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D E C I S I O N
of 10 November 2005

Case Number: T 1176/02 - 3.4.01

Application Number: 93112608.0

Publication Number: 0594957

IPC: A61N 1/368

Language of the proceedings: EN

Title of invention:
Device for identifying atrial depolarization

Patentee:
St. Jude Medical AB

Opponent:
Biotronik GmbH & Co

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 54, 56

Keyword:
"Novelty - (yes)"
"Inventive step - (yes)"
"Late filed documents - (disregarded)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1176/02 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 10 November 2005

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 19 August 2002 rejecting the opposition filed against European patent No. 0594957 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
R. Bekkering

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 21 October 2002, against the decision of the opposition division, dispatched on 19 August 2002, rejecting an opposition against the European patent No. 0 594 957 (application number 93112608.0). The appeal fee was paid on 21 October 2002. The statement setting out the grounds of appeal was received on 27 December 2002.

II. The opposition had been filed against the patent as a whole and was based on the grounds pursuant to Article 100(a) EPC that the subject-matter of the patent was not patentable within the terms of Articles 52(1), 54 and 56 EPC.

During the opposition procedure the following document, among others, was referred to:

(E3) EP-B-0 077 806.

In the decision under appeal, the opposition division held that the raised grounds for opposition did not prejudice the maintenance of the patent as granted.

III. With the grounds of appeal, the appellant filed the following further documents:

(E4) DE-C-39 14 680;

(E5) US-A-4,712,555;

(E6) US-A-4,856,524.

IV. Oral proceedings before the Board of Appeal were held on 10 November 2005.

V. The appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety.

VI. The respondent (patent proprietor) requested that the appeal be dismissed. Moreover, the respondent requested that the new documents E4, E5 and E6 not be introduced into the proceedings. Should documents E4 to E6 be admitted into the proceedings, remittal of the case to the first instance for further prosecution was requested.

VII. The wording of claim 1 of the patent as granted reads as follows:

"*A device for identifying an event, among events detected in the atrium in a heart (5), as an atrial depolarization and comprising*
an atrial detector (3) which emits a first signal when there is an event detected in the atrium,
and
a ventricular detector (11) which emits a second signal when there is an event detected in the ventricle,
characterized in that
a window generator (50) creates a time window with the first signal inside the window, and
a comparator (60) compares the second signal to the time window, emitting an identification signal (ID) for atrial depolarization when the second signal is not inside the window."

Claims 2 to 11 of the patent as granted are dependent claims.

Reasons for the Decision

1. The appeal is admissible.

2. *Documents E4, E5 and E6*

2.1 *Procedural considerations*

2.1.1 The appellant submitted that it was surprised by the narrow interpretation of the subject-matter of claim 1 made by the opposition division in the decision under appeal. For this reason, to cope with this situation, it filed documents E4, E5 and E6 with the grounds of appeal.

2.1.2 On 24 January 2002, the parties were summoned to attend oral proceedings before the opposition division. In an annex to the summons, the opposition division, on the basis of a quite literal interpretation of the wording of the claim, took the provisional view that the subject-matter of claim 1 was novel over document E3. In particular, the opposition division considered that E3 did not teach to identify an event as an atrial depolarization among events detected in the atrium. Moreover, E3 did not disclose the features concerning the window generator and the comparator "*as defined in the second part of claim 1*". The opposition division also took the view the opponent's argumentation as to inventive step was not convincing. The opponent was thus explicitly warned that the opposition would probably be rejected.

At the oral proceedings before the opposition division on 10 July 2002, the issue of the claim interpretation was discussed.

2.1.3 In view of the foregoing, it does not seem plausible that the opposition division's interpretation of claim 1 in the decision under appeal might have taken the appellant by surprise. Rather, if the appellant considered that filing of new evidence became necessary in reaction to the opposition division's position, it had the opportunity to do this in due time after it received the summons. In this respect, at the oral proceedings before the Board on 10 November 2005, the appellant itself admitted that it did not file any new evidence in opposition procedure in view of the low - according to its experience - chances of their admission into the opposition procedure and, moreover, in view of the likelihood of an appeal. This, however, is not an objective justification for delaying the submission of the new documents until the filing of the grounds of appeal.

