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D E C I S I O N
of 24 June 1997

Case Number: T 0577/93 - 3.2.2

Application Number: 86118095.8

Publication Number: 0234046

IPC: A61M 1/10

Language of the proceedings: EN

Title of invention:
Intra-aortic balloon apparatus

Patentee:
AISIN SEIKI KABUSHIKI KAISHA

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

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0577/93 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 24 June 1997

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 23 April 1993 rejecting the opposition filed against European patent No. 0 234 046 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: H. Seidenschwarz
Members: M.Bidet
J.-C. De Preter

Summary of Facts and Submissions

I. On 24 June 1993 an appeal was filed against the decision of the opposition division, issued on 23 April 1993 rejecting the opposition against the European patent No. 0 234 046, the appeal fee being paid on the same date. The statement setting out the grounds of appeal was received on 30 August 1993.

Claim 1 of the patent as granted has the following form:

"An intra-aortic balloon apparatus comprising

- a first connector (3) having a gas supply port (7),

- a tubular first catheter(2) having a proximate end and a distal end, the proximate end being fixedly secured to said first connector (3),

- a balloon (4) having a proximate end and a distal end, the proximate end being fixedly secured to the distal end of said first catheter (2),

- a central tubular member (5) inserted in said first catheter (2)and defining therein a passageway extending the length thereof and having a distal end projecting from the distal end of said first catheter (2) and a proximate end extending through said first connector (3), the distal end of said balloon (4) being fixedly secured to the distal end of said central tubular member(5),

- said balloon (4), said central tubular member (5) and said first catheter (2) being insertable into the aorta of a patient,

characterised by

- a second catheter (8) freely insertable into the passageway of said central tubular member(5) and having a distal end and a proximate end, the length between said distal and proximate ends thereof being longer than that of said central tubular member (5), the distal end of said second catheter (8) being provided with a pressure transducer (11),

- a second connector (9) having a proximate end to which the proximate end of said second catheter (8) can be fixedly secured for feeding a signal produced by said pressure transducer (11) to the outside of the apparatus,

- said second catheter (8) being insertable into said passageway in said central tubular member (5) with said pressure transducer (11) being projectable into the aorta from the distal end of said central tubular member (5)."

II. The opposition was against the patent as a whole and based on Article 100(a) EPC contending that the subject-matter of the patent did not involve an inventive step.

The opposition division held that the ground of lack of inventive step did not prejudice the maintenance of the patent unamended having regard to the following documents:

(1) US-A-4 362 150 (previously R5 or D1)
(2) DE-A-2 801 553 (previously R9 or D2)
(3) US-A-4 274 423 (previously R4 or D3) and
(4) US-A-4 077 394 (previously R2)

III. In its statements of grounds the appellant (opponent) introduced for the first time in appeal proceedings the following new documents:

(5) US-A-3 585 983 (previously R1)
(6) US-A-4 456 000 ((previously R3)

These documents were cited in the description of the patent as granted (document (5)) and in the search report (documents (5) and (6)). The appellant submitted that the subject-matter of Claim 1 of the patent as granted was obvious in view of the teaching derivable from document (5) in combination with the teaching according to one of the documents (1),(3),(4) and (6).

In its reply to the statement of grounds the respondent (patentee) considered that the late-filed documents were not relevant and therefore they should not be accepted in the proceedings.

IV. An oral proceedings was held on 24 June 1997.

(i) Having regard to the indication given by the Board at the beginning of the oral proceedings that the documents (5) and (6) were not submitted in due time, the appellant based its ground of lack of inventive step on the combination of the teaching of document (1) with that of document (3). The catheter according to document (1) included an inner tube within the outer tube of the catheter, the ends of the balloon being secured to the ends of the two tubes as specified in the preamble of Claim 1 of the patent in suit. It argued that, referring to the teachings of the documents (2)

and (4), it was within the common knowledge of the skilled person to insert in place of a guide wire a pressure micro-sensor catheter according to document (3) in the inner tube of the catheter according to document (1) -disclosing the features of the preamble of Claim 1- in order to provide a balloon catheter with accurate measurement of central aortic pressure and which can be introduced percutaneously, as required from the stated object of the invention of the patent in suit.

