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**Datasheet for the decision
of 25 October 2022**

Case Number: T 1382/18 - 3.4.01

Application Number: 06780471.6

Publication Number: 1937357

IPC: A61N1/36

Language of the proceedings: EN

Title of invention:

APPARATUS AND METHOD FOR DELIVERING ELECTRICAL SIGNALS TO A
HEART

Applicant:

Impulse Dynamics NV

Headword:

Delivering therapeutic signals to the heart / Impulse Dynamics
N.V.

Relevant legal provisions:

RPBA 2020 Art. 12(1)(d)

EPC Art. 56

Keyword:

Basis of proceedings - written reply of the appellant



Beschwerdekammern

Boards of Appeal

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Case Number: T 1382/18 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 25 October 2022

Appellant: Impulse Dynamics NV
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 18 January 2018
refusing European patent application No.
06780471.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman T. Petelski
Members: P. Fontenay
D. Rogers

Summary of Facts and Submissions

I. This decision relates to the applicant's appeal against the Examining Division's decision to refuse European patent application 06 780 471.

II. In their decision, the Examining Division referred to a document entitled "Result of consultation" which reproduced the content of an exchange between the first examiner and the applicant on 1 December 2017.

In the course of this exchange, the applicant was informed that the Examining Division were of the view that the subject-matter of claim 1 of the main request and auxiliary requests 1, 2, 6 and 7 did not involve an inventive step in the sense of Article 56 EPC over document:

D1: US-B-6 370 430 (erroneously identified as US-A-6 370 430).

The additional limitations in claim 1 of auxiliary requests 3, 4, 5 and 8 were considered to be either known from D1 or to refer to obvious details. The subject-matter of claim 1 of these requests was accordingly considered not to be inventive in the sense of Article 56 EPC.

III. The appellant (applicant) requested that the impugned decision be set aside and that a patent be granted on the basis of a new main request or, in the alternative, one of a first to fourth auxiliary requests, submitted

with the statement of grounds. The main request corresponded to the auxiliary request 2 underlying the impugned decision.

In substance, it was stressed that the Examining Division erred in considering that the sensing unit in D1 was adapted to sense global intra-cardiac ECG (electrocardiogram) signals between a ventricular electrode and a distant electrode. There was also no indication in D1 that the processing means were adapted for receiving both local and global ECG signals from the sensing means, and to process these signals to distinguish between ventricular and supra-ventricular electrical events such that an electrotherapeutic signal is inhibited only in the first type electrical event, as defined in claim 1 of the appellant's request.

IV. In a communication pursuant to Article 15 RPBA, the appellant was informed of the Board's preliminary opinion.

With exception of dependent claim 14, the claims according to the main request were considered to meet the requirements of Article 123(2) EPC as to added subject-matter.

In contrast to the Examining Division, the Board held that the objective technical problem solved by the invention extended beyond the mere provision of alternative means fulfilling the same purpose as those known from D1. Relying on the preliminary finding that the claimed device could distinguish between ectopic signals originating, for example, in the atria, and others having their origins in the ventricular, the

invention provided effects that were not achieved by the system of D1. By reducing the number of false positives, the claimed device was able to deliver stimulating signals when required, that is without being inhibited for the wrong reasons. The objective problem appeared thus to consist in reducing the non-application of therapeutic stimulation signals during safe beats. Therefore, the claimed device was not limited to providing redundant sensing and processing means, as assumed by the Examining Division. The claimed subject-matter according to the main request was considered to be inventive (Article 56 EPC).

The applicant was invited to file an amended version of the claims taking due account of the objection that had been raised against dependent claim 14 of the main request and to file an adapted version of the description.

- V. In a reply to the communication of the Board, the appellant filed an amended main request and amended pages of the description. The request for oral proceedings was withdrawn. The amended main request differed from the previous one essentially in that dependent claim 14 was deleted.