2.1.4 For these reasons, the Board considers that documents E4, E5 and E6 were not submitted in due time.

2.2 *Substantive considerations*

2.2.1 According to Article 114(2) EPC, the Board has a discretionary power to disregard evidence which is not submitted in due time. In the case law of the boards of appeal, a criterion widely used while exercising the discretionary power is based on the technical relevance of the new evidence for the case to be judged. In particular, the new evidence should be more relevant

than the prior art already cited. Moreover, it should be likely that the new evidence prejudices the maintenance of the patent at least in the form on file.

2.2.2 The appellant filed document E6 as evidence for the opposition ground of lack of novelty of the subject-matter of claim 1.

This document relates to a physiologically responsive rate adaptive pacemaker that does not require additional sensors to provide rate responsiveness (see column 1, first paragraph; column 3, lines 3-7). The pacemaker relies on a measurement of the duration of the AV interval and provides cardiac stimulation at a rate related to the measured AV interval duration (see claim 1). The pacemaker according to E6 is not provided with the functionality of identifying an event as an atrial depolarization among events detected in the atrium.

The appellant referred to Figure 5A that shows a flow chart illustrating the operation of the AV responsive pacemaker. In its view, detection of a P-wave caused the start of a time window corresponding to the AV interval. A ventricular stimulation took place if no Q-wave was detected during this window. The control pulse generating the ventricular stimulation corresponded to the claimed identification signal. Thus, E6 anticipated the subject-matter of claim 1.

The respondent contested this argumentation in a convincing way. Namely, the Board agrees with the respondent that, for a skilled person, the generation of the AV interval unmistakably indicates that the

detected atrial event is considered by the pacemaker to represent a depolarization and not a signal that still needs to be identified as such. This results from the basics of operation of a pacemaker. Thus, it is incorrect to interpret the control signal for generating the ventricular stimulation as an identification signal for atrial depolarization within the meaning of claim 1.

2.2.3 The appellant filed documents E4 and E5 as evidence for the opposition ground of lack of inventive step of the subject-matter of claim 1.

Document E4 relates to a physiologically responsive rate adaptive pacemaker that relies on control signals derived from the heart activity for adapting the heart frequency synchronously with the atrium (see column 3, lines 36-43; claim 1; Figure 5).

Document E5 also relates to a physiologically responsive rate adaptive pacemaker. Physiological need is derived from a selected time interval associated with the rhythm of the heart (see column 1, line 60 to column 2, line 2; column 3, lines 20-56).

The inventions according to E4 (see column 1, lines 24-32) and E5 (see column 2, lines 19-27) underline the importance of reliably sensing atrial signals. Nevertheless, both documents are not considered to be relevant. As for E6, they do not disclose pacemakers intended for identifying an event as an atrial depolarization among events detected in the atrium. The atrial signals are treated as representing depolarizations.

2.3 In conclusion, documents E4, E5 and E6 were not submitted by the appellant in due time. They are not technically more relevant than the prior art already on file and, moreover, it is not likely that they prejudice the maintenance of the patent as granted. Therefore, they are disregarded pursuant to Article 114(2) EPC.

3. *Ground for opposition of lack of novelty with regard to E3*

3.1 The appellant submitted that a lack of clarity and support by the description of claim 1 rendered difficult the comparison of the claimed subject-matter with the disclosure of E3. In this respect, it drew attention to various issues. A difficulty consisted in that the connection between the atrial detector and the window generator was not defined. Moreover, the claimed "*first signal*" and "*second signal*" corresponded to signals A_a and V_v represented in Figure 2 although, according to the description and claims 5 and 6, the comparator compared prolonged signals A_{a+y} and V_{v+x}. It was also doubtful whether, in the light of the description, the claimed terms "*window generator*" and "*comparator*" might be understood with their usual meanings. In particular, the appellant drew attention to the fact that the paragraph in column 8, lines 15-26, referring to the operation of the device, did not mention a comparator at all.

In these circumstances, it was appropriate to interpret claim 1 in the light of the description. Thus, the claimed feature concerning the "*window generator*" 50

should be understood as meaning the atrial and ventricular pulse prolonging circuits 25, 45 according to Figure 2. With regard to the claimed "*comparator*" 60, it resulted from Figure 2, with particular regard to the operation of the flip-flop 61 and the shift register 62, that its function corresponded to that of a blanking circuit for the atrial channel.

