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D E C I S I O N
of 1 July 2003

Case Number: T 1196/00 - 3.2.2

Application Number: 92309822.2

Publication Number: 0540290

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Expandable stents

Patentee:
ADVANCED CARDIOVASCULAR SYSTEMS, INC.

Opponents:
1. Schmiedl, Roland
2. NOVIS S.r.l.
3. Terumo Kabushiki Kaisha

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty (yes)"
"Inventive step (no)"

Decisions cited:
-

Catchword:
-



Case Number: T 1196/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 1 July 2003

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted 24 October 2000
revoking European patent No. 0540290 pursuant
to Article 102(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
R. T. Menapace

Summary of Facts and Submissions

- I. The appellant (proprietor of the patent) lodged an appeal against the decision of the Opposition Division to revoke the European patent No. 0 540 290.

Three oppositions had been filed against the patent as a whole on the grounds of lack of novelty and inventive step (Article 100(a) EPC). Two of the opponents additionally objected that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC) and that its subject-matter was extended beyond the content of the application as filed (Article 100(c) EPC).

The Opposition Division, in the decision now under appeal, held that the claimed subject-matter lacked novelty having regard to one of the documents

D6: EP-A1-0 364 787 or

D11: "Hepatic Inferior Vena Cava Obstruction: Treatment of Two Types with Gianturco Expandable Metallic Stents" by Shigeru Furui, MD et al., Radiology 1990, vol 176, pages 665 to 670.

- II. During appeal proceedings only two respondents (opponents 2 and 3) made substantial submissions.

Opponent 1 withdrew its opposition by letter dated 27 June 2001 and since then has no more been a party to the proceedings.

Of the documents discussed in the appeal proceedings,
documents

D2: EP-A2-0 421 729 (cited in the opposition
proceedings) and

D12: US-A-4 856 516 (first cited during appeal
proceedings),

in addition to documents D6 and D11, have a bearing on
the present decision.

III. Oral proceedings were held on 1 July 2003, during which
two sets of amended claims according to a main request
and an auxiliary request, respectively, were filed.

At the end of the oral proceedings the requests of the
parties were as follows:

The appellant requested that the decision under appeal
be set aside and that the patent be maintained on the
basis of the sets of claims submitted as main or as an
auxiliary request during the oral proceedings.

The respondents requested that the appeal be dismissed.

IV. Independent claims 1 of the two requests read as
follows:

Main request:

"A kit comprising:

(a) an elongated stent delivery catheter (11) having proximal and distal extremities, and an expandable member (14) on the distal extremity; and

(b) a longitudinally flexible stent (10) formed from an elongated tubular member, the stent (10) being adapted to be slidably mounted on to the expandable member (14) of said catheter (11) and comprising a plurality of cylindrically shaped elements (12) which are independently expandable in the radial direction and which, in an unexpanded condition, when mounted on the delivery catheter, have an axial length which is less than their diameter, the cylindrically shaped elements (12) being connected to one another by interconnecting elements (13) so as to be generally aligned on a common longitudinal axis such that, other than at an end of the stent (10), each cylindrically shaped element (12) has two adjacent cylindrically shaped elements (12) spaced in opposite axial directions, the or each interconnecting element (13) connecting one of said cylindrically shaped elements (12) to one of said adjacent cylindrically shaped elements (12) being circumferentially displaced from the or each interconnecting element (13) connecting said cylindrically shaped element (12) to the other of said adjacent cylindrically shaped elements (12)."

Auxiliary request:

"A kit comprising:

(a) an elongated stent delivery catheter (11) having proximal and distal extremities, and an expandable member (14) on the distal extremity; and

(b) a longitudinally flexible stent (10) formed from an elongated tubular member, the stent (10) being adapted to be slidably mounted on to the expandable member (14) of said catheter (11) and comprising a plurality of cylindrically shaped elements (12) which are formed of structural members in an undulating pattern, the undulating pattern being relatively flat in transverse cross-section, the cylindrically shaped elements (12) being independently expandable in the radial direction and which, in an unexpanded condition, when mounted on the delivery catheter, have an axial length which is less than their diameter, the cylindrically shaped elements (12) being connected to one another by interconnecting elements (13) so as to be generally aligned on a common longitudinal axis such that, other than at an end of the stent (10), each cylindrically shaped element (12) has two adjacent cylindrically shaped elements (12) spaced in opposite axial directions, the or each interconnecting element (13) connecting one of said cylindrically shaped elements (12) to one of said adjacent cylindrically shaped elements (12) being circumferentially displaced from the or each interconnecting element (13) connecting said cylindrically shaped element (12) to the other of said adjacent cylindrically shaped elements (12)."

