines 28 to 33, page 3, lines 1 to 5 and 17 to 18, etc, and in the "Description of the first embodiment" it is stated on page 6, lines 1 to 8 that "After F_c and F_p are determined by predictive parameter determining apparatus 20, it is then determined at 30 whether F_c and/or F_p are equal to or above particular thresholds", and "If F_c and/or F_p are equal to or above their respective thresholds, defibrillator 21 is instructed by apparatus 20 at 32 to issue a countershock".

Claim 1 of the refused set of claims is consistent with the above in that its characterising features is that the apparatus is arranged to determine from the power spectrum a parameter that is predictive of a clinically relevant cardiac arrest outcome for the subject. Also, according to the grounds of appeal, page 2, fifth

paragraph, claim 1 of the application requires that a successful outcome be predicted by the frequency parameter exceeding a threshold.

Therefore, this feature of claim 1 will be interpreted according to the description and the argumentation of the appellant, i.e. that it is the parameter itself that is predictive of a clinically relevant cardiac arrest outcome for the subject and not a characteristic derived from the frequency parameter which is predictive of the outcome.

Moreover, claim 1 states that the processor is arranged such that, in operation, the characteristic is predictive of a successful outcome if the frequency parameter exceeds a threshold value. This feature is not supported by the above description, since according to page 6, lines 7 and 8 if Fc and/or Fp are equal to or above their respective thresholds, defibrillator 21 is instructed by apparatus 20 at 32 to issue a countershock. There is no mention of the prediction of a successful outcome here. On page 6, lines 24 and 25 it is said that Fp and Fc are predictive of successful outcomes from countershock, but this information is not related to the construction of the processor. Therefore, this part of the claim will be construed as saying that if the parameter is equal to or above a threshold a defibrillation shock is issued.

The same comments apply to claim 1 of the first and second auxiliary requests, although the latter uses a slightly different wording ("positive prediction of said ability").

1.2 Novelty

D1 describes three different inventions, of which the "second aspect" described on page 3, lines 18 to 33 and page 9, line 24 to page 11, line 22 is relevant to the present application. These passages of D1 describe taking an ECG and converting it into the frequency domain, and disclose the measurement of the peak power frequency of the power spectrum, F_p (see page 3, lines 28 to 33 and 10, lines 28 to 37), and that it is also determined whether this frequency is above or below a certain threshold, for example 10Hz.

Starting on page 9, line 24 there is described a method wherein the ECG is Fourier-transformed to give an indication of the heart condition in ventricular fibrillation. The peak of the frequency spectrum is determined and if the energy peak in the frequency domain spectrum is at a relatively high frequency (i.e. above the threshold value of about 10Hz), the heart will be difficult to revert with a shock and will require a relatively high energy shock to defibrillate the patient (see page 3, lines 24 to 27, page 10, lines 32 to 37 and page 11, lines 20 to 22). The location of the peak frequency above the threshold of about 10Hz is, therefore, a predictor of the outcome of the shock. It is noted that the appellant agrees with this analysis in its letter dated 4 March 2005, page 2, fifth paragraph.

Therefore, D1 discloses apparatus for indicating the condition of a heart in ventricular fibrillation or asystole, the apparatus including an analyser 704 (Figure 7) arranged to receive samples representative

of a time-domain sampled electrocardiogram of a heart under test, to transform the samples to a frequency-domain power spectrum and to determine a frequency parameter (the peak energy) from the power spectrum, which parameter is predictive of a clinically relevant cardiac arrest outcome for the subject if the frequency parameter exceeds a threshold value.

The appellant argued that D1 did not relate to a device including an analyser and a processor. This is not correct since the processor 704 is a spectrum analyser and a processor (page 11, lines 12 to 15). The appellant also argued that it was unreasonable to construe D1 as disclosing that the presence of the high frequency was predictive of a successful outcome. This argument is not accepted since, as shown above, the described apparatus also does not possess this feature.

The apparatus of claim 1 of the main request lacks novelty, accordingly.

2. *First auxiliary request*

Claim 1 specifies that the frequency parameter comprises at least one of the centroid frequency (F_c) and the peak power frequency (F_p) of the power spectrum. As noted above, D1 discloses the use of the peak power frequency as the frequency parameter which is predictive of a successful outcome. Therefore, this feature of claim 1 fails to endow the claim with novelty.

3. *Second auxiliary request*

The apparatus of D1 has a processor which is arranged so that if the energy peak in the FFT is relatively low, the processor 704 causes a shock device to administer a small shock to the patient, and if the energy peak in the FFT is relatively high, the processor 704 causes a shock device to administer a large shock to the patient (page 11, lines 15 to 20).

Since the administration of a shock to a patient is done with the expectation of ending a fibrillation episode, the processor may, indeed, be said to predict the ability of a heart in ventricular fibrillation or asystole to be converted to a pulsatile rhythm following countershock. As stated in point 1.1 above, the feature "to provide a positive prediction of said ability when the frequency parameter exceeds a threshold value" is ignored in this analysis.

As may be ascertained from the discussion of the previous requests D1 includes all the other features of claim 1. The subject-matter of this claim also lacks novelty, accordingly.

4. *Refund of the appeal fee*

Since none of the requests is allowable the appeal fails. Since, pursuant to Rule 67 EPC, reimbursement of the appeal fee is conditional upon the appeal being found allowable, the request of the Appellant in this respect cannot be granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner