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D E C I S I O N
of 8 July 2004

Case Number: T 1000/02 - 3.2.2

Application Number: 97202436.8

Publication Number: 0807424

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Expandable stents

Patentee:
ADVANCED CARDIOVASCULAR SYSTEMS, INC.

Opponent:
TRE ESSE PROGETTAZIONE BIOMEDICA S.r.l.

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56

Keyword:
"Inventive step - main request and first auxiliary request (no)"
"Inventive step - second auxiliary request (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1000/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 8 July 2004

Appellant: (Proprietor of the patent)
ADVANCED CARDIOVASCULAR SYSTEMS, INC.
3200 Lakeside Drive
P.O. Box 58167
Santa Clara
California 95052-8167 (US)

Representative:
McLeish, Nicholas Alistair Maxwell
Boult Wade Tennant
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT (GB)

Respondent: (Opponent)
TRE ESSE PROGETTAZIONE BIOMEDICA S.r.l.
Via Zaccherini Alvisi, 2/2
I-40138 Bologna (IT)

Representative:
Bosotti, Luciano
c/o Buzzi, Notaro & Antonielli d'Oulx
Via Maria Vittoria 18
I-10123 Torino (IT)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 18 July 2002 revoking European patent No. 0807424 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 17 September 2002 against the decision of the opposition division posted on 18 July 2002 on the revocation of the European patent EP-B-0807424. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 28 November 2002.

II. Opposition was filed against the patent as a whole and based on Article 100(a) EPC in conjunction with Articles 52(1), 54, 56 EPC, on Article 100(b) EPC and on Article 100(c).

The Opposition division held that the grounds for opposition mentioned in Articles 100(a) and (c) EPC prejudiced the maintenance of the patent having regard to the following documents:

D1 = EP - A - 0 364 787

D2 = EP - A - 0 335 341

D3 = US - A - 4 994 071

D4 = Shigeru Furui et al.: Hepatic inferior vena cava obstruction: Treatment of two types with Gianturco expandable metallic stents; Radiology 1990; 176, pp 665-670

D5 = EP - A - 0 421 729.

III. Oral proceedings took place on 8 July 2004.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, in alternative, of the first or second auxiliary request as filed with the letter of June 7, 2004.

The respondent (opponent) requested that the appeal be dismissed.

IV. Claim 1 of the main request reads as follows:

"A longitudinally flexible stent (10) comprising a plurality of cylindrically shaped elements (12) having an undulating pattern of peaks and valleys, the cylindrically shaped elements (12) being independently expandable in the radial direction from an unexpanded condition to an expanded condition and having, in the unexpanded condition, an axial length which is less than their diameter, the cylindrically shaped elements (12) being generally aligned on a common longitudinal axis such that, other than at the end of the stent (10), each cylindrically shaped element (12) has two adjacent cylindrically shaped elements (12) spaced in opposite axial directions, the undulating pattern of each of said cylindrically shaped elements (12) being out of phase with the undulating pattern of each of said adjacent cylindrically shaped elements (12) and each of said cylindrically shaped elements (12) being interconnected to one of said adjacent cylindrically shaped elements (12) at a location circumferentially displaced from the location at which said cylindrically

shaped element (12) is interconnected to the other of said adjacent cylindrically shaped elements (12)."

Claim 1 of the first auxiliary request reads as follows:

"A longitudinally flexible stent (10) formed from a single piece of tubing (21) and comprising a plurality of cylindrically shaped elements (12) having an undulating pattern of peaks and valleys, the cylindrically shaped elements (12) being independently expandable in the radial direction from an unexpanded condition to an expanded condition and having, in the unexpanded condition, an axial length which is less than their diameter, the cylindrically shaped elements (12) being generally aligned on a common longitudinal axis such that, other than at the end of the stent (10), each cylindrically shaped element (12) has two adjacent cylindrically shaped elements (12) spaced in opposite axial directions, the undulating pattern of each of said cylindrically shaped elements (12) being out of phase with the undulating pattern of each of said adjacent cylindrically shaped elements (12) and each of said cylindrically shaped elements (12) being interconnected to one of said adjacent cylindrically shaped elements (12) at a location circumferentially displaced from the location at which said cylindrically shaped element (12) is interconnected to the other of said adjacent cylindrically shaped elements (12)."

Claim 1 of the second auxiliary request reads as follows:

"A longitudinally flexible stent (10) formed from a single piece of tubing (21) and comprising a plurality of cylindrically shaped elements (12), the cylindrically shaped elements (12) being independently expandable in the radial direction from an unexpanded condition to an expanded condition and having, in the unexpanded condition, an axial length which is less than their diameter, the cylindrically shaped elements (12) being generally aligned on a common longitudinal axis such that, other than at the end of the stent (10), each cylindrically shaped element (12) has two adjacent cylindrically shaped elements (12) spaced in opposite axial directions, each of said cylindrically shaped elements (12) being interconnected to one of said adjacent cylindrically shaped elements (12) by three or four or more interconnecting elements (13) disposed at locations circumferentially displaced from the location at which said cylindrically shaped element (12) is interconnected to the other of said cylindrically shaped elements (12), said cylindrically shaped elements (12) having a serpentine circumferential undulating pattern of peaks and valleys which is out of phase with the undulating pattern of each of said adjacent cylindrically shaped elements (12) such that flexibility is provided along the length of the stent (10) and about its longitudinal axis."

Each of the independent claim 9 of the main request, independent claim 8 of the first auxiliary request and independent claim 7 of the second auxiliary request refers to a kit comprising an elongated stent delivery

catheter (11) having proximal and distal extremities, and an expandable member (14) on the distal extremity; and a longitudinally flexible stent as defined in claim 1 of the corresponding request.

V. In support of his request the appellant relied on the following submissions.

D1, which had to be considered as representing the closest prior art, did not disclose elements having an undulating pattern. Undulating meant a gentle raising and falling, which was not the case by the elements of D1. Furthermore it was only with the benefit of hindsight that one would arbitrarily split up the overall pattern of the elements of D1 in order to find an undulating pattern. The only document showing elements having an undulating pattern in the sense of the patent in suit was D4. Moreover, none of the documents D1, D2, D4 and D5 disclosed the range of the ratio length-diameter of the elements claimed by the invention. D2 did not disclose offset connections, and D3 did not disclose cylindrical elements, but merely successive loops of a single wire which could not provide any axial strength to the stent. Furthermore, the elements shown in D3 were not interconnected at circumferentially offset locations.

Starting from D1, the object to be achieved by the invention according to the patent in suit had to be seen in improving the longitudinal flexibility of the stent so that the stent could adapt to the irregularities of the vessel during insertion. The stent should at the same time maintain a sufficient strength in order to avoid collapse. This object was

achieved by providing a stent made of cylindrical elements shorter than their diameter and presenting an undulating pattern having peaks and valleys out of phase with the adjacent elements and connected to them through circumferentially displaced connections.

As shown by R. Heuser, The multi-link stent, another good idea; The journal of catheterization and cardiovascular diagnosis, 39:420 (1996); Y. Nakano, Initial and follow-up results of the ACS multi-link stent, a single center experience; The journal of catheterization and cardiovascular diagnosis, 45:368-374 (1998); R. A. Schatz, The Palmaz-Schatz coronary stent: new developments, in: P. Serruys, Handbook of coronary stents, 1998, pages 17 to 22, the author of D1 was aware of the need of improving flexibility of his stent. However since it was not possible to shorten the elements of this stent so that their axial length was less than their diameter, he improved the flexibility in a completely different way, namely by thinning the walls of the stent.

The first and second auxiliary request narrowed the scope of the invention. The additional feature of claim 1 of the first auxiliary request according to which the claimed stent was formed from a single piece of tubing excluded the consideration of documents D3, D4 and D5. The additional feature of the second auxiliary request according to which the elements had a "serpentine circumferential" undulating pattern, was clearly not disclosed in D1. The provision of such element which resulted in an even more improved flexibility was not suggested by any of the available documents.

Therefore the subject-matter of claim 1 of all the present requests was based on an inventive step.

VI. The respondent disputed the views of the appellant. His arguments can be summarized as follows: The previous decision of the board of appeal T 1196/00 already stated with respect to a claim practically identical to the present claim 1 of the main request, that the subject-matter of this claim did not involve an inventive activity in consideration of a combination of the teachings of D1 and D5.

