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D E C I S I O N
of 10 January 2001

Case Number: T 0660/96 - 3.4.1

Application Number: 89830567.7

Publication Number: 0376904

IPC: A61N 1/36

Language of the proceedings: EN

Title of invention:

A connector device, particularly for connecting an electrical catheter to a heart pacemaker

Patentee:

SORIN BIOMEDICA CARDIO S.p.A.

Opponent:

Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro
Berlin

Headword:

Connector device connecting a pacing lead or catheter to a
pacemaker/SORIN BIOMEDICA CARDIO S.p.A.

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes) "

Decisions cited:

T 0910/90

Catchword:

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Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 10 May 1996, rejecting the opposition against European patent No. 0 376 904. The notice of appeal was received on 11 July 1996, the prescribed fee being paid on the same day. The statement setting out the grounds of appeal was received on 11 September 1996.
- II. Opposition had been filed against the patent as a whole and based on Article 100(a) together with Articles 52(1) and 56 EPC.
- III. Oral proceedings were held on 10 January 2001.
- IV. The appellant requested that the decision under appeal be set aside and that the patent be revoked. Reference was made to the following documents:
 - E1: DE-A-24 36 438,
 - E2: DE-B-1 216 399,
 - E3: FR-A-2 062 750,
 - E4: DE-U-80 19 782, and
 - E5: FR-A-2 504 383.
- V. The respondent requested that the appeal be dismissed and that the patent be maintained as granted.

VI. Claim 1 of the patent as granted reads as follows:

"1. A system comprising in combination a pacemaker (ES) having a connector device for connecting a pacing lead, and a helically wound pacing lead (EC), characterised in that said connector is constituted by a body (2) of conductive material with a threaded end part (4) which tapers towards its proximal end and is screwed into the turns of the end portion of the pacing lead, which expand resiliently."

VII. The opposition division held in its decision that the claimed subject-matter was inventive because document E5, being the only cited document which related to a system of a pacemaker and a pacing lead, did not show a screwing connection and none of the other cited documents which related to the field of electrical connectors in general gave an example for a connection between a tapered screw and a conductor coil.

VIII. The appellant essentially relied on the following submissions:

The subject-matter of claim 1 of the main request was rendered obvious by the teaching of document E5 when taken in combination in particular with that of document E4. E5 constituted the closest prior art and disclosed a system of a pacemaker and a pacing lead according to the preamble of patent claim 1. The only difference between the system according to claim 1 under consideration and that according to E5 was the modification of the connector constituting the male member to form a tapered threaded screw whereas in E5 the connector was formed by a bent piece of wire. The advantages of such a modification were apparent from column 1, lines 11 to 15, and column 2, lines 28 to 34,

of the patent specification and consisted in forming a strong, irreversible connection to the pacing lead and in increasing the versatility of connection so as to allow for connections of the connector to pacing leads of different dimensions. These advantages defined the objective problem to be considered when assessing the issue of inventive step. Having been faced with said objective problem, the skilled person would have immediately recognized that any modification of the known structure of connection had to be effected on the male member only since otherwise an important advantage of the known system would have been lost, i.e. the capability of adapting the length of the helical pacing lead by simply cutting off a piece of the lead at its free end facing the pacemaker. Further motivation for modifications to the male member was given by repeated references in E5 to other means than the metallic wire to form the connector. Starting from E5 and concentrating on the male member for solving the posed problem, it would have been immediately evident for the skilled person that the measure of choice for increasing the versatility of connection was the provision of a conical male connector member to be screwed into the helically wound pacing lead. In this context, in particular document E4 had offered a specific example of such a type of connector which used the same means as the claimed solution for the purpose of obtaining the same effect. Further examples of tapered threaded connector parts were given by documents E1 to E3. In summary, the use of a tapered threaded connector as known from E4 in the system of E5 was the only practicable solution which could be imagined to solve the identified objective problem. Thus the claimed solution did not involve an inventive step, the more so as the success of the combined teachings of E5 and E4 in terms of increased flexibility and mechanical rigidity of connection had been readily foreseeable.

According to established case law as given for instance by decision T 910/90, it was irrelevant for the above assessment of lack of inventive step that the objective problem was not indicated in E5 itself. What mattered was that, when trying to solve the posed problem, the skilled person had only to follow routine practice such as to resort to already existing solutions in the field of electrical connectors.

IX. The respondent disputed the appellant's view, relying essentially on the following arguments:

In clear distinction to the system known from document E5, in which the necessary mechanical connection between the connector device and the pacing lead was separate from the electrical connection and achieved by mechanical friction between insulating members, the invention, by exploiting specific properties inherent to helically wound pacing leads, achieved a combined electrical and mechanical connection from the interaction of the electrically conductive members only. In the absence of any indication as to the advantages obtained by the invention in terms of increased flexibility and improved rigidity of connection, the claimed connection could only be devised with the benefit of hindsight.

Even if the skilled person had taken note of examples of connections as shown by documents E1 to E4 he would not have arrived at the claimed subject-matter because, in distinction to the claimed solution, the prior art examples relied without exception on radial forces to be exerted on the male connector member and none of them exploited the resilient properties of a helical female connector member. In particular, the solution

offered by document E4 relied on a female connector member which had a cylindrical metric inner thread and had to be so rigid that it could cut into the crests of the outer thread of the male connector member.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is therefore admissible.
2. The sole issue to be considered is that of inventive step (Articles 52(1) and 56 EPC).
 - 2.1 Document E5 (cf. in particular Figures 1 to 3 and their corresponding description) constitutes the closest prior art. It shows a pacemaker which is connected to a pacing lead by a plug-type connection. The (male) connector on the side of the pacemaker is provided in the form of a bent metallic wire which is inserted into a helically wound conductor of the pacing lead so as to establish the necessary electrical contact. The required mechanical strength of the interconnection is provided by friction forces between the inner surface a hollow cylindrical member of insulating material surrounding the metallic wire and the cylindrical outer surface of an insulator surrounding the helical conductor of the pacing lead (cf. also claim 1 of E5).
 - 2.2 The subject-matter of claim 1 under consideration differs from the system known from E5 in that the male connector is constituted by a body of conductive material with a threaded end part which tapers towards its proximal end and is screwed into the turns of the end portion of the pacing lead, which expand resiliently.

The claimed measures result in an electrical connection between the pacemaker and the pacing lead in which the interconnection between the electrically conductive members not only establishes the required electrical contact but at the same time provides sufficient mechanical strength to the connection so that no further mechanical fixing means are required (cf. column 1, lines 37 to 47, and column 2, lines 50 to 58, of the patent specification). As an additional advantage, the same connector can be used for connection to pacing leads of different dimensions (cf. column 2, lines 28 to 34, of the patent specification).

Hence, the objective problem associated with the aforementioned differences is to be seen in the desire to provide a structurally simple but versatile connection of increased mechanical strength of a pacing lead to a pacemaker.

- 2.3 Although individual aspects of the objective problem, such as for instance a need for increased mechanical strength of an electrical interconnection, could be considered as occasionally resulting from routine practice of an expert designing implantable pacemaker systems, their purposeful combination of desirable goals to be achieved is not indicated in the available prior art and in particular not hinted at in document E5.

Hence, an assessment of lack of inventive step, as that submitted by the appellant, which presupposes the skilled person's knowledge about the objective problem already before the filing date of the present invention, without providing any evidence with regard to that, involves an element of hindsight analysis. In this context, the Board does not share the appellant's

interpretation of the established case law. In decision T 910/90 (cf. in particular point 5 of the reasons) the board had considered the question how the objective problem had to be established and found in this context that it was irrelevant whether the objective problem had been mentioned in the closest prior art. What mattered was only which technical problem a skilled person would objectively recognize from a comparison of the invention with the teaching of the closest prior art. There is no indication, however, in the cited decision nor from any other decision of the existing case law that the thus determined objective problem was automatically to be considered as forming part of the knowledge of the skilled person before the filing date of the invention under examination. As a matter of fact, the board in T 910/90 found that the properly established objective problem had already been hinted at in the relevant prior art (cf. point 6.2 of the reasons) and hence could not support an inventive step.

In consequence, the Board notes that, in the circumstances of the present case, the skilled person had not found in the prior art any motivation for modifying the connection of a pacemaker to the corresponding pacing lead as known from E5 with a view to simplifying the connector structure whilst at the same time increasing the mechanical strength and maintaining the versatility thereof.

- 2.4 Since the skilled person would not have been aware of the objective problem as identified above, it is not plausible that he would have called into question basic functional principles underlying the connector structure known from E5.

It is evident *inter alia* from claim 1 of document E5 that one of the fundamental structural features of the known system is the provision of a mechanical connection between the pacemaker and the pacing lead separate from the electrical connection.

There is nothing in the available prior art which had prompted the skilled person to abandon this principle of structure when contemplating for instance possibilities for increasing the mechanical strength of the connection. In fact, a variety of modifications could have been imagined which would have increased the mechanical strength of the connection shown by E5 without abandoning the principle of separate electrical and mechanical interconnections, some of which are even indicated in E5 (cf. page 7, lines 4 to 16, and Figures 7 and 8), such as the provision of ligatures or elastic rings exerting a radial pressure onto the insulating cylindrical member of the connector surrounding the bent wire. Therefore the Board does not agree with the appellant's submission that starting from the system according to E5 the only option practically available to the skilled person was a modification to the male electrical connector.

- 2.5 Moreover, even if the skilled person had contemplated a modification to the bent connector lead plugged into the coiled pacing lead in the system according to E5, there is nothing in the available prior art which would have induced the skilled person to devise by purposeful considerations the specific structure of the screwing connection as defined in claim 1 under consideration.

Although the possibility of forming screwing connections is to be considered as falling within the scope of the everyday experience of any technically skilled person, it is to be noted that there is no example in the prior art for the use of screwing

connections between a pacemaker and a pacing lead. Nor is any evidence on file that a screwing connection in the claimed specific form could have been expected to produce the beneficial effects disclosed in the patent in suit.

As a matter of fact, none of the documents referred to by the appellant shows an example for the claimed structure of connection. In particular there is no evidence even from the general field of electrical interconnections as to forming a rigid and versatile connection by screwing a tapered threaded male conductor into a helically wound female conductor. Documents E1 (cf. the Figure and the corresponding description on page 2) and E2 (cf. Figures 1 and 4) show examples of electrical connections in which a threaded male connector member is screwed into a homogeneous mass of conductive material. Whereas according to E1 the threaded end part of the connector is tapered, the threaded part according to E2 is made cylindrical based on the recognition that a tapered threaded end does not provide the required pulling strength to the connection (cf. claim 1 and column 1, lines 10 to 46, in E2). According to document E3 (cf. Figures 1 and 2), the female member of the electrical connection has an outside thread by which it is screwed into an insulator, whereas the male connector is simply plugged into an orifice of the female member. Finally, according to document E4 (cf. Figure 1 and the description on pages 3 and 4), a cylindrical female electrical connector member with a metrical inside thread is screwed onto the tapered threaded end part of a male electrical connector member. The mechanical strength of the connection relies on the use of different materials for the male and female members, the material of said inside thread being sufficiently hard so as to permanently deform the crests of the tapered thread on the male connector.

It follows that even if the skilled person had contemplated adopting one of the examples of an electrical connection by means of screwing as known from E1 to E4 for the connection between a pacemaker and a pacing lead, he would not have arrived at a connection structure as specified in claim 1 of the patent in suit.

- 2.5 Hence, in the Board's opinion, the appellant has only shown that the skilled person **could** have replaced the bent lead of the connector in the system according to E5 by a tapered, threaded end-part but has failed to prove that, on the basis of the technical information available before the priority date of the patent in suit, the skilled person **would** have devised such a structure.

Consequently, the Board is satisfied that the subject-matter of claim 1 as granted complies with the requirements of Articles 52(1) and 56 EPC having regard to inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

G. Davies