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File Number: T 96/88 - 3.4.1

Application No.: 81 304 763.6

Publication No.: 0 050 038

Title of invention: Heart pacemaker with separate A-V intervals for atrial synchronous and atrial-ventricular sequential pacing modes

Classification: A61N 1/36

D E C I S I O N
of 10 December 1991

Proprietor of the patent: MEDTRONIC, INC.

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

Headword:

EPC Article 56

Keyword: "Notice of opposition filed at and accepted by the German Patent Office in Berlin - admissible (yes) - inventive step (no)"

Headnote



Case Number : T 96/88 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 10 December 1991

Appellant :
(Opponent)
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Decision under appeal :
Decision of the Opposition Division of the
European Patent Office dated 30 November 1987
rejecting the opposition filed against European
patent No. 0 050 038 pursuant to Article 102(2)
EPC.

Composition of the Board :

Chairman : G.D. Paterson
Members : Y. van Henden
H. Reich

Summary of Facts and Submissions

I. European patent No. 0 050 038 was granted to the Respondent.

II. Claim 1 of the patent reads:

"A timing circuit for a heart pacemaker having atrial and ventricular terminal means (15,16) for connection respectively to the atrium and ventricle of a patient's heart (10);

atrial and ventricular pulse generating means (21,22) connected for selectively delivering stimulating pulses to said atrial and ventricular terminal means; and

atrial sensing means (25) connected to said atrial terminal means, and operative for sensing atrial contractions of the patient's heart; characterised by

timing control means (30,31,34) operatively connected to said atrial sensing means and said atrial and ventricular pulse generating means, and operative in response to a sensed atrial contraction to cause said ventricular pulse generating means to deliver a stimulating pulse at the end of a first atrial-ventricular delay interval from said sensed atrial contraction, and operative in the absence of sensed atrial contractions to cause said atrial and ventricular pulse generating means to deliver sequential atrial and ventricular stimulating pulses at a pre-determined pacing rate, with said atrial and ventricular sequential pulses being separated in time by a second atrial-ventricular delay interval which is independent of said first atrial-ventricular delay interval."

The remaining Claims 2 to 8 are dependent on Claim 1.

III. The patent was opposed by the Appellant on the grounds mentioned in Article 100(a) EPC, referring inter alia to the prior art which can be derived from document:

D3: B. Lüderitz, "Elektrische Stimulation des Herzens", 1st edition, Springer Verlag, Berlin, Heidelberg, New York, 1979, pages 175 to 177.

In a later submission, the Appellant furthermore cited DE-A-2 701 104, correspondent to document FR-A-2 377 190, already cited in the European Search Report, and to document:

D1: GB-A-1 594 902.

IV. The Opposition Division rejected the opposition.

V. The Opponent lodged an appeal against the decision of the Opposition Division.

VI. During the procedure before the Opposition Division, the Respondent submitted that the opposition should be rejected as inadmissible, the reason being that it had been filed at the German Patent Office in Berlin and received from the latter after expiry of the 9-month period for giving notice of opposition under Article 99(1) EPC. In a decision dated 21 July 1988, the Board referred to the Enlarged Board of Appeal under Article 112(1)(a) EPC a point of law concerning the legal effect of the Administrative Agreement dated 29 June 1981 (OJ EPO 1981, 381). With decisions G 5/88, G 7/88 and G 8/88 (OJ EPO 1991, 137), the Enlarged Board of Appeal ordered that documents intended for the EPO and filed at any time since publication of the Agreement and before 1 July 1989 at the GPO in Berlin (otherwise than by hand) had to be treated as if the EPO had received them at the date of receipt at the GPO in Berlin.

VII. In a communication on behalf of the Board dated 14 January 1991, the Rapporteur took the view that the Appellant's notice of opposition had been filed in due time and otherwise than by hand at the GPO in Berlin, and resumed the examination of the appeal.

Besides (D1) and (D3), the Rapporteur mentioned in said communication the further documents:

D2: FR-A-2 342 721 and
D4: GB-A-2 026 870,

already cited in the European Search Report, and explained that, in the light of the teachings disclosed in documents (D1) through (D4), none of the granted claims appeared to be allowable.