The appellant emphasized that in the embodiments according to Fig. 11 to 13 of document (3), the sensor was introduced in the body according to a two-step sequence. First a needle was inserted into the portion of the living body, then the pressure sensor was inserted into the hollow core of the needle, giving a clear hint to the skilled person to insert such pressure sensor into the inner tube of the catheter according to document (1).

In response to a question of the Board about the relevance and the purpose of the late filed documents (5) and (6), the appellant stated that they were no more relevant than the documents already available. They were cited with the view to illustrating the above line of reasoning relating to the combination of teaching known from the documents (1) and (3).

(ii) The respondent contested the argument that the skilled person would take the teaching of document (3) into consideration, since this document referred to a catheter tip pressure transducer generally used for many kinds of applications, among them for medical purposes.

As regards the structure of the pressure sensor, it noted that the sensor remained within the needle, so that it did not extend from the needle. From the other documents cited in the decision of opposition division, the catheters according to documents (4) and (2) are not of the type of the preamble, since the ends of the balloon are secured on a single tube, rendering the percutaneous insertion more difficult than a catheter according to document (1) having a reduced diameter at the location of the wrapped balloon. The skilled person would therefore not consider them.

IV. The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained, as its main request, and that if the newly cited documents are considered as relevant, the case be remitted to the first instance.

Reasons for the Decision

1. The appeal is admissible

2. *Late filed documents*

Since the appellant acknowledged that the late filed documents (5) and (6) were no more relevant than the documents already cited in the opposition proceedings, these documents are rejected by the Board, taking also account that they really illustrate merely the knowledge of the skilled person.

3. *Prior art*

3.1 Document (1) discloses an intra-aortic balloon apparatus comprising a connector having a gas supply port, a tubular first catheter in which a central tubular member is inserted defining a passageway through the first catheter and a balloon fixedly secured at its proximal end to the distal end of the first catheter and its distal end to the distal end of the central tubular member. The balloon, the central tubular member and the first catheter are insertable into the aorta of a patient (see column 2, lines 34 to 36, and line 65 to column 3, line 1; column 3, lines 60 to 64 and column 4, lines 41 to 53; Figure 1).

An object of this apparatus is to ensure proper control and positive wrapping of the balloon before and during insertion, control and positive unwrapping of the balloon after it has been inserted, as well as control over rewrapping of the balloon prior to removal (see column 1, lines 55 to 68).

The intra-aortic balloon apparatus according to Claim 1 of the patent in suit differs from that disclosed in document (1) in that a second catheter being longer than the central tubular member, is freely insertable into this central tubular member and its distal end is provided with a pressure transducer which is able to project into the aorta from the distal end of that central tubular member, the apparatus further including transmitting means from the pressure transducer to the outside of the apparatus.

3.2 Document (2) relates to a balloon catheter apparatus comprising a balloon fixedly secured to a tube which connects the interior of the balloon to a pump allowing the balloon to be inflated and deflated. The pressure in the balloon is measured by an external pressure gauge.

An object of this apparatus is to close or partially close sensible cavities in the medical or non-medical field without giving rise to mechanical damages during use or progression of the apparatus inside the cavities.

This document does not disclose a balloon apparatus which has a second tube provided with a pressure transducer and being freely insertable within the tube on which the balloon is secured.

3.3 Document (3) concerns a catheter tip pressure transducer which comprises an hollow tube catheter closed by an end portion of a support member and which hollow tube catheter is provided with a pressure inlet hole in its side surface at a predetermined distance from its end. A pressure sensor is disposed on the support member which is joined together with the hollow tubular catheter in order to prevent slippage of the pressure sensor from its predetermined position in relation to the pressure inlet hole. Lead wires are secured to an opening in the support member for connection to the pressure sensor so that electrical signals can be received remotely from the catheter tip (see column 4, lines 5 to 15 and 45 to 48; column 5, lines 44 to 65; column 6, lines 58 to 61).

This catheter has a wide spectrum of various applications, for example for detecting the pressure at various portions of a living body.

According to an alternative embodiment shown in Figures 11 to 13, a supporting member - similar to the support member in the catheter tip pressure transducer according to the above first embodiment shown in the Figures 3 to 10A - is disposed within an inner tube. Again a pressure sensor is positioned at the predetermined position on the supporting member and elastic attachment means prevent slippage of the pressure sensor on the supporting member. This embodiment relates to a small-sized pressure transducer for medical use, called a needle-type pressure transducer. A needle is inserted into the portion of the living body wherein pressure is to be measured; then the inner tube provided with the pressure sensor is inserted into the hollow core of the needle to detect the pressure at the end of the inner tube (see column 8, lines 16 to 31).

3.4 Document (4) relates also to an intra-aortic balloon apparatus of the type having a balloon secured to a tubular catheter or pneumatic conduit. A central tubular member is located within the catheter and defines therein a passageway extending the length of the tubular catheter. A pressure sensing probe integral with the balloon terminates the central tubular member.

The object of this catheter is to provide means to sense the aorta pressure which do not tend to clog, which take no time to insert and remain accurate over an extended time (see column 2, lines 8 to 11).

However, the balloon of this known intra-aortic balloon apparatus is only fixed to the tubular catheter or pneumatic conduit. There is therefore no wrapping of the balloon, so that the deflated balloon has an outer diameter larger than the tubular catheter. Furthermore, the central tubular member is integral with the tubular catheter. This apparatus differs from the subject-

matter of Claim 1 of the patent in suit also in view of the features that the central tubular member is not freely insertable within the tubular catheter, is not longer than the catheter and does not project from the distal end of the central tubular member.

4. *Novelty*

None of the documents of the state of the art discloses in combination all the features specified in Claim 1 of the application in suit.

The subject-matter of Claim 1 is therefore considered to be new within the meaning of Article 54(1) EPC.

5. *Inventive step*

5.1 From the above point 3, it follows that the intra-aortic balloon apparatus according to document (1) represents the state of the art nearest to the subject-matter of Claim 1, since this known apparatus can be inserted into a living body by percutaneous introduction (see patent specification, column 1, lines 19 to 22).

5.2 It is an object of the present invention to provide an intra-aortic balloon apparatus as known from document (1) which apparatus enables the accurate measurement of central aortic pressure (see patent specification, column 1, lines 52 to 56).

5.3 This object is achieved according to the characterising portion of Claim 1 by the features cited in the last paragraph of point 3.1 above.

With the introduction of a second catheter freely insertable into the central tubular member and provided with a pressure transducer and being longer than the central tubular member, it is possible accurately to measure arterial pressure and, hence, to achieve counter pulsation timing far more precise than that obtainable in the prior art.

5.4 Since there is no indication in document (1) of using means which would allow the measurement of the central aortic pressure, this document alone cannot suggest any a solution to the above problem.

5.5 According to document (3) two types of pressure transducers are described, namely a catheter tip pressure transducer and a needle-type pressure transducer.

(i) In order to work properly the pressure sensor has to face the pressure inlet hole of the hollow tube catheter. The position of this pressure sensor within the catheter must be therefore precisely determined and maintained, so that both elements form an integral unit. Consequently, the pressure sensor is not projectable from the distal end of the hollow tube catheter and the measurement is not performed at this distal end. Furthermore, there is no mention of inserting this catheter tip pressure transducer in the passageway of a central tubular member of a first catheter. Therefore, the skilled person would not find in this known device any hint leading him to take account of it to solve the problem underlying the present invention.

(ii) According to the second embodiment of document (3), the inner tube provided with its pressure sensor is freely insertable into the needle inserted into the portion of a living body. There is no indication in document (3) how to carry out this last insertion. However, with the mention that by using such a needle type pressure transducer, the pressure **under the skin** of the living body can be **easily** measured, the skilled reader notes that this small-sized pressure transducer needing a needle remains near under the skin. The length of insertion of the pressure sensor is therefore relatively short and does not exceed the length of its supporting member. As a result this embodiment is inappropriate for insertion within a catheter of an intra-aortic balloon apparatus which is introduced into a patient's aorta.

5.6 Since the apparatus according to document (2) and (4) do not have a catheter freely insertable into the passageway of a central tubular member, which catheter has a distal end with a pressure transducer being able to be projected into the aorta as set out above in points 3.2 and 3.4, these documents as well as document (3) do not give any hint to the skilled person of a need to change the structure of the apparatus known from document (1) to arrive at the claimed intra-aortic balloon apparatus.

5.7 Therefore, the subject-matter of Claim 1 is considered to involve the inventive step as required by Articles 52(1) and 56 EPC.

6. Claim 1 being allowable, the same applies to the dependent claims 2 and 3 whose patentability is supported by that of Claim 1.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani H. Seidenschwarz