The subject-matter of claim 1 of the main request did not involve an inventive step in particular when considering the teaching of D1 in combination with D3, which disclosed the feature that the axial length of the cylindrical elements in unexpanded condition was less than their diameter. Since there was no prejudice against the use of elements having a length-diameter ratio according to the patent in suit, it was obvious for the skilled person to shorten the elements according to D1 so that their axial length was less than their diameter.

Since the additional feature of claim 1 of the first auxiliary request (according to which the stent was formed by a single piece of tubing) was known from D1, the subject-matter of this claim was also not based on an inventive step.

With respect to the second auxiliary request D4 (see page 669, at the bottom of the middle column) suggested the use of two or more connections. Since the pattern

of the cylindrically shaped elements shown in D1 could be regarded as serpentine circumferential pattern, the subject-matter of the second auxiliary request was also obvious.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 Amendments

Claim 1 has been modified with respect to the granted version by including the features of the granted claim 3. The dependent claims have merely been renumbered. The features of claim 1 are disclosed in claims 1, 3, 4, 7 and in Figure 11 of the originally filed application.

Consequently, the amended claims meet the requirements of Article 123 EPC.

2.2 Inventive step

2.2.1 D1 is considered to represent the most relevant prior art and discloses (see in particular Figure 7) a longitudinally flexible stent comprising a plurality of cylindrically shaped elements (71), having an undulating (wavelike) patterns of peaks and valleys (pattern of the axial ends of the elements 71), the cylindrical shaped elements (71) being independently expandable in the radial direction from an unexpanded

condition to an expanded condition (compare Figures 1a and 1b) and being generally aligned on a common longitudinal axis such that, other than at the end of the stent, each cylindrically shaped element (71) has two adjacent cylindrical shaped elements (71) spaced in opposite axial directions (see Figure 7), the undulating pattern of each of said cylindrically shaped elements (71) being out of phase with the undulating pattern of each of said adjacent cylindrically shaped elements (71) and each of said cylindrically shaped elements (71) being interconnected to one of said adjacent cylindrically shaped elements (71) at a location circumferentially displaced from the location at which said cylindrically shaped element (71) is interconnected to the other of said adjacent cylindrically shaped elements (71) (see Figure 7).

2.2.2 Contrary to the assertion of the appellant, D1 discloses elements having an undulating pattern. Certainly, the best mode of carrying out the invention (as disclosed in the figures of the patent in suit) comprises elements whose overall form is an undulating pattern. However, the wording chosen for claim 1 is not restricted to such an embodiment. It also covers elements whose contour only is in the form of a wave. Furthermore, the expression "undulating pattern" does not necessarily mean "having a gentle profile", in particular since also the embodiments shown in the figures of the patent in suit have sharply rising and falling vertical parts (see Figures 4, 5 and 10).

2.2.3 Starting from D1, the object underlying the patent in suit may be regarded as to improve the longitudinal flexibility of the stent, see patent specification, column 1, section 0007.

This object is achieved by the distinguishing feature of claim 1, according to which the elements have, in the unexpanded condition, an axial length which is less than their diameter.

This increases the number of elements per unity of length and correspondingly the number of deformable junction between the elements, thereby attaining a higher deformability.

2.2.4 The person skilled in the field, facing the problem of increasing the flexibility of the stent, will certainly consider shortening the length of the elements, since it is evident that such measure will increase the number of junctions per unity of length of the stent and therefore will result in an improvement of the longitudinal flexibility.

The appellant's argument that the skilled person would not consider to shorten the elements shown in D1 so that, in the unexpanded condition, their axial length was less than their diameter, is not convincing. D1 itself does not exclude such a shortening of the length of the elements. On the contrary, according to D1, the length of each element (graft) can be made longer or shorter as desired (see column 8, lines 14 to 19). Moreover, since the opinion of the author of D1 that a stent of the type disclosed in D1 could not be shortened to the extent defined in claim 1 is not

sufficient to prove that there was a prejudice against the use of such elements in a stent according to D1, there was no reason which could prevent the skilled person from shortening the elements of the stent disclosed in D1 in order to improve their flexibility.

This measure is even more obvious since it is known in the field of stents, see D3. Since D3 suggests the use of a stent made of elements forming undulating patterns each having a length shorter than their diameter, and since the skilled person recognizes that the use of such elements improves the flexibility of a multilink stent, it was obvious for him to shorten the elements shown in D1 according to the teaching of D3.

Therefore, in the light of the teaching of D1 and D3, the subject-matter of claim 1 of the main request does not involve an inventive step.

