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D E C I S I O N
of 2 August 2000

Case Number: T 0728/96 - 3.2.2

Application Number: 88120561.1

Publication Number: 0321796

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:
Extendable guidewire for cardiovascular procedures

Applicant:
ADVANCED CARDIOVASCULAR SYSTEMS, INC.

Opponent:
BIOTRONIC Mess- und Therapiegeräte GmbH & Co Ingenieurbüro

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0728/96 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 2 August 2000

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 5 June 1996 concerning maintenance of European patent No. 0 321 796 in amended form.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
J. C. M. De Preter

Summary of Facts and Submissions

I. The appellant (opponent) filed on 31 July 1996 an appeal against the decision of the opposition division to maintain the patent in amended form and paid the fee for appeal on the same day. The statement of the grounds for appeal has been filed on 1 October 1996.

II. The opposition division held that the grounds brought forward by the opponent and based on Article 100(a) EPC (lack of novelty and inventive step) and 100(b) EPC (insufficient disclosure) did not prejudice the maintenance of the patent as amended.

III. In the grounds of appeal, the appellant only maintained its objections on the grounds of lack of novelty and inventive step having regard to the documents:

E2: US-A-4 617 715

E3: GB-A -708 884

E6: JP-62-116746 (introduced by an observation under Article 115 EPC and admitted by the opposition division under Article 114(1) EPC)

submitted during the opposition proceedings, and cited document:

E7: US-A-4 411 276

for the first time.

IV. Oral proceedings were held on 2 August 2000, at the end of which the requests of the parties were as follows:

The appellant (opponent) requested that the decision under appeal be set aside and the patent revoked.

The respondent (proprietor of the patent) requested that the appeal be dismissed (main request) or that the patent be maintained on the basis of one of the four auxiliary requests submitted with letter of 30 June 2000.

V. The wording of the independent claims 1 and 6 of the main request which are the basis for the decision under appeal is as follows.

"1. An extendable guidewire system (10) comprising:
a main guidewire section (11) adapted to be inserted into a patient's vascular system and which has a first mating end;
a guidewire extension section (12) having a second mating end; and
a means for releasably connecting the first and second mating ends, said means comprising a tubular member (19) fixed to the mating end of one of the guide wire sections (11, 12) and a male member (14) on the mating end of the other guidewire section (11, 12), the male member (14) having a maximum radial dimension (A) slightly greater than the inner diameter (B) of the tubular member (19) and being adapted to be inserted into the tubular member (19) to thereby releasably secure the two guidewire sections (11, 12) together, characterized in that
the male member (14) is provided with an undulated shape."

"6. An extendable guidewire system (10) comprising:
a main guidewire section (11) adapted to be inserted

into a patient's vascular system and which has a first mating end;
a guidewire extension section (12) having a second mating end; and
a means for releasably connecting the first and second mating ends, said means comprising a tubular member (19) fixed to the mating end of one of the guidewire sections (11, 12) and a male member (30) on the mating end of the other guidewire section (11, 12), the male member (30) having a maximum radial dimension (A) slightly greater than the inner diameter (B) of the tubular member (19) and being adapted to be inserted into the tubular member (19),
characterized in that
the male member (30) has protrusions (31) on an outer surface thereof which engage an inner surface of the tubular member (19) to thereby releasably secure the two sections (11, 12) together."

VI. The appellant argued as follows.

The novelty of the subject-matter of claim 1 was not challenged. The guidewire system according to claim 1 of the main request distinguished from the one disclosed in document E6 by the feature in its characterizing part, that the male member was provided with an undulated shape. The problem to be solved by the invention was to find a better or a different way to connect the two ends of the guidewire. The distinguishing feature was disclosed either by document E7 or by document E2. Document E7 belonged to the same field of the invention and showed the same type of connection of the invention, see Figure 1, reference numbers 15 (undulated wire) and 11 (tubular member). Document E2 described a general principle which

belonged to the general knowledge of the person skilled in the art. The skilled person in the field of medical appliances would also consult this document because it related like the invention to connections. Accordingly claim 1 was not inventive.

The subject-matter of claim 6 according to the main request was not novel or at least did not involve an inventive step having regard to document E6. The features in the precharacterising parts were known from document E6. Furthermore this document, Figure 2, disclosed also the characterizing feature of the claim, that is a male member having protrusions. Using protrusions to improve the reliability of a junction belonged to the general knowledge of a person skilled in the art; see for example the cap connection of a usual felt pen. Since document E3 disclosed a connection comprising protrusions, the inventive merit of the subject-matter of claims 6 was also challenged by the combined teaching of documents E6 and E3.

