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Veröffentlichung im Amtsblatt	Ja/Nein
Publication in the Official Journal	Yes/No
Publication au Journal Officiel	Oui/Non

Aktenzeichen / Case Number / N° du recours : T 160/89 - 3.4.1

Anmeldenummer / Filing No / N° de la demande : 82 306 181.7

Veröffentlichungs-Nr. / Publication No / N° de la publication : 0 080 347

Bezeichnung der Erfindung: Implantable dynamic pressure transducer system
Title of invention:
Titre de l'invention :

Klassifikation / Classification / Classement : A 61 N 1/362

ENTSCHEIDUNG / DECISION

vom / of / du 13 November 1990

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent / Titulaire du brevet : Medtronic, Inc.

Einsprechender / Opponent / Opposant : 01) Biotronic Meß- und Therapiegeräte GmbH & Co.
02) Siemens-Elema AB, Solna (SE)

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Article 56

Schlagwort / Keyword / Mot clé : inventive step (no);
disregarding auxiliary request newly submitted at outset of oral proceedings.

Leitsatz / Headnote / Sommaire

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Case Number : T 160 /89 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 13 November 1990

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Decision under appeal :
Decision of Opposition Division of the European Patent Office dated 3 November 1988 rejecting the opposition filed against European patent No. 0 080 347 pursuant to Article 102(2) EPC.

Composition of the Board :

Chairman : K. Lederer
Members : H.J. Reich
C.V. Payraudeau

Summary of Facts and Submissions

I. European patent 0 080 347 was granted on the basis of European patent application No. 82 306 181.7. The two independent claims of this patent read as follows:

"1. An implantable dynamic pressure and motion transducer system for use in an implantable medical device comprising:

a force responsive transducer (48) for converting a physiological signal into a corresponding electrical signal;

buffer amplifier means (40), receiving said transducer electrical signal, and producing an amplified output signal; and

signal recovery means (40), responsive to said output signal for recovering a signal corresponding to said physiological signal; characterised by

clock means (70) generating energizing pulses coupled to said buffer amplifier (40) for periodically activating said buffer amplifier.

6. An implantable pacer system including an implantable dynamic pressure and motion transducer comprising:

a force responsive transducer (48) for converting a physiological force signal into a corresponding electrical signal, said transducer being incorporated in a transducer capsule (18) incorporated in turn in a lead body (9) for placement in cardiac tissue:

buffer amplifier means (40) adapted to receive said electrical signal, and producing an amplified output signal, said buffer amplifier means being incorporated in said transducer capsule (18);

clock means (70) for generating energizing pulses coupled to said buffer amplifier (40) for periodically activating said buffer amplifier (40), said clock means (70) being incorporated in said implantable pacer; and

signal recovery means (66) responsive to said output signal for recovering a signal corresponding to said physiological signal, said signal recovery means being incorporated in said implantable pacer."

Claims 2 to 5 are dependent on Claim 1; Claims 7 to 12 are dependent on Claim 6.

II. The Appellant "Biotronik" and the Opponent "Siemens-Elema" separately filed notices of opposition against this patent on the ground that its subject-matter did not involve an inventive step in view of a series of prior art documents, among which, inter alia, was document:

D1: "IEEE Transactions on Electron Devices", Vol. ED-26, No. 12, December 1979, pages 1906-1910.

III. The Opposition Division rejected the oppositions.

IV. The Appellant "Biotronik" lodged an appeal against this decision. The Opponent "Siemens-Elema" filed no comments.

V. In a communication accompanying a summons to oral proceedings, the Board notified to the parties its provisional view that the subject-matter of independent Claims 1 and 6 might be regarded as obvious essentially in

view of document D1 and the following newly cited document known to the Board from another recently decided case:

D2: EP-A-0 030 135.

VI. Oral proceedings were held, at the end of which the Appellant requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent (Patentee) requested that the appeal be dismissed and

1. that the patent be maintained unamended (main request);

2. that the patent be maintained as amended according to auxiliary requests 1, 2 or 3 presented at the oral proceedings.

The Opponent "Siemens-Elema" did not appear at the oral proceedings.

VII. In support of his request, the Appellant argued essentially as follows:

(a) The subject-matter of the claims according to the Respondent's auxiliary requests 1, 2 and 3 differs from that of the independent claims according to his main request only by simple technical features, which have long since been known in the art, so that at the priority date of the patent in suit their use in the claimed systems was obvious to a skilled person.

(b) As also the Respondent admits in his statement in the description of the patent in suit, column 1, lines 43-53, the features of the pre-characterising part of Claim 1 are known form document D1. The provisional

opinion of the Board that it would be obvious to use in the system of document D1 the explicitly mentioned teaching of document D2, page 11, lines 13-31 - i.e. to only periodically activate an energy consuming circuit element of an implanted pacemaker by clock means in order to increase the longevity of its battery - is agreed to. The generally known short time intervals needed for signal processing in a logical electronic circuit, would also incite a skilled person to only energise the corresponding circuit elements for a short time. Hence, additionally for this reason, the subject-matter of Claim 1 would be obvious.

(c) In the integration of the transducer and its amplifier in one sensor chip in Figure 2 of document D1, a skilled person would be able to recognise the advantages of a constructional unit of a transducer and its downstream amplifier. Thus, it would be obvious to provide the buffer amplifier means together with the transducer in a separate transducer capsule and the clock and signal recovery means in the remaining alternative, the pacer housing. The subject-matter which independent Claim 6 adds to Claim 1 would, therefore, be of no inventive merit.

(d) Additionally the sawtooth-like form of the reloading current of capacitor P_{C1} of Fig. 1 in document US-A-4 140 132 wold teach a skilled person how to save energy in apacer.

VIII. The above opinion was contested by the Respondent, who argued essentially as follows:

(a) The overall aim of the invention is to provide a transducer system which is suited for a chronic implant application of about ten years as stated in

the description of the patent in suit, column 1, lines 28-38. The prior art transducersystems would not be suitable for this purpose, in particular not the system known from document D1.

(b) The transducer system described in document D1 is an experimental device, wherein only the sensor chip elements of Figure 2 are introduced into the human tissue for a relatively short time (D1, page 1906, right column), whereas the detector means have the form of a micro-computer, which is installed outside the human body (D1, page 1908, right column, paragraph 4).

Hence, there exist no restraints in the known device on power consumption, long term reliability and mechanical complexity. These facts are evident to a skilled person so that he would not consider document D1 as the technical starting point for the present invention.

(c) Having regard to subject-matter of Claim 6, it would not be obvious to a skilled person to transfer the detector elements from their external position in document D1 into a pacer can.

The Representative of the Respondent excused the late filing of the auxiliary requests by the fact that the patentee and the inventors were involved in another patent suit and that he had received their instructions only three days before the oral proceedings, and commented on the subject-matter of these requests.

Reasons for the Decision

1. The appeal is admissible.

2. **Novelty - Main Request**

2.1 From document D1, in particular Figure 2 with the corresponding description, there is known an implantable dynamic pressure and motion transducer system as defined by the wording of the pre-characterising part of Claim 1, i.e. comprising transducer, buffer amplifier and signal recovery means. In this known device, the amplifier means are continuously energised. The subject-matter of Claim 1 differs from the system of document D1 in the characterising features of Claim 1, i.e. by:

(a) "clock means generating energising pulses coupled to said buffer amplifier for periodically activating said buffer amplifier."

The subject-matter of independent Claim 6 differs from the system of document D1 additionally in that:

(b) transducer and buffer amplifier means "are incorporated in a transducer capsule incorporated in turn in a lead body" and the clock and signal recovery means "are incorporated in the implantable pacer".

2.2 Document D2 describes an implantable pacer system without a force responsive transducer, wherein "clock means generating energising pulses (see 142 in Figure 2b and 220 in Figure 4) are coupled to an amplifier 216 and periodically activate said amplifier" for driving a Hall element (page 8, line 26 to page 9, line 4). The Hall element is part of a security switch which, upon activation by an external magnet, closes circuitry within the pacemaker for reprogramming its output parameters.

2.3 The remaining documents on file do not come closer to the subject-matter of Claims 1 and 6.

2.4 For the above reasons, the subject-matter of Claims 1 and 6 is considered to be novel within the meaning of Article 54 EPC.

3. **Inventive Step - Main Request**

3.1 Starting from the nearest prior art as disclosed in document D1, the objective problem underlying the present invention as claimed in Claims 1 and 6 respectively is to adapt this known pressure sensor system for chronic implant applications by making it operate at very low average current.

3.2 Starting from the system of document D1 - with admittedly an implantable pressure sensor head and an external signal recovery means - a clearly obvious overall integration of this system into an implantable pacer leads a skilled person automatically to the problem of low current operation in the signal processing within the implanted system in order to improve the longevity of the implanted pacer battery. Such energy problems arising with the implantation of electronic components of medical devices are generally known in the art. For these reasons, no positive contribution to inventive step can be seen in formulating the above technical problem.

The further technical aims mentioned in the patent in suit, such as less mechanical complexity, hermetic sealing and small dimensions, are not achieved or influenced by the technical means claimed in Claims 1 or 6 and, therefore, cannot form part of the objective problem for considering the existence of an inventive step; see the Respondent's adverse view mentioned in point VIII-b above.

