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D E C I S I O N
of 27 January 2003

Case Number: W 0007/01 - 3.4.1

Application Number: 00923527.6

Publication Number: -

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:

Ultrasound for autocapture or other applications

Applicant:

Cardiac Pacemakers, Inc.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 154(3)

PCT Art. 17(3)(c), R. 13.1, 13.2, 13.3, 40.1, 40.2

Keyword:

"Lack of unity (no)"

"Invitation to pay additional fee - sufficiently reasoned (no)"

Decisions cited:

-

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: W 0007/01 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal
of 27 January 2003

Appellant: Cardiac Pacemakers, Inc.
4100 North Hamline Avenue
St. Paul,
Minnesota 55112 (US)

Representative: -

Decision under appeal: Protest according to Rule 40.2(c) PCT made by the applicant against the invitation of the EPO (ISA) to pay additional fees dated 22 August 2000.

Composition of the Board:

Chairman: M. Rognoni
Members: G. Assi
C. Holtz

Summary of Facts and Submissions

- I. International patent application PCT/US00/10570 was filed on 19 April 2000 with 31 claims including an independent claim 1 for a system and an independent claim 18 for a method.

Claims 1, 2, 3, 4 and 14 read as follows:

"1. A system, comprising:
a lead, where the lead includes one or more ultrasonic elements, and
an electronics unit coupled to the lead, where the electronics unit includes:
an ultrasound driving circuit to drive at least one of the one or more ultrasonic elements; and
a signal processing circuit that processes a signal based on ultrasound which is received by at least one of the one or more ultrasonic elements."

"2. The system of claim 1, where the one or more ultrasonic elements include a first ultrasonic element, where ultrasound driving circuit drives the first ultrasonic element and where the first ultrasonic element receives the ultrasound."

"3. The system of claim 1, where the one or more ultrasonic elements include a first ultrasonic element and a second ultrasonic element, where the first ultrasonic element is coupled to the ultrasound driving circuit and the second ultrasonic element receives the ultrasound."

"4. The system of claim 1, where the one or more

ultrasonic elements include a first ultrasonic element on the lead, and a second ultrasonic element in a case carrying the electronics unit."

"14. The system of claim 1, in which the signal processing circuit controls delivery of the ultrasound energy for lowering stimulation thresholds."

- II. With an invitation dated 22 August 2000 pursuant to Article 17(3)(a) and Rule 40.1 PCT, the European Patent Office (EPO), acting as International Searching Authority (ISA), informed the applicant that the application did not comply with the requirement of unity of invention (Rule 13.1, 13.2 and 13.3 PCT) and invited the applicant to pay eight additional fees.

According to the invitation, the application claimed nine inventions. In particular, Claims 1 to 4 concerned a first invention and Claim 14 a sixth invention. The different inventions were not so linked as to form a single general inventive concept. There was no technical relationship among the inventions involving different special technical features, which could not be regarded as corresponding since they solved different problems. Moreover, the subject-matter of Claims 1 to 3 of the first invention was known from document US-A-5 188 106.

- III. By a fax dated 6 October 2000, the applicant paid two additional fees under protest (Rule 40.2(c) PCT) for the fifth and the sixth invention.

According to the applicant, the application complied with the requirement of unity of invention insofar as Claims 2 to 17 were dependent on Claim 1.

- IV. The ISA, pursuant to Rule 40.2(e) PCT, issued a communication dated 27 November 2000 informing the applicant that, after a prior review of the justification for the invitation to pay additional fees, the protest was only partially justified. Since all the features of Claim 1 were disclosed in document US-A-5 188 106, a single general inventive concept linking the different inventions could not be found in the features of Claim 1. Thus, the invitation to pay an additional fee for the sixth invention was justified. However, it was not justified with regard to the fifth invention. Hence, one of the two additional fees should be refunded.
- V. By a fax dated 27 December 2000, the applicant paid the protest fee.

Reasons for the Decision

1. According to Rule 40.2(c) PCT, a payment under protest shall be accompanied by a reasoned statement. In the present case, the protest of 6 October 2000 only contained one sentence of reasoning, namely that "*the application complies with the requirements of unity of invention insofar as claims 2-17 are dependent claims to independent claim 1*". Such a general statement would normally not be sufficient for considering the protest admissible because it does not explain why the invitation to pay additional fees of 22 August 2000 should be regarded as wrong.

On the other hand, according to Rule 40.1 PCT, an invitation to pay additional fees shall specify the reasons for which the international application is not

considered as complying with the requirement of unity of invention. In the present case, the invitation is based on a statement that the subject-matter of Claim 1 is not novel having regard to document US-A-5 188 106 and, therefore, implies a lack of unity *a posteriori*. After a list of the alleged different inventions with the mention of the technical features and problems, it is simply stated that "*for each subject, special technical features have been respectively defined, which are in each case different, and cannot be regarded as corresponding since they solve different problems*". In the Board's opinion, however, the allegation of lack of unity *a posteriori* would require explaining the reasons why this conclusion was drawn, i.e. the subject-matters of the claims directly depending on Claim 1 should be regarded as unrelated inventions rather than different embodiments of the invention specified in Claim 1.

The simple statement that each of such dependent claims mentions different technical features solving different problems is not sufficient. This could lead to a nullification of the part of the invitation itself against which the protest is directed. The Board has however found that it is more expedient if a decision is taken on the merits of the protest.

Since the invitation was not well-reasoned, the applicant could not be expected to give sufficient reasons for the protest.

For these reasons, the Board considers that the right to a fair hearing would be jeopardized, if the applicant could not have the protest examined. In this respect, it is noted that the review panel considered

itself capable of dealing with the applicant's argument. The Board thus concludes, by way of exception, that the invitation is valid and that the protest is admissible.

2. The applicant paid two additional fees under protest for the fifth and sixth inventions. Since the ISA concluded that the invitation to pay an additional fee was not justified with regard to the fifth invention and ordered to refund one additional fee, the Board has only to deal with the question whether the application complies with the requirement of unit of invention having regard to the sixth invention.
3. The Board agrees with the conclusion of the ISA that the subject-matter of Claim 1 is known from document US-A-5 188 106. This raises the question of lack of unity *a posteriori* with regard to the sixth invention. Although the applicant is correct in stating that Claim 14, in particular, is dependent on Claim 1, this statement is not sufficient for concluding that there is unity. Indeed, Claim 14 in combination with Claim 1 defines a claim (sixth invention) which is independent from Claim 1 (first invention).
4. According to the invitation of the ISA to pay additional fees, the first invention concerns Claims 1 to 4 and deals with a "*system with second ultrasound element mounted in electronics case*".

This statement is not fully correct. Claim 1 refers to a system comprising *inter alia* a lead including "*one or more ultrasonic elements*", in other words a lead including at least one ultrasonic element. Claim 2 concerns the function of "*a first ultrasonic element*"

which is driven by the ultrasound driving circuit and is also used for receiving ultrasounds. The wording of Claim 2, however, does not exclude the presence of other ultrasonic elements, this being in conformity with the teaching of Claim 1. Claim 3 defines the function of "a *first ultrasonic element*" coupled to the ultrasound driving circuit and "a *second ultrasonic element*" receiving ultrasounds. Claim 4 defines the location of "a *first ultrasonic element*" on the lead, in conformity with Claim 1, and of "a *second ultrasonic element*" in a case carrying the electronics unit.

In summary, Claim 1 defines, in general, a system comprising *inter alia* a lead including at least one ultrasonic element, whereas Claims 2, 3 and 4 refer to specific forms of this system, in particular the lead includes a both transmitting and receiving ultrasonic element (Claim 2), the lead includes two ultrasonic elements, one transmitting and the other receiving (Claim 3), and the lead includes a first ultrasonic element, a second one being located in the case of the electronics unit (Claim 4).

5. In the application as filed (see page 2, lines 10 to 29, page 13, lines 20 to 29), the system of Claim 1 is presented as a solution to the problem faced by cardiac rhythm management systems to provide therapy at appropriate energy levels. Indeed, the provision of ultrasound autocapture capability allows to determine whether a stimulation has evoked a response from the heart, and to adjust the stimulation energy on the basis of the observed response, whereby "*adjusting*" means that only the energy needed to ensure reliable capture is provided.

Claims 2 to 4 represent specific forms of the general solution according to Claim 1 and thus solve the same problem. In fact, page 5, lines 12 to 29, and Figure 2 of the application show a system comprising a first and a second ultrasonic element both "*for transmitting ultrasound, receiving ultrasound, or both transmitting and receiving ultrasound*", the first ultrasonic element being located on the lead and the second one within the case enclosing the electronics unit. It is obvious that a second ultrasonic element is only necessary if the first one is either transmitting or receiving. In any case, the embodiments of Claims 2 to 4 provide ultrasound autocapture capability for determining the response from the heart evoked by a stimulation, the response being then used by the electronics unit for adjusting the stimulation energy.

According to Claim 14, the signal processing circuit, which according to Claim 1 is part of the electronics unit, controls delivery of the ultrasound energy. This feature is intended for "*lowering stimulation thresholds*", as the claim itself recites. In other words, the signal processing circuit avoids the production of stimulation pulses having unnecessarily high energy. This corresponds to the problem of adjusting the stimulation energy in the sense that only the energy is provided, which is needed to ensure reliable capture (*supra*). Indeed, considering that the ultrasound autocapture capability of the claimed system saves energy and prolongs the life of the implanted device (see page 2, lines 27 to 29, and page 13, lines 27 to 29), "*adjusting the stimulation energy*" can only mean "*lowering stimulation thresholds*". Thus, Claim 14 concerns a specific form of the invention, which solves the same technical problem as the subject-

matters of Claims 1 to 4 (see page 12, lines 24 to 31).

6. Therefore, in the invitation of the ISA to pay additional fees it was not correct to state that, with particular regard to the first and sixth inventions, special technical features have been defined, which cannot be regarded as corresponding since they solve different problems. It should rather be concluded that Claims 2 to 4 and 14 concern specific forms of the invention according to Claim 1, all of them solving the same problem. An objection of lack of unity is, under these circumstances, not justified.

7. For these reasons, the invitation to pay an additional fee for sixth invention is not legally effective. The protest is entirely justified.

Order

For these reasons, it is decided that:

1. The refund of the additional fee for the sixth invention is ordered.

2. The refund of the protest fee is ordered.

The Registrar:

The Chairman:

R. Schumacher

M. Rognoni