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D E C I S I O N
of 26 March 2002

Case Number: T 0933/99 - 3.2.2

Application Number: 92301503.6

Publication Number: 0506230

IPC: A61B 5/0464

Language of the proceedings: EN

Title of invention:
Medical device with morphology discrimination

Patentee:
VENTRITEX, INC.

Opponent:
Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54

Keyword:
"Novelty (yes)"

Decisions cited:
G 0007/95, G 0010/91, T 0105/94

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0933/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 26 March 2002

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 15 July 1999 rejecting the opposition filed against European patent No. 0 506 230 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
U. J. Tronser

Summary of Facts and Submissions

I. The appellant (opponent, Biotronik Meß- und Therapiegeräte GmbH & Co. Ingenieurbüro Berlin) lodged an appeal against the decision of the opposition division to reject the opposition to the grant of European patent No. 0 506 230. The decision was dispatched on 15 July 1999.

The appeal and the fee for the appeal were received on 15 September 1999. The statement setting out the grounds of appeal was received on 25 November 1999.

The notice of opposition, filed on 14 January 1997, cited the documents E1 and E2, and Article 100(a) EPC as the ground of opposition, and stated that the subject-matter of the opposed patent was not patentable in the sense of Articles 52 to 57 EPC, and lacked novelty within the meaning of Article 54 EPC, or at least did not involve an inventive step within the meaning of Article 56 EPC.

However, the only ground substantiated during the nine month opposition period was that of lack of novelty, and no arguments were submitted within this period regarding inventive step. The opposition division decided that Article 100(a) in combination with Article 56 EPC was not an admissible ground of opposition, accordingly, and examined, as the only ground of opposition, the alleged lack of novelty.

The cited documents are:

E1: US-A-4 905 708

E2: EP-A-0 469 817 (cited under Article 54(3) EPC)

The opposition division decided that, having regard to documents E1 and E2, the contested patent met the novelty requirement of the Article 52(1) EPC.

The appellant, with its Grounds of Appeal, has cited documents E3 and E4, of which only document E3 (US-A-5 000 189) was relied upon during the oral proceedings before the Board.

II. The oral proceedings took place on 26 March 2002 , at the end of which the following requests forming the basis of the decision were put forward:

The appellant requested that the decision under appeal be set aside and that European patent No. 0 506 230 be revoked.

The respondent (patent proprietor, Ventritex Inc. USA) requested that

- the appeal be dismissed and that the patent be maintained as granted (main request)

- or that the decision under appeal be set aside and the patent be maintained in the amended form according to one of the four auxiliary requests as submitted with the letter dated 25 February 2002. As a fifth auxiliary request and in the case the Board would admit the belatedly submitted grounds of appeal remittal back to the department of the first instance is requested and if remittal is not permitted amendment of the patent to exclude claims 6 to 11 is requested. In the event of a

change in the scope of appeal beyond the ground of novelty award of costs against the appellant is requested.

III. The independent claims 1 and 6 of the main request read as follows:

1 "A medical device for monitoring waveform complexes of intracardiac electrograms, which comprises electrode means adapted to be coupled to a patient's heart, sensing means (20) having an input coupled to said electrode means for sensing analog intracardiac electrograms, and analog to digital converter means (26) for converting the analog intracardiac electrogram to digital form;

characterised by:

examining means (28,10) for examining the intracardiac electrogram and comprising means for determining, with respect to a waveform peak of said digitized intracardiac electrogram, its amplitude, width and polarity, to provide identification criteria; storing means (16) for storing said identification criteria, and concluding means (10) for concluding if the examined peak is within the same waveform complex as a previously examined peak."

6 "A method for monitoring waveform complexes of intracardiac electrograms, which comprises the step of providing electrode means adapted for coupling to a patient's heart, sensing analog intracardiac electrograms from said electrode means, and converting the analog intracardiac

electrograms to a digital format;

characterised in that:

said method further comprising the steps of, examining the intracardiac electrogram, said examining step comprising the step of determining, with respect to a waveform peak of said digitized intracardiac electrogram, its amplitude, width and polarity, to provide identification criteria; and concluding if the examined peak is within the same waveform complex as a previously examined peak."