3. *First auxiliary request*

3.1 Amendments

The first auxiliary request differs from the main request only in that the independent claims (1 and 8) contain the additional feature according to which the stent is formed from a single piece of tubing. This feature is disclosed in the originally filed claim 11. Hence, the amended claims of the first auxiliary request meet the requirements of Article 123 EPC.

3.2 Inventive step

The additional feature is implicitly disclosed in document D1 (see figures and column 13, lines 21 to 25 together with column 7, lines 23 to 27). It is clear that a stent whose elements and connector member are made integrally and from the same material (metal or plastic) has commonly and advantageously to be formed from a single piece of tubing.

Therefore, there is no difference in the assessment of inventive step between the main request and the first auxiliary request. Consequently the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step either in the light of the teaching of same documents D1 and D3.

4. *Second auxiliary request*

4.1 Amendments

With respect to the first auxiliary request, each of the independent claims (1 and 7) of the second auxiliary request contains the additional features according to which:

the cylindrically shaped elements are interconnected to each other by three or four or more interconnecting elements,
the undulating pattern of the cylindrically shaped elements is a serpentine circumferential undulating pattern, and
each pattern is out of phase with the corresponding pattern of the adjacent element such that flexibility

is provided along the length of the stent and about its longitudinal axis.

These additional features are all disclosed in the figures of the original application and restrict the scope of the claims. Moreover, the description has been adapted to the claims of the second auxiliary request.

Therefore, the amendments to the patent meet the requirements of Article 123 EPC.

4.2 Inventive step

4.2.1 With respect to claim 1 of the second auxiliary request, D1 is still considered to represent the most relevant state of the art.

Starting from D1 and under consideration of the features of claim 1 of the second auxiliary request the object to be achieved is to be seen in improving the flexibility and in maintaining a sufficient strength of the stent (see sections 0005 and 0007 of the patent specification).

This object is achieved by a stent comprising the features according to which

(a) the elements have in unexpanded condition an axial length less than their diameter;

(b) the cylindrically shaped elements are interconnected each other by three or four or more interconnecting elements;

(c) the undulating pattern of the cylindrically shaped elements is a serpentine circumferential undulating pattern, and

(d) each serpentine pattern is out of phase with the corresponding pattern of the adjacent element such that flexibility is provided along the length of the stent and about its longitudinal axis.

4.2.2 D1 itself does not disclose any of the features (a) to (d). In particular D1 does not disclose cylindrical elements having a serpentine circumferential undulating pattern. Serpentine is a term which narrows the scope of the term undulating and requires that the shape of the undulating pattern is snake-like, or, in other words, that the pattern is free of any edges. As the appellant convincingly explained, the provision of elements having such a pattern results in a further improvement of the flexibility of the stent, since they are more flexible than elements having a pattern as shown in D1, D2, D3 and D5, in particular when the interconnecting elements are arranged in the peaks and valleys of the serpentine undulating pattern.

4.2.3 The board is convinced that the replacement of the undulating pattern shown in D1 by a serpentine undulating pattern according to the feature c) is not obvious. It is true that the provision of elements having a serpentine undulating pattern is known from D4, and that the skilled person could use this pattern in the elements of D1. However, it is not likely that he would select such a serpentine undulating pattern for the elements of D1. When the skilled person decides to replace the elements of D1 by elements which, in their

unexpanded condition, have an axial length less than their diameter (feature a), he would maintain the undulating pattern shown in D1, which essentially corresponds to the undulating pattern of the elements shown in D3. However, there is no reason to replace this pattern by the serpentine undulating pattern disclosed in D4, in particular since D4 does not suggest to use such a pattern for improving the flexibility of a stent, and since the elements of D4 have a relatively high length-diameter ratio in the unexpanded condition.

Therefore, the board concludes that the provision of a serpentine undulating pattern according to the feature (c), in particular in combination with features (a), (b) and (d), in a stent according to D1 is not obvious.

Therefore, the subject-matter of claim 1 and claim 7 (which includes all features of claim 1) of the second auxiliary request involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the following documents:

– claims 1 to 7 of the second auxiliary request;
– columns 1 to 9 of the description;
– Figures 1 to 10

all filed at the oral proceedings.

The Registrar: The Chairman:

G. Magouliotis T. Kriner