3.3 The objective problem as stated in point 3.1 is solved by the provision of "clock means generating energy pulses coupled to said buffer amplifier for periodically activating it". The amplifier remains unpowered and inactive between each two subsequent clock pulses and thus consumes less energy.

3.4 Looking for solutions to the above problem within the pacer art, a skilled person comes across document D2, wherein clock means generating energising pulses are coupled to a Hall element for periodically activating it in order to "prolongate the life expectancy of a battery powered pacemaker."; (see D2, page 11, lines 13 to 31). In the Board's view, a skilled person is able to recognise the general teaching of document D2, i.e. that a periodical activation of an energy consuming pacemaker element by pulses saves energy and extends the lifetime of the pacemaker battery. The fact, that amplifiers have a high energy consumption is generally known. Hence, the Board regards it to be obvious for a skilled person to make use of the teaching of document D2 in the closely analogous situation of the amplifier in the transducer system known from document D1. No technical prejudices or difficulties have to be surpassed in coupling the clock means generating energising pulses of document D2 to the buffer amplifier of document D1 for its periodic activation. Furthermore, no unexpected effect of this coupling was put forward by the Respondent. For the above reasons, no inventive merit can be seen in arriving from the above prior art at the subject-matter of Claim 1.

3.5 In the system known from document D1, transducer and amplifier means already form a constructional unit (integrated in the same chip) which is separated from a remote signal recovery means by a connecting lead. The Board regards it to be routine skill to incorporate this given transducer-amplifier-unit in a separate "transducer

capsule". Furthermore, it follows directly from document D1 that for diagnostic uses in the heart and its adjacent vessels, the transducer capsule has to be of a small size. This necessity leads the skilled person automatically to maintain the local separation of the electronic compounds according to document D1 and to provide circuit elements which are not necessary for producing a transmittable electrical signal corresponding to the sensed physiological signal - such as the clock means - out of the transducer capsule. In the intended overall implanted system the pacer can represents the only existing alternative housing for the clock and signal recovery means. Therefore, distinguishing feature (b) mentioned in point 2.1 above is held to be the result of only logic considerations within the skilled person's normal abilities in maintaining the usability of a known system in its implanted application form.

In view of the above reasons and for the grounds indicated in point 3.4 above, no inventive step can be seen in the subject-matter of independent Claim 6.

3.6 For these reasons, the subject-matter of Claims 1 and 6 of the Respondent's main request is considered to lack an inventive step within the meaning of Article 56 EPC and it is, therefore, not patentable (Article 52 EPC).

4. Accordingly, the ground of opposition set out in Article 100(a) EPC prejudices the maintenance of the European patent on the basis of the documents according to the Respondent's main request.

5. **Auxiliary Requests 1, 2 and 3**

5.1 In the present case, the parties have been informed of the Board's provisional opinion concerning a possible lack of inventive step in the subject-matter of granted

independent Claims 1 and 6 in view of documents D1 and D2 in a communication posted on 21 May 1990, together with a summons for oral proceedings scheduled and held on 13 November 1990. In this communication, the parties were explicitly invited to file in particular new requests at least one month before the scheduled date of the oral proceedings. The Respondent (Patentee) thus was given a period of at least four months to prepare comments and amendments in due time. However, the Respondent filed his three auxiliary requests only during the oral proceedings itself, i.e. at a very late stage.

5.2 In view of the above mentioned regular term of four months for answering an office action, the reason of high workload put forward by the Respondent (see point IV above), in the Board's opinion, does not represent an exceptional hindrance which justifies late filing. It is only in the most exceptional circumstances, where there is some clear justification for the late submission of an amendment, that it is likely that an amendment not submitted in good time before oral proceedings will be considered on its merits in those proceedings by a Board of Appeal; see also the decision T 95/83, OJ EPO 1985, 75, point 8.

5.3 Even if the Respondent had presented an acceptable justification for his late filing, the Board would not have held the Respondent's three auxiliary requests as admissible for the following reason: The Board finds it evident already at first sight that the subject-matter added by the amendments in the auxiliary requests to that of the corresponding claims of the main request, represents obvious routine measures; see also point VII-(a). If late-filed alternative claims are not clearly allowable a Board may justifiably refuse to consider them; see also the decision T 153/85, OJ EPO 1988, 1, point 2.1, paragraphs 2 and 3.

5.4 For the above reasons, the Respondent's auxiliary requests 1, 2 and 3, presented at the oral proceedings on 13 November 1990 are rejected as inadmissible.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The auxiliary requests 1, 2 and 3 are rejected as inadmissible.

3. The patent is revoked.

The Registrar: The Chairman:

P. Martorana K. Lederer