IV. The appellant argued as follows in respect of the main request:

Scope of the appeal proceedings

In the present case the criteria for judging novelty overlapped strongly with the criteria for judging inventive step. If a small difference were to be found between the claimed subject-matter and a prior art document, then the difference could be examined for inventive step with ease since there was a seamless transition from examining for novelty to examining for inventive step. It was recognised legal practice to handle these subjects together for procedural economy, particularly since no new documents were required. Hence there would no conflict with the decision G 7/95 if the issue of inventive step were to be considered in the present case.

Late filed document E3

Should document E1 not be seen as anticipating the

claimed subject-matter then document E3 would become important. This document showed clearly that both a signal or its time derivative could be used to study the morphology of an intracardiac signal.

Novelty

The wording of claim 1 was so broad and indefinite that the disclosure of document E1 read onto the claim. In particular the use of the expressions "digitized intracardiac electrogram" and "to provide identification criteria" opened up the scope of the claim so as to include all kinds of features. The patent did not disclose any example of how the signal was digitised, so this expression covered any conceivable way of doing this, including the use of a digital camera. Moreover, it covered any mathematical process that resulted in numbers that could be stored in a microprocessor, for example the use of Fourier analysis or compression techniques, and there was only a very vague connection between a waveform peak and the digitised signal.

Moreover, the use of the expression "digitized intracardiac electrogram" meant that the amplitude, width, and polarity of the signal could only be related indirectly to the digitised signal, which meant that claim 1 also covered the use of a time derivative of the signal.

V. The respondent argued as follows in respect of the main request:

Scope of the appeal proceedings

Novelty and inventive step were two different grounds of opposition and had to be substantiated separately within the opposition period, as set out in decision G 7/95. Therefore, lack of inventive step should not be admitted as a ground of appeal.

Late filed document E3

Document E3 was either relevant or not, its relevance could not be conditional on that of document E1. Document E3 clearly referred to the use of the first derivative of the signal and employed a complicated algorithm. There was nothing in this document about analysing the morphology of a raw signal.

Novelty:

Claim 1 was clear in that it stated that the raw intracardiac signal was digitised and that the amplitude, width, and polarity of the raw signal were measured. Only digital values could be handled by a microprocessor, so this was why the analog signals were digitised.

There was a fundamental difference between processing a raw signal, as in the patent in suit, and processing a time derivative of that signal, as in document E1. These two signals had quite different morphologies. Moreover, neither document E1 nor document E2 disclosed the concluding means as defined at the end of claim 1.

Reasons for the Decision

1. The appeal is admissible.

2. *Scope of the appeal proceedings (main request)*

Decisions G 7/95 and G 10/91 (OJ 1996, 615 and 626) clearly rule that the question of lack of novelty is a different ground of opposition to that of lack of inventive step, and that in principle, the opposition division shall examine only such grounds for opposition which have been properly submitted and substantiated in accordance with Article 99(1) in conjunction with Rule 55(c) EPC, and only exceptionally, may the opposition division in application of Article 114(1) EPC consider other grounds for opposition which, prima facie, in whole or in part would seem to prejudice the maintenance of the European patent. The decision T 105/94 held that a ground of opposition raised but not substantiated in the opposition period was a new ground of opposition when raised in appeal proceedings. In view of these decisions the jurisprudence regarding the admissible grounds of opposition is quite consistent.

The appellant did not dispute that the ground of lack of inventive step was not substantiated in detail in its letter of opposition. It argued, however, that, if novelty of the claimed subject-matter with respect to document E1 were to be conceded, the degree of overlap between the claimed subject-matter and the prior art was so large that the remaining tiny difference prima facie did not involve an inventive step.

The detailed analysis under point 4 below reveals, however, that the difference between the claimed subject-matter and the disclosure of document E1 lies in a difference in the working principle and not in a marginal detail. Since document E2 cannot be used to

assess inventive step, there is no prima facie evidence that document E1 alone would lead the person skilled in the art to the claimed subject-matter.

It follows from the above that the opposition division acted correctly in refusing to consider the alleged lack of inventive step as a ground of opposition. In the appeal proceedings a fresh ground for opposition may only be considered with the approval of the patentee, which is not the case here. Therefore, the appeal procedure is confined to the question of alleged lack of novelty.

3. *Admissibility of the late filed document E3*:

Document E3: Like document E1 (see point 4.2 below) this document describes the comparison of the time derivative of a detected cardiac signal, and not the raw signal, with a template, as summarised in the abstract of this document. Document E3 also fails to disclose the last feature/step of the independent claims of the patent in suit, the use of concluding means. Therefore, this document is not more relevant than either of documents E1 and E2, and is not admitted into the procedure, in accordance with Article 114(2) EPC.

4. *Novelty*

Novelty is the only topic to be considered in the appeal procedure. Moreover, the only documents against which novelty of the claimed subject-matter is to be assessed are documents E1 and E2.

The appellant argues that claim 1 is so unclear and

broad that the disclosures of these documents read onto the claim. Therefore, the claim is first analysed for any obscurities.

4.1 The scope of claim 1

The preamble of the claim defines a conventional medical device for monitoring waveform complexes, wherein analog to digital (A/D) converter means convert the analog intracardiac electrogram to digital form. A/D converter means are well known in the art for converting an analog signal to digital form, as exemplified by document E1, since the digital format is the only form of signal a microprocessor can handle. The conversion is done, for example by sampling the raw signal at several points. The result is a digital version of the raw analog signal and is referred to as a "digitized intracardiac electrogram" in claim 1. The Board sees no difficulty with the use of this expression in claim 1.

Problems arise only if the claim is so badly misconstrued as to give it a meaning totally out of context. The appellant distorts the meaning of the claim in an attempt to stretch its true meaning so as to cover the disclosure of documents E1 and E2, which is not permissible. By pretending that the expressions "digitized intracardiac electrogram" and "to provide identification criteria" are unclear and admit all kinds of different interpretations, the appellant puts an alien construction on the patent that is borne out neither by the wording of the claim nor by a fair reading of the supporting disclosure.

On the contrary, it is clear, both from the context of

claim 1 as well as from the supporting disclosure, that the examining means examines the raw intracardiac electrogram and determines, from the digital representation of this analog signal, its amplitude, width, and polarity with respect to each waveform peak of the signal, so as to provide identification criteria for the peaks. The final part of the claim states that concluding means conclude if the examined peak is within the same waveform complex as a previously examined peak. This is also perfectly clear in itself and from the supporting passages of the description, for example page 4, lines 25 to 30. Again, there are no problems in this respect.

4.2 Document E1

There is a clear distinction between examining a raw signal, as is the case in the patent in suit, and examining its first time derivative, as is the case in document E1. This is clearly so if the question is seen from a purely mathematical point of view, but in the present case there are also different practical consequences arising from examining a signal and examining its derivative.

The patent in suit is concerned with examining the morphology of intracardiac electrograms, which means examining the form and structure of the intracardiac electrograms. As may clearly be seen from Figures 1 to 3 of document E1, the morphology of a signal has little correlation with the morphology of its time derivative. This is illustrated not only pictorially in document E1, but also practically, since it is the time derivative signal that is subjected to threshold tests and not the raw signal, the two giving different

results.

A further difference arising from the processing of the time derivative of the intracardiac electrogram rather than the raw signal in document E1 is that this document does not disclose means for determining, with respect to a waveform peak of the digitised intracardiac electrogram, its amplitude, width and polarity, since it is the amplitude, width and polarity of the derived signal that is determined in this document.

This document also does not disclose concluding means for concluding if the examined peak is within the same waveform complex as a previously examined peak. This feature means that a peak must be taken in relation to a previous peak as specified in claims 2 and 3 of the patent in suit. In particular, a peak must occur within a prescribed time window of a previous peak to be considered a member of the same complex, and there is a limit on the number of peaks in a complex, so if the previous peak has reached this number the next peak is not considered to be part of the same complex.

The disclosure at the end of column 3 and in claim 6 of document E1 is not clear, but at most says that all peaks must occur within prescribed time window, but this is short of relating a peak to a previous peak for concluding if the examined peak is within the same waveform complex as the previously examined peak.

4.3 Document E2

Document E2 describes an arrhythmia control method and device which rely on an arrhythmia recognition

algorithm that involves examining the morphology of the detected R-waves. There is no disclosure of examining a complex of peaks since only the R-wave part of a QRS complex is examined. Moreover, this is examined only as regards polarity, width, and R-R interval, eg as defined in claim 9 of this document, there is no measurement of the amplitude of the wave. This document also fails to disclose the last feature of the independent claims of the patent in suit, the recognition of a complex by examining a peak in relation to a previous peak.

4.4 For these reasons, neither of documents E1 or E2 anticipates the device of claim 1 or the method of claim 6.

5. For the above reasons the main request is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

V. Commare W. D. Weiß