- VI. Claim 1 of the main request reads:

A device for controlling the delivery of electrotherapeutic signals to a heart of a subject within a cardiac beat cycle, the device comprising: at least one electrotherapeutic signal delivering unit configured for being coupled to one or more

ventricular electrodes for delivering one or more electrotherapeutic signals to said heart;
a sensing unit operatively couplable [sic] to at least one of said one or more ventricular electrodes and to a distant electrode implanted in said subject, said sensing unit is configured for sensing at least one global intra-cardiac electrocardiac signal between a ventricular electrode and a distant electrode implanted in said subject, and for sensing at least one locally sensed electrical signal from said ventricular electrode;
a processing unit operatively coupled to said at least one electrotherapeutic signal delivering unit and to said sensing unit, said processing unit is configured for controlling the operation of said electrotherapeutic signal delivering unit, for receiving from said sensing unit signals representing said global intra-cardiac electrocardiac signal and said locally sensed electrical signal; and
a power source for providing power to said at least one electrotherapeutic unit, said sensing unit and said processing unit;
characterized in that said processing unit is configured for processing said global electrocardiac signal and said locally sensed signal to detect a suspected ectopic electrical event within said cardiac beat cycle and distinguish between a ventricular ectopic electrical event and an electrical event originating from a supra-ventricular source; and for inhibiting the delivery of said electrotherapeutic signal to said heart upon detecting said ventricular ectopic electrical event.

Reasons for the Decision

Main request - Admissibility (Article 12(1)(d) RPBA 2020)

1. The amended main request is the answer to the communication of the Board in which the appellant was invited to file an amended request according to the guidance provided by the Board. Concretely, the appellant was informed that a claim-request which would not include dependent claim 14 of the main request then pending would meet the requirements of the EPC.
2. The main request is thus considered to fall under the definition of Article 12(1)(d) RPBA 2020. Article 12(1)(d) specifies that the appeal proceedings shall be based on any communication of the Board and any answer thereto filed pursuant to directions of the Board. The amended main request is thus admissible.

Main request - Added subject-matter (Article 123(2) EPC)

3. Claim 1 derives from original claim 11 and the passage in the original description on page 12, line 26 to page 13, line 14. The reference in the claim to "at least one global intra-cardiac electrocardiac signal" is supported by the original application documents (see e.g. page 4, lines 14-27; page 68, lines 15-29). Similarly, the characterising feature that the processing means "is configured ... to distinguish between a ventricular ectopic electrical event and an electrical event originating from a supra-ventricular

source" is supported by the original disclosure. It is based on the passage of the description on page 4, lines 23-27.

4. Dependent claims 2 to 8 are based on original claims 12 to 18. Dependent claims 9 to 12 are based on claim 19 in combination with claims 28 to 31. Although referring primarily to methods of controlling the delivery of electrotherapeutic signals, it is acknowledged that said methods necessitate the presence of corresponding technical means. The passage on page 15, lines 25-32, provides a sufficient basis for claim 13, insofar as it discloses that the suspected ectopic electrical events may result from premature ventricular contractions. The application focuses on the case of CCM devices, thus providing ample support for claim 14.

Main request - Novelty (Article 54 EPC)

5. The Examining Division based their decision on the preliminary finding that the subject-matter of claim 1 differed from the device for controlling the delivery of electrotherapeutic signals disclosed in D1 "in that the sensing unit is configured for sensing at least one intra-cardiac electrocardiac signal between a ventricular electrode and a distant electrode implanted in said subject and for sensing at least one locally sensed electrical signal from said ventricular electrode".
6. The Board concurs with this finding. It is stressed, in this respect, that the Board, contrary to the appellant's assessment, further shares the view of the Examining Division according to which the sensing unit in D1 is adapted to sense global intra-cardiac ECG

signals between a ventricular electrode and a distant electrode. Reference is made, in this respect, to the paragraph in column 20, lines 35-37, of D1 where explicit reference is made to signals measured between electrodes 2A, 4A and 6A and case 3 of the device. The Board failed to see any difference between this embodiment in D1 and the embodiment according to the claimed invention described in relation with Figure 3 on page 29, line 28 to page 30 line 16, of the published application, insofar as global measurement is concerned.