The appellant further submitted that the idea of the present invention as disclosed in column 3, lines 51-55, i.e. the fact that information available in the pacemaker could be utilized for identifying atrial depolarization, was similar to that underlying E3 (see column 2, lines 39-44), according to which the system permitted an evaluation of the information obtained from the heart, the effect of noise signals being thus reduced. From a structural point of view, the known pacemaker undisputedly comprised atrial input means 101 and ventricular input means 201 (see Figure 1). It also comprised a "*window generator*" and a "*comparator*" with the meaning mentioned above. The known pacemaker comprised a "*window generator*" as claimed because the monoflop 218 (see Figure 1) acted as a ventricular pulse prolonging circuit and, moreover, the atrial input means 101 could be regarded as an atrial pulse prolonging circuit in view of its function of forming a logic pulse on the basis of the detected atrial signal. The known pacemaker also performed the function of the claimed "*comparator*" since the ventricle took priority ("*Vorrang*") over the atrium in case of simultaneous occurrence of atrial and ventricular signals (see column 13, lines 50-56 and claim 3). In particular, the monoflop 218, by controlling the blanking means 3, blocked the atrial input means 101. Thus, the blanking

means 3 and the claimed "*comparator*" performed the same function.

In conclusion, the subject-matter of claim 1 was not novel over the disclosure of E3.

3.2 The respondent disagreed with the appellant's argumentation. In its view, the claimed window generator, when interpreted in the context, created a time window on the basis of a prolonged atrial signal and a prolonged ventricular signal as well. Thus, the window could not be generated without detection of an atrial signal. As to the further claimed feature concerning the comparator, the term "*comparator*" reflected the concept of monitoring whether a ventricular signal occurred during the generated time window.

The respondent further submitted that, with a correct understanding of the claim, the ground of lack of novelty with regard to E3 was unfounded. In particular, the monoflop 218 was activated following detection of a ventricular event and controlled the blanking means 3 to block the detection of any atrial event by the input means 101. The meaning of the term "*Vorrang*" in the quotation cited by the appellant should be understood in this context, i.e. atrial sensing was blanked as soon as a ventricular event occurred. Since the blanking function prevented the atrial input means 101 from detecting atrial events and thus from emitting a "*fist signal*" as claimed, the monoflop 218 in combination with the atrial input means 101 could not perform the functions of the claimed device with regard

to the generation of the time window and the comparison of the time window with the ventricular event.

3.3 The Board is not convinced by the appellant's interpretation of claim 1. The claim is formulated in quite general terms. A skilled person can, however, understand it. According to the wording, it is essential that a first atrial signal be detected, which is inside the time window created by the window generator. It is also clear that the comparator has the function of monitoring whether the second ventricular signal, which is also detected, is not inside the window. As such, the term "*comparator*" appears to be justified by the fact that a comparison is made between the ventricular signal, i.e. its duration, and the time window.

Thus, a skilled person has no difficulty in understanding the claim in the context of identifying an event, among events detected in the atrium, as an atrial depolarization. The description discloses an embodiment (see Figure 2) that, in the Board's view, falls within the scope of the claim. It cannot, however, be excluded that the claimed device with its functionality could be realized in a different way. Thus, the appellant's interpretation of the claim is not justified.

3.4 The appellant saw a close similarity between the ideas underlying the present invention (see column 3, lines 51-55) and the disclosure of E3 (see column 2, lines 39-44). The Board doubts this conclusion which the appellant drew without considering the whole disclosure of E3 but rather having regard to a single quotation.

Document E3 discloses the monoflop 218 and its function, which is relevant for the present invention, in the context of preventing the pacemaker from being synchronised by retrograde conduction immediately after a ventricular extrasystole (see column 12, line 60 to column 13, line 49; Figure 1). Thus, in spite of the fact that the monoflop 218 *per se* may be considered as an element creating a time window, its function, which is related to the block ("*Sperrung*") of retrograde conduction (see, in particular, column 13, lines 7 and 8), differs from that of the claimed window generator, which in combination with the claimed comparator is intended for achieving reliable identification of a P-wave, in particular for distinguishing a genuine P-wave from a spurious P-wave resulting from cross-talk (see the patent in suit, column 1, line 48 to column 2, line 22). In this respect, it is noted that the time window created by the monoflop 218, i.e. about 400 ms, does not substantially differ from the propagation time value, i.e. about 100 ms, mentioned by the patent in suit in relation to retrograde conduction. This would confirm that the pacemaker of E3 is indeed protected against retrograde conduction, which differs from cross-talk characterised by a faster (10 ms) propagation time. The phenomenon of spurious P-waves resulting from retrograde conduction is expressly disregarded in the description of patent in suit (see column 2, lines 10-12).

3.5 Both parties agree that, in E3, the monoflop 218 controls the blanking means 3 so as to block detection by the atrial input means 101 (see grounds of appeal, page 3, first paragraph; letter of 8 May 2003, page 2,

second paragraph). In this respect, the blocking effect occurs without delay because it results from the positive flank of the signal at the output of the monoflop 218 (see column 4, lines 38-45).

3.5.1 Now, a first issue relates to whether E3 indeed discloses the claimed window generator, which the appellant interpreted as implying the provision of atrial and ventricular pulse prolonging circuits (see Figure 2). With regard to the atrial channel of E3, the allegation that the atrial input means 101 would have a pulse prolonging effect is not convincing. As a matter of fact, E3 only discloses the function of pulse forming (see column 4, lines 28-38), which does not necessarily imply pulse prolonging. With reference to the ventricular channel of E3, even if the monoflop 218 would be considered as a ventricular pulse prolonging circuit, the time window, which results, would not correspond to the claimed one. Indeed, an atrial signal, i.e. a "*first signal*" according to claim 1, could not be "*inside the window*" because of the blanking function of the monoflop 218. In summary, a window generator creating a time window with the atrial signal inside the window does not result from the disclosure of E3.

3.5.2 A further issue concerns the claimed comparator. The Board disagrees with the appellant's interpretation that the comparator simply performed the function of a blanking circuit. Indeed, as already stated, this interpretation is not justified. In any case, since the function performed by the claimed comparator relies on the provision of a time window having the first atrial signal inside, E3 cannot disclose a comparator with this function. Thus, the monoflop 128 together with the

blanking means 3 according to E3 differ from the claimed window generator in combination with the claimed comparator in the sense that they do not provide the same functionality.

3.6 In conclusion, E3 does not disclose a device comprising all the claimed features. Hence, the ground of lack of novelty, based on this document, is unfounded.

4. *Ground for opposition of lack of inventive step with regard to E3*

4.1 In appeal, the appellant based the ground of lack of inventive step on document E3 alone. The appellant admitted that the claimed window generator interpreted as a pulse-prolonging circuit ("*beanspruchte Impulsverlängerungsschaltung*") could represent a structural difference (see grounds of appeal, page 3, No. III, first sentence). This difference, however, did not involve an inventive step in view of the disclosure of E3 as understood when assessing novelty.

4.2 The respondent disagreed with the appellant's argumentation. In its view, the pacemaker according to E3 did not comprise the claimed combination of the window generator and the comparator. Since the appellant's argumentation was based on an incorrect definition of the differences, the allegation of lack of inventive step was unfounded.

4.3 The Board notes that the technical backgrounds and the problems underlying the disclosure of E3 (see column 1, lines 3-36) and the present invention (see column 1, lines 16-51) are different. In particular, whereas the

pacemaker of E3 maintains the cardiac own rhythm even if ventricular events like extrasystoles occur without a natural time relation with the atrium activity, the device of the present invention is intended for identifying an event, among events detected in the atrium, as an atrial depolarization. As regards the solutions, whereas E3 blanks the detection of an atrial event after the occurrence of a ventricular extrasystole, the claimed invention (see Figure 3B) presupposes the detection of an atrial event, which has to be identified as a genuine P-wave or a result of cross-talk.

Thus, the invention of E3 is basically different from the present one. The differences are such that the definition of a technical problem would be artificial and considerations as to modifications of the known pacemaker meaningless. As a matter of fact, the Board doubts that E3 represents a suitable starting point for assessing inventive step.

4.4 Hence, the ground of lack of inventive step, based on the document E3, is unfounded.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann