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Bezeichnung der Erfindung: Rate adaptive pacemaker
Title of invention:
Titre de l'invention :

Klassifikation / Classification / Classement : A61N 1/36

ENTSCHEIDUNG / DECISION

vom / of / du 5 July 1988

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent / Titulaire du brevet : Vitatron Medical B.V.

Einsprechender / Opponent / Opposant : Siemens-Elema AB

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Article 56 EPC

Schlagwort / Keyword / Mot clé : "Inventive Step (Yes)"

Leitsatz / Headnote / Sommaire

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Case Number : T 432 /86

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 5 July 1988

Appellant : (Opponent)
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Representative :
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Decision under appeal :
Interlocutory Decision of Opposition Division of the European Patent Office dated 22 January 1986 maintaining the European patent No.0 017 848 in amended form pursuant to Article 102(3) EPC.

Composition of the Board :

Chairman : J. Roscoe
Members : E. Turrini
R. Schulte

Summary of Facts and Submissions

I. European patent No. 0 017 848 was granted in response to European patent application No. 80 101 742.7.

II. Opposition was filed against the European patent by the Appellant Siemens-Elema AB and full revocation of the patent requested.

The following prior art documents were cited by the Appellant to support the objection of lack of inventive step: "Changes in Myocardial Threshold, Physiologic and pharmacologic factors in patients with implanted pacemakers", Thomas A. Preston et al., American Heart Journal St. Louis, Vol. 74, No. 2 pages 235 to 242, August 1967 (D9); "Threshold Studies in Transvenous Cardiac Pacemaker Treatment", Carl-Johan Westerholm, Scandinavian Journal of Thoracic and Cardiovascular Surgery, Supplementum 8, Uppsala 1971 (D10); DE-A-2 717 659(D12), DE-A-2 809 091(D13), DE-A-2 609 365(D14), "Cardiac pacing", Proceedings of the 5th International Symposium, Tokyo, March 14 to 18, 1976, pages 414 to 419 (D15), Siemens-Elema Datenblatt ME 431/5315.101, Aeroconsulter AB, Västeräs 1976 (D16), DE-B-2 254 928(D17) and DE-A-2 619 001(D18).

III. The Opposition Division, in an interlocutory decision maintained the patent in amended form on the basis of the documents specified in the communication pursuant to Rule 58(4) EPC dated 19 March 1986.

IV. The reasons for the decision were as follows:

- the subject-matter of the independent Claim 1 was new, because none of the cited prior art documents disclosed

the utilisation of threshold-sensitive control means for controlling the rate of the pulses, and was considered inventive despite the disclosure in documents D9 and D10;
and

- the subject-matter of the independent Claim 6 was new, despite the disclosure in document D16 and EP-A-0 007 189(D1), the latter falling within the terms of Article 54(3) EPC, and was also considered to involve an inventive step despite the disclosure in document D16.

V. An appeal was lodged against this decision. In the Statement of Appeal the Appellant requested that the interlocutory decision of the Opposition Division be set aside and the patent be revoked, and, as auxiliary request, that oral proceedings be held.

VI. Following a communication from the Board accompanying the summons to oral proceedings, the Respondent (Patentee) filed on 3 June 1988 revised Claims 7 and 8 and a revised description.

VII. At the oral proceedings the Appellant requested that the decision under appeal be set aside and the Claims 1 to 5 of the patent be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained on the basis of the documents, mentioned in the communication pursuant to Rule 58(4) EPC dated 19 March 1986, pages 3 and 12 being replaced by pages 3, 3a, 3b and 12 filed on 3 June 1988 with correction on page 3a, line 20 of the expression "QRSall" to QRS or".

VIII. Current Claim 1 reads as follows:

" A pacemaker having a stimulus generator (105) for delivering pacing stimuli, means for controlling the rate of said delivered pacing stimuli (59), and threshold tracking means (101, 102) for tracking said patient's threshold to delivered stimuli, said pacemaker being characterized by having threshold-sensitive rate control means (95, 60) for controlling said stimulus rate as a function of said tracked patient threshold."

Claims 2 to 5 are dependent on Claim 1.

IX. Current Claim 6 reads as follows:

"A demand pacemaker having a stimulus generator (105) for delivering pacing stimuli only in the absence of detected natural heart beats, and rate control means (59, 60) for controlling the rate of said delivered pacing stimuli, said pacemaker being adapted to operate in combination with electrode means (55) for delivering said pacing stimuli to a patient's heart and detecting heart signals from the patient's ventricle characterized by means (82-89) for determining at least one characteristic of a QRS or T wave portion of a heart signal and means for controlling said rate as a predetermined function of said characteristic determination (95)".

Claims 7 to 14 are dependent on Claim 6.

X. The main arguments presented by the Appellant were essentially as follows:

It was known from the prior art to control the rate of delivering pacing stimuli to the heart by means of a signal which was a function of physiologic characteristics

such as blood pH value, body temperature, etc., said physiologic characteristics being correlated with the exercise level.

Starting from this state of the art, the skilled person was faced with the problem of seeking a physiologic characteristic which made the rate control easier by avoiding the need for an extra sensor such as was required e.g. for blood pH or body temperature measurements. Document D9 showed the correlation between heart rate and myocardial threshold, i.e. the level of the stimulus pulse necessary to evoke a heartbeat. However, the claimed choice of technical means to realise such a correlation, i.e. the means for tracking the patient's threshold and means for controlling the stimulus rate as a function of the tracked patient threshold would not solve the problem because, as clearly set out in document D9, the myocardial threshold was susceptible "to manipulation by physiologic activities and pharmacologic agents" (page 242, lines 3 and 4). In other words, the choice of said means mentioned in Claim 1 did not involve an inventive step since the means did not provide a solution to the problem.

The description of the patent itself supported this point of view in so far as the embodiment illustrated in the only drawing employed the threshold only in combination with other characteristics such as at least one characteristic of the QRS or T wave portion for rate control.

Thus, the subject-matter of Claim 1 was not patentable, since it lacked an inventive step.

At the oral proceedings the Appellant withdrew his objection that the subject-matter of Claim 6 was lacking in novelty and/or inventive step.

XI. The Respondent argued essentially as follows:

The closest prior art documents related to pacemakers wherein the means for determining a physiologic characteristic necessarily included sensors other than the standard electrodes of the pacemaker.

The skilled man wishing to solve the problem of utilising a physiologic characteristic, whose determination could be effected by the standard sensors of a pacemaker would look at further documents and he would indeed consider document D9. However, although document D9 referred to the correlation between myocardial threshold and heart rate, said document could not give the skilled man any hint to use myocardial threshold characteristic for controlling the stimulus rate, because it discussed in only a general way the physiologic and pharmacologic factors which affected the myocardial threshold and showed that the myocardial threshold was largely influenced by said factors.

Furthermore, the solution proposed by Claim 1 allowed the pacemaker to work at least under certain restricted conditions.

The subject-matter of Claim 1 should therefore be considered as involving an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. The present version of the claims is not objectionable under Article 123(2) or (3) since it is supported by the original application and what is now claimed lies wholly within the scope of one or other of the two independent granted Claims 1 to 6.

3. Novelty.

Following a comprehensive study of the prior art documents to which reference has been made during the examination and opposition procedures, the Board of Appeal is satisfied that the subject-matter of independent Claims 1 and 6 is novel within the meaning of Article 54 EPC. As the Appellant during the oral proceedings has not alleged lack of novelty, the Board deems it unnecessary to deal with this in greater detail.

4. Inventive step.

4.1 As far as Claim 1 is concerned, documents D12 to D15 represent in the Board's opinion the nearest prior art. Each of them relates to a pacemaker having a stimulus generator for delivering pacing stimuli, means for controlling the rate of said delivered pacing stimuli and means for measuring a physiologic characteristic (e.g. body temperature (D14), or blood pH value (D15), etc.), said controlling means being sensitive to said physiologic characteristic in order to control the stimulus rate as a function of said physiologic characteristic.

Contrary to the subject-matter of Claim 1, said documents relate to physiologic characteristics which need an extra sensor, e.g. a temperature measuring sensor or a pH measuring sensor, etc., in addition to the electrodes normally used in a pacemaker for sensing and delivering heart stimuli.

Starting from the disclosure of one of said documents, the general objective problem to be solved is to realise an effective controlled stimulus rate pacemaker which does not require an extra implanted sensor for controlling the stimulus rate, thus simplifying the implantation and the operation of the pacemaker in the body.

Said problem is solved by the features which distinguish Claim 1 from the disclosure of one of the documents D12 to D15, i.e. by choosing myocardial threshold as physiologic characteristic to be measured, providing means for tracking the patient's threshold, and constructing the controlling means to be sensitive to the threshold whereby to control the stimulus rate as a function of it.

The identification of the problem does not contribute to the inventive step, since the man skilled in the art would as matter of course try to reduce the number of sensors required. Indeed, the simplification of the device installation and operation is a common goal in any technical field, the more so in the medical field of thoracic surgery, where the device has to be implanted in a live body.

As far as the solution to the problem is concerned, the skilled man would, in order to achieve his aim, look at prior art in the field of implanted pacemakers and he would thus be expected to consider document D9 which refers to measurements of the myocardial threshold in patients with implanted pacemakers. However, this document merely discusses in a general way changes in myocardial threshold due to different physiologic and pharmacologic factors, among them the physiologic act of exercise which is directly related to the heart rate.

Indeed, document D9 does not give any hint to use the myocardial threshold for controlling the stimulus rate. On the contrary, it would rather discourage the skilled man from doing so, since the myocardial threshold is defined as being "highly variable, subject to spontaneous changes, as well as being significantly modified by certain common drugs" (page 235, left column, lines 16 to 19). Furthermore it is stated in document D9 that "The investigation has demonstrated the lability of myocardial threshold in man, and the susceptibility of threshold to manipulation by different physiologic activities and pharmacologic agents" (page 241, right column, last line, to page 242, left column, line 4).

It should also be remarked that document D9 was issued in 1967, about 12 years before the priority date of the patent in suit. In this rather long time interval nobody apparently had the idea of utilising the myocardial threshold for controlling the stimulus rate despite the fact that during this period it was known to use the myocardial threshold in pacemakers for other purposes. Thus document D17, the Offenlegungschrift and the equivalent US-3 757 792 of which were published in 1973, discloses a pacemaker where the myocardial threshold is utilised, for pacing the heart at just above threshold level to reduce the battery power consumption to a minimum (column 4, lines 1 to 17 of D17 and summary of invention at col. 2 of the US document).

Document D4 published in 1975 discloses essentially the same thing.

The other cited prior art documents are not more relevant for judging the inventive step of Claim 1 and thus need not be discussed here.

The Appellant's opinion that the features of Claim 1 concerning the utilisation of the myocardial threshold did not solve the problem posed because the threshold-sensitive rate control means could not be utilised directly for controlling the stimulus rate, since the myocardial threshold was strongly dependent on factors such as e.g. drugs which are in no way correlated with the required heart rate, and should for this reason not be considered as involving an inventive step, cannot be followed by the Board. The pacemaker according to Claim 1 can apparently function correctly under particular conditions of the patient, e.g in periods in which no drugs are administered to him, and when other disturbing factors are not present and the Appellant has produced no evidence to convince the Board that the skilled man would have any difficulty in providing a satisfactory arrangement on the basis of the information given in the patent.

The Appellant's further objection that the description of the patent contemplates control of the rate only by a combination of the threshold and other physiologic characteristics is not well founded. While it is true that the embodiment described with reference to the only drawing contemplates the combined use of the myocardial threshold and other physiologic characteristics, the description supports also the utilisation of the myocardial threshold alone (e.g. column 3, lines 3 to 8 and lines 32 to 44) to control the stimulus rate.

Thus, the subject-matter of Claim 1 is considered to involve an inventive step within the meaning of Article 56 EPC and the grounds for opposition mentioned in Article 100(a) EPC do not therefore prejudice the maintenance of Claim 1.

Claims 2 to 5 are dependent on Claim 1 and for this reason they are also acceptable.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained on the basis of the documents mentioned in the communication pursuant to Rule 58(4) EPC dated 19 March 1986, pages 3 and 12 being replaced by pages 3, 3a, 3b and 12 filed on 3 June 1988 with correction on page 3a, line 20 of the expression "QRSall" to "QRS or".

The Registrar: F. Klein

The Chairman: J. Roscoe