VIII. With telefax dated 30 July 1991, the Respondent attempted to refute the Rapporteur's argumentation as regards inventivity, and requested the appeal to be rejected and the patent to be maintained without amendments. Subsidiarily, he requested the patent to be maintained in amended form on the basis of a new Claim 1 formed by adding, at the end of the granted Claim 1, the feature "and wherein said second time delay is longer than said first time delay", as claimed in granted dependent Claim 3.

To substantiate his assertions regarding the advantages of his invention, the Respondent filed with the confirmation of above telefax the additional document:

D5: D.L. Janosik et al., "The hemodynamic benefit of differential atrioventricular delay intervals for sensed and paced atrial events during physiologic

pacing", in "Journal of American College of Cardiology", Vol. 14, No. 2 (August 1989), pages 499 to 507.

IX. In support of his request, the Respondent substantially argued as follows.

None of the citations would incite the skilled person to modify the pacer known from (D1) so that the AV delay in actual synchronous (AS) mode would be independent of the AV delay in atrial-ventricular sequential (AVS) mode.

Document (D2) is concerned with a pacer operable in an AS mode, and in which the AV delay is shortened in dependence on the rate of successive sensed atrial signals. This result reflects the natural behaviour of the heart, in which the AV delay shortens with increasing frequency of atrial depolarisations owing to physical exercise. A person skilled in the art and attempting to implement the teachings of (D2) in the device of (D1) would thus enable the pacer to continuously alter the AV delay in response to the detected value of said rate.

Document (D3) is concerned with monitoring the transmission time of atrial signals to the His bundle (AH time) at increasing atrial stimulation rates in the absence of physical activity, the purpose being to determine whether a subject is fit for receiving an atrial pacemaker. Although it is noted that AV time shortens with increasing atrial frequency, the skilled person would not attempt to imitate such a behaviour, since the relatively longer transmission delay for atrial applied stimulation is indicated as an abnormality of heart action. Said person would only infer from (D3) that, if operating in the atrial stimulating mode, the patient's heart could block at lower atrial frequency than expected.

The argument that it could be detrimental to maintain the AV interval constant when heart beat frequency becomes high is based on the assumption that, normally, the AVS mode would be initiated at rest whilst the AS mode would be initiated during exercise. This, however, is not discussed in the prior art. Besides, the passage of (D2) mentioning the drawbacks of a constant AV delay is a preamble to the solution proposed there, i.e. varying said delay in response to the sensed atrial rate.

- X. The Appellant requested cancellation of the impugned decision and revocation of the patent in suit. Subsidiarily, he requested oral proceedings to be held if the Board were to find against him. In support of his view, he substantially put forward the following arguments.

Starting from an event in the atrium, the stimulation delays for both chambers are, in a pacemaker according to (D1), dealt with in the same manner. Since dual chamber pacemakers were made available to the public, however, it is known to set each delay separately instead of considering the ventricle stimulation as main event determining the heart beat frequency. Such pacers actually consisting of two pacers working cyclically the one after the other, it necessarily follows that the resulting rate is not determined by only one of both delays. At the priority date of the patent, finally, it was known to the skilled person that the AV interval is liable to be influenced by physiological conditions, as mentioned in (D3).

Reasons for the Decision

1. Admissibility of the opposition

According to Article 1(4) of the Administrative Agreement of 29 June 1981, no documents intended for the EPO should be accepted by a filing office of the German Patent Office if brought by hand. The stamp put on the first page of the Appellant's notice of opposition nevertheless establishes that said notice was accepted on 18 June 1985 by the filing office of the German Patent Office in Berlin. Pursuant to point (ii) of the order in Decision G 8/88, the EPO was accordingly bound to treat the notice of opposition as if it had been filed at the EPO on 18 June 1985. In the Board's judgment, therefore, the opposition was admissible.

2. Novelty

2.1 Document (D1) discloses a heart pacemaker with a timing circuit having atrial terminal means (10) and ventricular terminal means (12) for connection to the atrium and ventricle of a patient's heart, respectively, atrial and ventricular pulse generating means connected for selectively delivering stimulating pulses to said terminal means (10,12), atrial and ventricular sensing means connected to the terminal means (10,12) and operative for sensing atrial and ventricular contractions of the heart, and timing control means operatively connected to the sensing and pulse generating means. Said timing control means are operative in response to a sensed atrial or ventricular contraction to cause the ventricular or atrial pulse generating means, respectively, to deliver a stimulating pulse at the end of a time interval starting from the sensed contraction and, according to whether the latter is an atrial or a ventricular one, having a first

or second duration - see: page 1, lines 10 to 15; from page 1, line 98 to page 2, line 77. It thus appears that the pacemaker described in (D1) is of the dual type, that it is operative either in the AS mode or in the AVS mode and that it is of the "demand" type. Furthermore, it can readily be understood that the AVS mode determines the lowest allowed beat frequency of the heart.

2.2 With respect to the state of the art that can be derived from (D1), the subject-matter of Claim 1 is novel in that, according to whether the sensed atrial contraction is a natural or a stimulated one, the duration of the time interval separating said contraction from the resulting emission of a ventricular stimulation pulse is set at values which are independent of each other.

3. Inventive step

3.1 Document (D2) teaches that, when the heart beat frequency increases, the time interval between atrial and ventricular contractions becomes shorter - see page 1, lines 16 to 18. This teaching is confirmed by document (D3), from which the reader learns that a natural increase of beat frequency, such as the one resulting from physical exercise or intellectual effort, is concomitant with a shortening of the AV interval - see page 175, first six lines of the last paragraph.

To the skilled person it is thus clear that, according to whether a patient is at rest or taking exercise, the natural working conditions of his heart will be the best approximated by a pacemaker if the maximum allowed duration of the AV interval is respectively made longer or shorter. Furthermore, document (D2) points out that maintaining said duration constant could be detrimental when heart beat frequency becomes high, for instance as a

consequence of a physical effort - see page 1, lines 7 to 16. An incentive to improve the pacemaker known from (D1) by rendering the AV delay longer in the AVS mode than in the AS mode is, therefore, given to the skilled person. This, however, leads to the subject-matter of Claim 1 according to any of the Respondent's main and auxiliary requests without the exercise of inventive ingenuity being apparently needed.

3.2 To invalidate above conclusion, the Respondent interprets the mention of a second AV delay interval which is independent of the first AV delay interval as implicitly meaning that the respective durations of said delay intervals are predetermined and constant. He furthermore puts forward that the state of the art would incite the skilled person to continuously alter the AV delay in response to the detected rate of successive sensed atrial signals.

The Board nevertheless observes that variable quantities too can be independent from one another. Such is for instance the case if the variables on which a first function depends are not the same as those on which a second function depends. Now, it might be envisagable to make the second AV delay interval vary within given limits dependent on the value of some particular physiological parameter, whereby the latter would not influence the duration of the first AV delay interval. In such a case, both AV delay intervals still would be independent of each other.

The Board furthermore observes that, in a pacemaker according to (D1), the events commanding timers resets are of a dual nature, since they consist in the detection of depolarisation waves or in failing to detect such waves. To the skilled person not wishing to provide means for

determining the atrial signal rate, therefore, no other possibility than setting the AV delay intervals at predetermined different values is afforded and, anyway, an improvement with respect to prior art achievements is thereby obviously provided. Now, the additional document (D5) introduced by the Respondent into the proceedings furthermore reveals that, before the priority date of the patent in suit, the needlessness of providing a continuously variable AV delay interval was already known to the skilled person. This document mentions indeed the existence of an optimal AV delay interval and a detrimental effect of deviations from this optimum - see page 504, last paragraph of the left-hand column. It further states that similar observations had already been made - see, on the same page, the first three lines of the right-hand column - and, as evidence thereof, refers to an older document issued in 1977 - to wit, ref. 6, article by G.O. Hartzler et al headed "Hemodynamic benefits of atrio-ventricular sequential pacing after cardiac surgery", Am. J. Cardiol, 1977, 40, 232-6. With regard thereto, no display of inventive talent was consequently required to set the first and second AV delay intervals at different predetermined durations, nor to make the second AV delay interval longer than the first one. Finally, it follows from the above that none of the cited documents was likely to deter the skilled person from adopting such measures.

4. In the Board's judgment, Claim 1 according to either of the Respondent's request lacks an inventive step and is not allowable - Article 52(1) EPC in relation to Article 56 EPC. The remaining claims of these requests fall because of their dependence on the respective Claim 1.

Order

For these reasons, it is decided that:

1. **The decision under appeal is set aside.**
2. **European patent No. 0 050 038 is revoked.**

The Registrar:

The Chairman:

M. Beer

G.D. Paterson