V. Arguments presented by the parties

(i) The appellant:

- The features added to claim 1 of the main request, according to which the plurality of cylindrically shaped elements "in an unexpanded condition, when mounted on the delivery catheter, have an axial length which is less than their diameter", are supported by the application as filed, in particular by original claim 3 and the text of the description in relation to Figures 1 and 4. Article 123(2) EPC is, therefore, satisfied.

- Claim 1 (main request) is novel with respect to document D12 which is concerned with a stent formed from a single elongated wire bent into a sequence of loops and not from a tubular member. Moreover, the elements interconnecting the loops are aligned in a backbone configuration, so that the longitudinal flexibility of the stent is not given in all directions of curvature.

- Claim 1 (main request) is also not obvious since none of the cited documents discloses all the claimed features taken in combination, each of them contributing on its own way to both radial rigidity and longitudinal flexibility. Document D6 discloses relatively rigid expandable tubular stents made of a plurality of rectangular slots deformable into a diamond configuration, whereas the stents according to document D2 are formed from straight wire segments welded together into a

tubular shaped structure. This latter prior art represents another approach of finding out a compromise between rigidity and flexibility, based on a different structure which necessarily provides for different results. Document D11 discloses stents of the same type as disclosed in D2, i.e. formed from wires bend into a zig-zag configuration. The great commercial success encountered by the stent according to the present invention is an additional evidence of inventive step over the state of the art.

- The incorporation of the features that cylindrically shaped elements are "formed of structural members in an undulating pattern, the undulating pattern being relatively flat in transverse cross-section" further distinguishes claim 1 of the auxiliary request. These specific features provide the stent as a whole with the required characteristics.

(ii) The respondents:

- The features added to claim 1 (main request) extend the subject-matter of the application as filed since a stent constructed to have a length which is smaller than its diameter may also have a length greater than its diameter when it is compressed for its mounting on a delivery catheter, the diameter of which is made variable according to the envisaged application. Besides, these features are not supported in combination by the original application.

- Claim 1 (main request) is not novel with respect to document D12 which discloses all the claimed features, in particular a generally tubular shaped stent comprising cylindrically shaped elements or loops spacedly mounted in an unexpanded condition on a delivery catheter (Figure 1), and having an axial length which is less than the diameter (Figures 2 and 4). Moreover, the adjacent cylindrical elements there are interconnected by a series of longitudinal connecting elements hitched to the successive cylindrical elements, so as to be circumferentially displaced from one another (Figure 2A).

- Claim 1 (main request) does not involve an inventive step either since all the cited documents disclose stents having spaced cylindrically shaped elements independently expandable and axially interconnected by circumferentially displaced connecting elements for providing as a whole appropriate axial rigidity and longitudinal flexibility. They all have generally the same structure and therefore produce the same effects. The additional feature according to which the length of the cylindrical element is less than its diameter is known *per se* from document D11 and cannot justify the presence of an inventive step, the more since said feature in combination with a stent mounted in an unexpanded state on a delivery catheter is not supported by the description. It cannot, therefore, be considered as an essential feature of the invention. The commercial success, if any, is not necessarily an indication of inventive step and is

not relevant as evidence that such success results from the claimed features.

- Claim 1 of the auxiliary request incorporates features (undulating pattern relatively flat in cross-section), the contribution of which to the desired characteristics of the stent is neither identified nor stressed in the description. They are, therefore, irrelevant to the solution of the stated problem. Moreover, a stent made of a structural tubular member being flat in cross-section, is known from document D6. Consequently, also the subject-matter of claim 1 according to the auxiliary request lacks an inventive step.

Reasons for the Decision

1. The appeal is admissible.
2. *Amendments (main request)*

Claim 1 is directed to the combination of a delivery catheter and of a flexible stent mounted on it. Claim 1 is formed by features taken from original claims 27 and 7 and by features originating from the description as filed (page 3, lines 7 to 10). Claim 1 differs from its version as granted by the incorporation of a feature relating to the plurality of cylindrically shaped elements which "in an unexpanded condition, when mounted on the delivery catheter, have an axial length which is less than their diameter". This additional feature is picked up from original claim 3 and passages from the description as originally filed (page 7,

lines 1 to 3 and lines 12 to 14; page 11, lines 4 to 7) in relation to the presentation of Figures 1 and 4. It results therefrom and also from the passage on page 9, lines 3 to 9, that the unexpanded condition of the stent applies to the stent mounted on the balloon-catheter and maintained in a slightly compressed state by a retractable sleeve before and during its implantation. This information is identically contained in the patent as granted.

Therefore, the Board accepts the appellant's interpretation that the unexpanded condition is actually the compressed state in which the stent is mounted and delivered.

In this respect it does not matter whether the length of the stent increases when compressed onto the delivery catheter, which necessarily modifies the length-to-diameter ratio. What is decisive is that the relation "length less than diameter" is satisfied and can be determined with certainty in the state of the stent as claimed, irrespective of the type and diameter of the catheter used.

The feature added to claim 1 is, therefore, clearly defined and supported and does not lead to any extension of the subject-matter of the application as filed in accordance with Article 123(2) EPC.

3. *Novelty (main request)*

Document D12 put forward by Opponent 3 against the novelty of claim 1 was already cited in the application as filed and in the European search report. It is,

therefore, not a newly cited document. It discloses a stent constructed from a single elongated wire having a series of tight bends or convolutions. The wire is then bent into a sequence of loops which are interconnected by half hitch junctions, such that a backbone is formed by the sections interconnecting the junctions. These sections are substantially aligned along the length of the stent. Alternatively, they can be spirally arranged or spaced around the stent's circumference (cf. column 2, lines 28 to 33 and column 4, lines 13 to 17). However, these alternative embodiments are not shown nor described in detail so that it is hardly conceivable how said interconnecting sections could be displaced, i.e. radially offset in the sense of the present patent, while still forming half hitch junctions. Therefore, the feature according to which the interconnecting elements arranged between two adjacent cylindrical elements are "circumferentially displaced" is not disclosed by document D12, which is thus not destroying novelty of the subject-matter of claim 1. In addition, the stent described in D12 is not formed from an elongated tubular member within the meaning of the patent in suit, which is not restricted to a tubular shape of the stent.

4. *Inventive step (main request)*

- 4.1 Document D6 represents the closest prior art and the starting point of the invention since it discloses a plurality of longitudinal flexible stents each formed from an elongated tubular member within the meaning of the contested patent. The structure consists in rectangular slots deformable upon expansion (cf. Figures 1A, 1B) so as to confer radial rigidity to the

stents in order to retain their expanded configuration and to resist radial collapse (column 7, lines 15 to 23). When the stents are connected together by interconnecting elements 100 (Figures 7 and 8) the stent as a whole exhibits improved flexibility in order to negotiate the curves within the vascular system in any direction (column 5, lines 20 to 24 and column 14, lines 27 to 38).

More specifically, following the terminology of claim 1 in suit, document D6 discloses in combination a delivery catheter having an expandable member and a longitudinally flexible stent slidably mounted on said expandable member (Figures 3 and 4). The stent comprises (Figure 7) a plurality of cylindrically shaped elements 70 which are independently expandable in the radial direction and which are connected to one another by interconnecting elements 100, so as to be generally aligned on a common longitudinal axis. Each cylindrically shaped element is spaced from an adjacent one in opposite axial directions and the elements interconnecting adjacent cylindrical elements, i.e. placed on both sides of an intermediate cylindrical element, are circumferentially displaced, i.e. radially offset in relation to each other (cf. column 13, lines 41 to 49 and column 14, lines 4 to 9).