VII. The respondent argued as follows.

Regarding claim 1 of the main request:

The person skilled in the technical field of the invention was not induced to modify the teaching of document E6, which represented the nearest state of the art, to arrive at the invention because the cited prior art contained no hints in this respect. Document E2 belonged in fact to a field totally remote and distinct from that of the invention. Document E7 related to the field of electrical or optical permanent connections. In contrast thereto, the connection according to the invention was a temporary, exclusively mechanical

connection. Furthermore, in document E7 the physical connection was ensured by the sheath means and not by the structure of the wire 15, 17.

Turning to claim 6 of the main request, document E6 did not disclose macroscopic protrusions but either a rough surface or a groove. A microscopic irregularity on the surface - such as a roughness - was neither a protrusion in the meaning of the invention nor in the ordinary meaning of the word. Document E3 concerned the remote technical field of railway constructions and had nothing to do with the invention.

Reasons for the Decision

1. The appeal is admissible

2. *Main request*

2.1 General considerations

Document E6 represents the closest state of the art since it discloses, together with the features in the preamble of the independent claims 1 and 6, the general object of the invention, which consists on providing a reliable, releasable connection for the extension of a guidewire (see page 6, from line 1 of the English translation of document E6).

Claim 1 distinguishes therefrom in that the male member is provided with an undulated shape, whereas claim 6 distinguishes therefrom in that the surface of the male member has protrusions.

The problem of the invention over document E6 is therefore to provide an alternative solution for a reliable, releasable junction of the guidewire.

The solution contained in claims 1 and 6 consists of providing a definite number of contact points between the male and the female member (tips of the undulations or of the protuberances, respectively). In this way it is possible to adjust exactly the force necessary to join and to separate the connection.

By contrast, document E6 discloses 3 different embodiments:

(1) The female member 16 of the embodiment according to Figure 2 comprises a ringlike projection 16a adjacent its open end which is adapted to snap into a corresponding ringlike groove 26a of the male member 26. This embodiment, although providing a connection which can be easily actuated, can be disconnected only by a jerking action which may harm the patient in whose artery the guidewire is located.

(2) The male member 27 of the embodiment according to Figure 5 is slightly tapered toward its distal end and its surface is roughly finished. Since this tapered male member has to be inserted into the cylindrical space of the corresponding female member 17, it is evident that the connection depends only on the frictional force along the line of contact between these two members, which is not particularly reliable.

(3) The female member 18 of the embodiment according to Figure 6 comprises a longitudinal slit 18a which enables a male member 28 having an diameter slightly larger than the inner diameter of the female member to be inserted and maintained therein being slightly pressed by the elastic female member. Bearing in mind the tiny dimensions of the parts to be fitted, it is evident that the surgeon may find some difficulties when he has to actuate the connection under stress and time constraints.

The person skilled in the field of the invention would not modify the teaching of document E6 in the sense of the invention because no hints are contained in the available prior art for doing that, as it will become clear from the considerations in the following paragraphs.

2.2 Claim 1

2.2.1 The appellant maintains that a combination of the teaching of documents E6 and E7 or of documents E6 and E2 would make claim 1 not inventive.

Documents E7 and E2 concern permanent non-detachable connections and already for this reason would not have been consulted by a skilled person in the field looking around for a solution to the problem of the patent in suit as defined above. Furthermore, E2 belongs to the field of civil engineering which is very unlikely to be searched by the person concerned with the development of medical equipment. In the following, documents E7 ad E2 are considered in more detail.

2.2.2 Document E7 relates to a surgical equipment like the invention and, more specifically, is concerned with electrical or optical (column 7, line 59) permanent connections (see column 1, line 42, where a duration of ten years or more is cited), that is connections which are designed to resist breaking (column 7, lines 30 to 33).

Document E7 does not disclose a male member of a releasable connection provided with an undulated shape like the invention.

In the sense of the invention, the means for releasably connecting first and second mating ends consists of a tubular member fixed to the first mating end and of a male member fixed to the second mating end. In contrast to that, the device according to document E7 comprises two distinct connections, namely a mechanical and an electrical or optical connection. The first one consists of: 1) two tubular members 10 (lead) and 11 (extension), each integral to one of the mating ends, and: 2) of a sheath 32. The contacting surfaces of the junction are such as to generate frictional forces when the two ends are pulled. If one would attempt to separate the lead 10 from the extension 11 by pulling, the sheath 32 would stretch, contract and thereby increase the frictional force and grip the lead 10 and the extension 11 more tightly (see column 4, lines 17 to 36; column 7, lines 21 to 33). If necessary, additional sutures 40, 41 or O-rings 71, 81 are provided to increase the compression of the sheath and ensure a more reliable permanent junction, see column 5, lines 32 to 56. The second connection is a preferably electrical connection consisting of a coiled conductor 18, 19

inside the two tubular members 10, 11 and of an undulated wire 15, 17 connected to the sheath 32. Joining the two ends 10, 11 to the sheath 32 realizes contemporarily the electrical and the mechanical connection.

The undulation of the male member 15, 17 of the electrical connection has the purpose of assuring the electrical contact with the coiled conductor 18, 19 and not to assure a releasable connection. The mechanical connection in document E7 is given by the sheath means 32 and not by the form of the wire 15, 17 (see also paragraph bridging columns 2 and 3, column 5, lines 25 to 32 and column 4, lines 26 to 36).

There are no reasons why the person skilled in the art in the light of document E7 would depart from the releasable connections disclosed in document E6, Figure 2 (projections 16a) or Figure 5 (rough surface) in order to adopt an undulated wire as disclosed by claim 1.

Accordingly, a combination of the teaching of documents E6 and E7 would not lead in an obvious way to the invention as claimed in claim 1 of the main request.

2.2.3 Document E2 relates to a system for preliminary anchoring a wire rope in excavation bores before the setting of the cement to be cast into the bore. The purpose is to avoid using wooden wedges for keeping in place the rope for the duration of the setting. For this purpose a permanent deformation (undulation) is produced in the wire rope so that the undulated

rope is anchored by friction to the bore wall. The field of this device (construction and mining) has nothing to do with that of the invention (cardiovascular appliances). Furthermore the junction of document E2 is not easily releasable. The skilled person in the field of the invention would not take in consideration the teaching of this document. There are also no indications that E2 discloses a general principle belonging to the general knowledge of the person skilled in the art. A single patent does not disclose, as a rule, a general knowledge.

Accordingly a combination of the teaching of documents E6 and E2 would not lead in an obvious way to the invention as claimed in claim 1 of the main request.

2.3 Claim 6

2.3.1 Claim 6 is novel having regard to document E6, the only difference being that the surface of the male part has protrusions.

Certainly, document E6 discloses a surface of the male part being roughly finished (Figure 5) or having a groove (26a, Figure 2), but this is not the same as having protrusions.

The ordinary meaning of the term "protrusions", which is consistent with its use in the patent in suit, is that some parts rise above an (even) surface.

That implies as a rule that the protrusions are of the same order of magnitude of the surface involved, in order for both to be practically comparable. Being

the wire macroscopic, the protrusions on its surface should be also macroscopic. A microscopic irregularity on the surface such as a roughness is not a protrusion.

Furthermore, the term protrusion implies that the reference surface is relatively broader than the protrusions themselves, so that the protruding elements are clearly distinguishable above the reference surface. Roughness is therefore, again, not made of "protrusions" because roughness means that said surface is uneven and irregular.

Regarding the embodiment with the groove (Figure 2), the bottom of a groove can not be considered as a reference surface in order to define the rest of the surface as "protrusion" because the surface of the bottom of a groove is as a rule relatively too narrow to be considered as a reference surface for the definition of protrusions.

Finally, the groove embodiment of Figure 2 of document E6 is not relevant in assessing inventivity also because the surface of the male element of Figure 2 does not engage the internal surface of the tubular member as required by the claim.

Accordingly, Document E6 does not disclose macroscopic protrusions but either a rough surface (Figure 5) or a groove (25a, Figure 2) and claim 6 of the main request should be considered as novel.

2.3.2 A combination of the teaching of document E6 with the general knowledge of the person skilled in the field, as exemplarily represented by the cap connection of a

felt pen, does not lead in an obvious way to the invention as claimed in claim 6. The cap connection of a felt pen - like the connection disclosed in Figure 2 of document E6 - is in fact typically a snap connection where the male part comes in contact with a protrusion in the inner surface of the tubular member and not necessarily with its inner surface. The presence of protrusions only on the surface of the male part by the invention as claimed in claim 6 allows on the other hand a carefully tuned regulation of the frictional force. This is not possible by the snap connection according to the general knowledge cited above. Furthermore, the form of the protrusions and the possibility of arranging them in a suitable manner along the male member, for instance like in Figure 4 of the patent in suit, allows also careful adjustment of the frictional force. This is not the case with a rough surface according to the known embodiment of document E6.

2.3.3 Also a combination of the teaching of documents E6 and E3 does not take away the inventive step of claim 6.

Document E3 relates to the remote technical field of railway constructions and discloses in particular fastening spikes designed to be driven in the concrete - typically with an heavy hammer - to ensure a permanent connection, the fastening spike being provided with projections 7, see Figure 4. The field of the device according to document E3 is far away from that of the invention and the junction is of a permanent character contrary to that of the invention.

2.3.4 Accordingly the subject-matter of claim 6 of the main request involves an inventive step.

3. *Auxiliary requests*

Since the patent as amended according to the main request meets the requirements of the EPC, the auxiliary requests do not need to be considered.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman

V. Commare W. D. Weiß