7. The claimed subject-matter differs from the known device in more respects than assumed by the Examining Division. There is, namely, no indication in D1 that the processing means are adapted for receiving both local and global ECG signals from the sensing means, as defined in claim 1.
8. Concretely, the Board considers that the claimed device is distinguished from the device known from D1 by the following features:

the processing unit is configured for ...receiving from said sensing unit signals representing said global intra-cardiac electrocardiac signal and said locally sensed electrical signal;...

...

and in that said processing unit is configured for processing said global electrocardiac signal and said locally sensed signal to detect a suspected ectopic electrical event within said cardiac beat cycle and distinguish between a ventricular ectopic electrical event and an electrical event originating from a supra-ventricular source;

and for inhibiting the delivery of said electrotherapeutic signal to said heart upon detecting said ventricular ectopic electrical event.

Main request - inventive step (Article 56 EPC)

9. The Examining Division defined the objective technical problem as the provision of an alternative for ectopic beat sensing.
10. The proposed definition is not persuasive considering the distinguishing features identified above with regard to D1.
11. A technical alternative to a known configuration or process refers to a different combination of technical means or steps in order to achieve the same purpose while providing the same effects. By relying on both global and local ECG signals, the claimed device aims however at better distinguishing between safe and unsafe beats. This determination is performed before deciding on the suitability, under the circumstances, of the electrotherapeutic signal to be generated.
12. True ventricular events, like PVC events, are indicative of ventricular arrhythmia disorders. They may lead to heart failure in case an electrotherapeutic signal is delivered to the heart by a stimulating device. Concretely, the claimed device permits distinguishing between signals originating, for example, in the atria, and others having their origins in the ventricular. By reducing the number of false positives, the claimed device is able to deliver

stimulating signals when required, that is without being inhibited for wrong reasons.

13. The claimed device is thus not just an alternative to the known configuration. It provides discriminating functionalities before deciding on the therapeutic treatment that are not disclosed in D1.
14. Hence, the objective problem consists in reducing the number of false positives and the resulting absence of therapeutic stimulation signals during safe beats.
15. Document D1 suggests relying on a multiplicity of local sensing electrodes in order to distinguish between normal pacing signals and ectopic signals. Even if the possibility of far-field (global) sensing means is envisaged, as stressed above, there is no suggestion in D1 that the two sensing approaches may be combined to achieve a better discrimination between ventricular signals and supra-ventricular signals. There is, accordingly, also no mention in D1 that one and the same electrode is to sense both the local and global electrical signals.
16. As stressed by the applicant, the configuration defined in D1 creates an over-protective safeguard, since any signal detected during a predefined artifact window will inhibit the generation of any stimulating signal, independently of its origin. This leads to stimulating signals being inhibited also in situations where such generation would be required and safe.
17. The present invention appears to rely on a totally different approach from the one disclosed in D1. Instead of relying on a multiplicity of local signals, the claimed invention relies on the combination of a

local and a global signal, the latter being considered, in the context of D1, as interfering with the primary information delivered by local sources (electrodes). The claimed device appears thus to extend beyond a system incorporating redundant sensing and processing means, as assumed by the Examining Division.

18. The claimed subject-matter differs substantially from the teaching disclosed in D1 and does not result in an obvious manner from D1. It is thus inventive (article 56 EPC).

Order

For these reasons it is decided that:

- The decision under appeal is set aside.

- The case is remitted to the department of first instance with the order to grant a patent on the basis of the following application documents:
 - Claims 1-14, as filed on 13 October 2022;
 - Description pages 1-53, as filed on
13 October 2022;
 - drawing sheets 1/32 - 32/32 as published.

The Registrar:

The Chair:



D. Meyfarth

T. Petelski

Decision electronically authenticated