The subject-matter of claim 1 differs from the disclosure of document D6 only in that the cylindrically shaped elements, when mounted on the delivery catheter in an unexpanded condition, have an axial length which is less than their diameter.

4.2 The technical problem underlying the present patent (cf. column 1, lines 31 to 41) is to provide a stent having satisfying radial rigidity to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery. The solution is provided by a stent having all the claimed features in combination since each of them contributes for a part to the rigidity and the flexibility of the stent as a whole.

Document D6 proposes a stent having the required characteristics and comprising all the features as claimed, except for the distinguishing feature mentioned previously. However, even if said feature is regarded as sufficiently supported in the meaning that it is implicitly referred to and comprised within the content of the application as filed, as is held in section 2 above, there is no support in the description that the length-to-diameter ratio assists in improving the stent flexibility in tortuous passageways or its radial rigidity to hold open a body lumen. The only passage of interest in the description (column 2, lines 18 to 21) is confined to mention a preference for the claimed ratio without indicating any purpose or effect, however. It has to be concluded therefrom that said only distinctive feature with respect to document D6 is of minor technical relevance and results from a mere dimensional optimisation falling within the normal competence of a person skilled in the art, as also suggested by document D6 (column 8, lines 14 to 19) where it is stated that the length of the stent (graft) can be made longer or shorter as desired.

Document D11 equally suggests to use a plurality of stents interconnected by struts, each stent being formed from a wire bent into a zig-zag configuration and having a length which is less than its diameter (cf. page 665, passage bridging middle and right columns), although no particular requirement was made as to the rigidity or the flexibility of the stent.

4.3 In consequence of the above considerations, the subject-matter of claim 1 according to the main request does not involve an inventive step vis-à-vis document D6. Therefore, the requirements of Article 52(1) in connection with Article 56 EPC are not met.

5. Auxiliary request

Claim 1 according to the auxiliary request differs from the main request by the incorporation of the feature according to which the cylindrical shaped elements are "formed of structural members in an undulating pattern, the undulating pattern being flat in transverse cross-section". The flat, rectangular cross-section results from the stent being formed from an elongated tubular member of thin uniform thickness. This allows for efficient holding of the artery in an opened and expanded state without damage and without interference with the blood flow through the artery (cf. patent, column 15, lines 48 to 56).

A similar result is achieved by the stent disclosed in document D6 which is also formed from an elongated and thin tubular member having a uniform thickness and being flat and rectangular in cross-section

(cf. Figure 2; column 7, lines 28 to 31 and column 8, lines 34 to 48). According to D6, the cylindrically shaped elements are made of a plurality of slots arranged in a staggered relationship (Figure 1A), which are deformable upon expansion into a diamond or hexagonal configuration (Figure 1B). The resulting meshed closed structure is supposed to be more rigid radially than the opened structure according to the invention, made of a plurality of elements in an undulating pattern.

However, document D2 discloses a succession of cylindrical stent elements made of a number of wire segments welded together in a zig-zag configuration around the circumference and then connected by flexible hinges to provide additional flexibility and better accessibility to arteries having curved portions (Figure 5). Further, the interconnecting hinges are radially offset (Figure 4) and the stent is mounted on a delivery guide-catheter in a compressed state (Figure 8). Although D2 is not specifically concerned with a circumferential undulating pattern or serpentine in the exact embodiment as shown on Figures 4 and 5 of the contested patent, the Board considers that the opened zig-zag structure used in document D2 is practically equivalent in terms of radial expansion and rigidity and represents a particular form of an undulating pattern within the general meaning of an alternating configuration.

Therefore, the subject-matter of claim 1 according to the auxiliary request derives in an obvious manner from a combination of the teachings of documents D6 and D2. A direct suggestion in this respect is to be seen in

the fact that both documents are concerned with stents providing, though at different degrees, radial retention and longitudinal flexibility by combining elements which are functionally equivalent. If, as submitted by the appellant, the invention resides in the combination of all its features with the purpose to optimize rigidity and flexibility, the same is true for the cited documents. The requirements of Article 56 EPC are, therefore, not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß