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D E C I S I O N
of 2 April 1996

Case Number: T 0818/93 - 3.2.2

Application Number: 86115473.0

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Language of the proceedings: EN

Title of invention:
Expandable intraluminal graft, and apparatus for implanting an expandable intraluminal graft

Patentee:
Palmaz, Julio C.

Opponent:
Advanced Surgical Intervention, inc.
Boston Scientific Corporation

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 83, 84, 123(2) and (3)

Keyword:
"Information not available to the public - implicit confidentiality"
"Features drawn solely from the drawings (acceptable)"
"Reformulation of the problem (allowed)"
"Novelty and inventive step (yes, after amendments)"
"Combination invention - new application of known means"

Decisions cited:
T 0039/82, T 0169/83, T 0013/84, T 0523/88, T 0386/89
T 0606/89, T 0830/90, T 0887/90, T 0697/92

Catchword:
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Case Number: T 0818/93 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 2 April 1996

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 12 July 1993 revoking European patent No. 0 221 570 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: M. G. Noël
C. Holtz

Summary of Facts and Submissions

I. By decision of 12 July 1993 the Opposition Division revoked European patent No. 0 221 570 on the grounds that the subject-matter of claim 1 lacked novelty vis-à-vis the state of the art represented by document

(1) US-A-3 657 744.

II. The Appellant (Proprietor of the patent) filed an appeal against the first instance decision on 17 September 1993 and paid the appeal fee on the dame day. A Statement of Grounds was filed on 22 November 1993 along with amended claims. Still further amendments were made to the claims by a letter received on 23 January 1995.

III. The Respondent (the sole Opponent, after the merger of Opponent 1 into Opponent 2) replied to the Appellant's arguments by letters dated 11 July 1994 and 18 January 1996 respectively, and filed each time new arguments and evidence in response of the successive amended claims from the Appellant.

IV. Following a communication dated 27 February 1996 accompanying the summons to oral proceedings, in which the Board considered document (1) as closest prior art, the Respondent replied by letter dated 12 March 1996 and filed further evidence (two Affidavits) in preparation of the oral proceedings.

V. Oral proceedings were held on 2 April 1996, at the beginning of which the Appellant, again, submitted new sets of claims according to a main request and two auxiliary requests said to be filed in response of the previous communication of the Board. After deliberation

by the Board, the Chairman announced the decision that the main request was rejected as inadmissible. The Appellant's requests were then recast, so as to end, finally, in a main request (previous first auxiliary request) and one auxiliary request (previous second auxiliary request).

Independent claims 1 and 3 according to the main request read as follows:

"1. An expandable intraluminal vascular graft or prosthesis (70) for a body passageway, comprising: a tubular shaped member (71) having first (72) and second (73) ends and a wall surface (74) disposed between the first and second ends, the wall surface (74) being formed by a plurality of first and second intersecting elongate members (78, 79), at least some of the first elongate members (78) intersecting with some of the second elongate members (79) intermediate the first and second ends of the tubular shaped member (71), the tubular shaped member (71) having a first diameter (d) which permits intraluminal delivery of the tubular shaped member into a body passageway having a lumen, and the tubular shaped member (71) having a second expanded diameter (d') which is determined by the application from the interior of the tubular shaped member (71) of a radially, outwardly extending force, which second diameter (d') is variable and controlled by the amount of force applied to the tubular shaped member (71), at least some of the elongate members (78, 79) being deformed by the radially, outwardly extending force, to retain the tubular shaped member (71) with the second expanded diameter (d'), whereby the tubular shaped member (71) may be expanded to expand the lumen of the body passageway and remain therein,

characterized
in that the first and second intersecting elongate members (78, 79) are a plurality of thin bars, each having a uniform thin rectangular cross-sectional configuration, wherein each pair of adjacent first bars (78) is interconnected by at least two of said second bars (79), each second bar (79) being formed integral with the respective pair of first bars (78) and extending only between said pair of first bars (78) and each second bar (79) extending on the circumference of a circle whose plane is perpendicular to the longitudinal axis of said tubular shaped member (71)."

"3. An apparatus for intraluminally reinforcing or expanding the lumen of a body passageway, comprising an expandable, tubular shaped prosthesis or intraluminal vascular graft (70) according to one of the preceding claims and a catheter for mounting the prosthesis or graft (70),
characterized
in that the catheter has an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, tubular shaped prosthesis or intraluminal vascular graft (70) on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis (70) is forced radially outwardly into contact with the body passageway to remain therein, and the expansion of the prosthesis (70) is controlled by the expansion of the inflatable portion of the catheter."

VI. The following documents were considered as particularly relevant by the Board.

(1) US-A-3 657 744

(2) "Expandable Intraluminal Graft: A Preliminary Study" By Julio C. Palmaz et al. Radiology, vol. 156 No. 1, July 1985, pages 73 to 77

(3) "Expandable Intrahepatic Portocaval Shunt Stents: Early Experience in the Dog" by Julio C. Palmaz et al., AJR: 145, October 1985, pages 821 to 825

(4) EP-A-0 183 372

(10) "Expandable Vascular Endoprosthesis" research project by Julio C. Palmaz, dated 18 May 1983, University of California, Davis, at the VA Medical Center, Martinez, CA 94553

(11) US-A-3 325 319

(17) Declaration of Julio C. Palmaz under 37 C.F.R. §1.131 before the US Patent and Trademark Office, dated 18 November 1992 and submitted in the re-examination proceedings of the parallel US Patent No. 4 733 665, plus Exhibits 1 and 4 mentioned therein.

(19) US-A-4 390 599

(21) Affidavit by Hans A. Mische, dated 3 June 1996, plus Exhibits 1 to 20 mentioned therein.

VII. At the oral proceedings and in their written submissions the parties argued essentially as follows:

(i) According to the Appellant:

- Amendments made to claim 1 are allowable since they are disclosed by Figures 2A and 2B of the original application.

- Documents (10) and (17) refer to subject-matter which was not available to the public before the priority date of the patent in suit, as they refer to research projects submitted to only authorised persons bound to secrecy (cf. Guidelines D.V.3.1.3.2). Further, the Respondent failed to provide any evidence to the contrary.

- Document (2) is considered to disclose the closest prior art since it relates to an intraluminal deliverable expandable graft and seeks to solve the same general technical problem as does the present invention, that is to provide a prosthesis which can be inserted and retained in place by controlled expansion so as to be fitted properly into a body passageway. However, the graft described in document (2) is made of a tubular wire mesh having soldered crossing points. Therefore, the integral configuration as claimed in accordance with Figure 2 of the present patent is not disclosed by document (2).

- All other documents are concerned with technical fields and applications different from those referred to in the contested patent and do not disclose an expandable intraluminal graft either, the wall surface of which is formed by a

plurality of integrally made thin bars intersecting each other so as to form, before expansion, rectangular shaped openings as shown in Figure 2A of the present patent.

- In particular, the device described in document (1) is expressly designed for providing quick and easy fixation or anchoring of an artificial bifurcated aortic graft. The fixation sleeve is formed of a plurality of intersecting ribbon-like members having an angular orientation with respect to the general axis of the sleeve and extending outwardly with respect to the perimeter of the sleeve to provide a plurality of sharp, preferably not flattened projecting edges, induced by construction. Moreover, after forming the sleeve, welding is needed to close the tubular structure. Therefore, because of the multitude of twisting ribbons with outwardly projecting edges the fixation device disclosed in document (1) has a different configuration than that proposed in the contested patent and neither is intended nor capable of being harmless intraluminally delivered through a body passageway to a desired position. Furthermore, there is no suggestion in this document that the ribbon-like structure should be modified in the way claimed to provide a smooth expandable graft not cutting into the surrounding tissue, upon expansion.

- Document (19) describes a sheet of memory metal having enhanced recovery properties due to a plurality of perforations of related shape and pattern. Despite similar configuration, the structure would not be appropriate for making an expandable graft according to the invention

since, in the absence of a radially, outwardly extending force from the interior of a tubular shaped member formed with such a memory metal sheet, the expansion thereof could not be satisfactorily controlled.

(ii) According to the respondent:

- The amendments introduced in the characterising portion of claim 1 result in extending its subject-matter beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC, since the added features are not explicitly disclosed in the original application and also not clearly derivable from the drawings. It is not believed that from merely schematic drawings such as Figures 2A and 2B any information can be taken that would support the original disclosure of said claim.

- The declaration by the inventor Julio C. Palmaz in document (17) relates to the circumstances in which the expandable graft described in detail in Exhibits 1 and 4 of said document was made available to the public. The information contained in these reports was submitted to several companies to interest them in developing and funding research for the graft now in suit. Since the appellant was not capable of providing any agreement of confidentiality binding the parties involved, the alleged invention was made available to the public in its entirely before the priority date of the contested patent. Therefore, the subject-matter of claim 1 lacks novelty.

- The subject-matter of claim 1 also lacks novelty vis-à-vis the disclosures made in either one of documents (1) or (19), it being admitted that in the embodiment of document (1) the ribbon-like members forming diamond shaped openings also extend, while in an oblique direction, on the circumference of the tubular structure, and that in document (19) expandable tubular structures are generally disclosed; in particular the metal sheet illustrated in Figures 1 and 2 of said document may be formed into a cylindrical configuration, having a pattern of perforation similar to that being now claimed in both the non-expanded and expanded states.

- Be that as it may, the subject-matter of claim 1 also lacks inventive step faced with the teachings of documents (1) or (19) considered either alone or in combination, having regard to the general knowledge of a person skilled in the art or to any specific information taken from either documents (2), (3), (4) or (11). The reasons are as follows:

  Document (1) represents the closest prior art since it discloses an expandable graft having most of the features contained in claim 1 in suit, including an integrally formed tubular structure. The expansion of the graft can be controlled by a force applied from the interior of the tube. Preferably, the graft is provided with outwardly projecting edges that will twist upon expansion, as is also the case in the patent embodiment, when considering the information given in document (10). However, the disclosure made in document (1) is not confined

to a graft having outwardly projecting edges but also embraces a graft made from a sheet that has been flattened prior to forming the tube, thus providing a smooth outer surface.

In the absence of any significant distinction between the embodiments disclosed in the patent and in document (1), a technical problem cannot be defined, which demonstrates that an invention does not really exist. The alleged advantages provided by the embodiment according to Figure 2 of the patent (smooth outer surface facilitating delivery of the graft to a desired location, less resistance to sliding and safer expansion) over the embodiment according to Figure 1 of the same or to that disclosed in document (1) cannot be contemplated either to reformulate a new technical problem since said advantages are not to be derived from the original application considered in relation to the nearest prior art (cf. decisions T 13/84 and T 386/89). Contrary to that, it is stated in the patent in suit that both grafts according to either Figure 1 or Figure 2 have the same properties and can be used interchangeably.

Documents (11) and (19) each generally describes a tubular structure similar to that used in the contested patent, i.e. having intersecting bars and etched-out openings therebetween, some of the bars extending on a circle whose plane is perpendicular to the longitudinal axis of the tubular member. Therefore, the replacement of the structure described in document (1) by the suitable structure proposed in documents (11) and (19) is obvious to the person skilled in the art. The use, in document (19), of a recovery

memory metal cannot act as a deterrent, since a possible use of heat sensitive material is also referred to in the contested patent itself and already used in document (4) for a similar application.

Still wire-mesh tubes similar to the configuration described in accordance with Figure 1 of the contested patent are known from documents (2) and (3). Bearing in mind that both embodiments according to Figures 1 and 2 of the patent are considered to be equivalent, therefore, the transition from the one embodiment to the other cannot be regarded as an inventive contribution to the art.

VII. The appellant requested that the decision under appeal be set aside and the patent maintained on the basis of the main request or, alternatively, of the auxiliary request.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of original main request (use claims)*

The original main request was only filed in the oral proceedings and is therefore late. As the change of category into use claims does not overcome the objections raised in the Board's communication and as the amendments are not easily understandable (in particular, the word "obtainable" in the characterising

portion of claim 1 seems to obscure the extent of protection - Article 84 EPC), these claims are not prima facie allowable. The original main request must therefore be rejected as inadmissible.

3. *Amendments (final main request)*

The amendments made to independent claims 1 and 3 are not open to objection by the Board. They are supported by the original application as a whole, including the drawings. In particular, the subject-matter of claim 1 is based on the embodiment according to Figure 2. The features introduced in the characterising portion of claim 1, according to which "each pair of adjacent first bars (78) is interconnected by at least two of said second bars (79), each second bar being formed integral with the respective pair of first bars (78) and extending only between said pair of first bars (78) and each second bar (79) extending on the circumference of a circle whose plane is perpendicular to the longitudinal axis of said tubular shaped member (71)" are directly and unambiguously derivable from the graft illustrated by Figure 2A, so that the subject-matter of claim 1 does not extend beyond the content of the application as filed, in conformity with Article 123(2) EPC.

In the same line, the subject-matter of independent claim 3 which refers to an apparatus for delivering and mounting the graft according to claim 1 by means of a catheter, is based on original claim 7.

With respect to the version as granted the amendments made to the independent claims by way of additional, more specific features result in restricting the protection conferred, in conformity with Article 123(3) EPC.

The respondent's assertion that the incorporation in claim 1 of specific features taken up from the drawings would extend the subject-matter of that claim beyond the content of the application as filed is not accepted by the Board. The Convention does not exclude features from the drawings being included in the claims provided that these features be unmistakably and fully derivable from the drawings in terms of structure and function by a person skilled in the art and in no way contradict the other parts of the disclosure. The drawings must be considered as ranking equally with the other elements of the application to satisfy the requirements of Articles 83 and 84 EPC. Further, the fact that features are disclosed solely in the drawings does not preclude these features from becoming essential in the course of the proceedings (cf. decisions T 169/83, OJ EPO 1985, 193, points 3.5 and 4.1 and T 523/88, 26 February 1991, unpublished, point 2.2).

In the present case the features added to claim 1 are directly to be read from Figure 2A of the contested patent so that all conditions recited above are fulfilled. The requirements of Articles 83, 84 and 123(2) EPC are thus satisfied.

4. *Prior art and novelty*

4.1 Document (10) is dated 18 May 1983, i.e. prior to the priority date of the contested patent. It relies on a research project by the inventor Julio C. Palmaz within his activities at the University of California. Document (10) outlines the invention in its principle and describes more specifically two configurations of an expandable graft illustrated schematically on page 5, which correspond to the embodiments according to Figures 1 and 2 in the contested patent, respectively.

The primary question to be considered is whether the information contained in document (10) was made available to the public and, hence, novelty destroying.

Document (17) is a declaration by the inventor submitted before the US PTO in the re-examination proceedings of the parallel US Patent No. 4 733 665. Document (17) is based, in particular, upon two Exhibits numbered 1 and 4. Exhibit 4 actually corresponds to document (10) mentioned above, whereas Exhibit 1, while not dated, was written as a preliminary draft at the very beginning of work on the invention (ca. 1980). This is why the invention is described therein in less details than it is in Exhibit 4. It is stated in document (17) that both Exhibits 1 and 4 were unpublished. However, several companies were contacted in an attempt (unsuccessfully) to interest them in developing and funding research for the intraluminal graft outlined in Exhibit 1. Exhibit 4 was sent to Dr S. Reuter (the superior to Mr Palmaz and Professor at the University of Texas Health Science Center at San Antonio (UTHSCSA) followed by discussions with Dr Reuter and Mr J. Peters (Research assistant at UTHSCSA) in order to obtain the necessary equipment for conducting the research and fabrication and for testing the graft.

In the Board's judgement, all these steps and approaches were taken within the context of business relationships which were necessary to bring the project to a successful conclusion. Such negotiations are confidential by nature in view of the comparable interests of the parties involved and imply a secrecy agreement. Contrary to the respondent's assertion a written agreement is not necessary to rule out any involvement of a third party so that, in the present case, implicit confidentiality has not been breached by the meetings and negotiations prior to the filing date

of the contested patent. (cf. Guidelines for Examination D.V.3.1.3.2, decisions T 830/90, OJ EPO, 1994, 713, point 3.22 and T 887/90, 6 October 1993, unpublished, point 3).

Furthermore, where lack of novelty is alleged, the burden of proof invariably lies with the party claiming that the information in question was made available to the public before the relevant date. More generally, each party carries the burden of proof for the facts it alleges. If one party furnishes convincing proof of the facts it has alleged, the burden of proof of the contrary assertion is shifted to the other party, (cf. T 270/90, OJ EPO 1993, 725). In the present case where an obligation to maintain secrecy was derived from the circumstances, as demonstrated above, the onus for proving the contrary lay entirely with the Respondent. Since however, the Respondent failed to file any evidence or convincing argument that the information contained in document (10) (i.e. Exhibit 4) was made available to persons other than the experts mentioned in document (17), all bound to secrecy, the Board's conclusion is that document (10) is not comprised in the state of the art within the meaning of Article 54(2) EPC and thus cannot be opposed to the patented invention.

4.2 In agreement with the respondent's view, document (1) is regarded by the Board as the prior art closest to the invention, by reason of a similar use which requires the minimum of structural and functional modifications (cf. T 606/89, 18 September 1990, unpublished, point 2).

Document (1) describes an expandable, tubular shaped prosthesis to be inserted and delivered to a desired location within the lumen of a body passageway. Although the described embodiment applies more specifically to the implantation of an artificial bifurcated aortic

graft 10 between a severed aorta 11 and arteries 13, 14 for which the use of three expandable sleeves 16 is required (cf. Figure 1), each sleeve can be used separably for many other applications such as vessel graft or other prosthetic member (cf. column 1, lines 54 to 56), similar to those recited in the contested patent (cf. patent specification, column 6, lines 16 to 52). In document (1) the term "fixation device", therefore, does not only refer to making a junction between ducts of a human body but also more generally to firmly implanting a prosthetic member into intimate engagement, upon expansion, with the surrounding tissue and retaining its expanded dimension after expansion (cf. column 1, lines 12 to 18 and column 2, lines 56 to 58).

In the preferred embodiment the sleeve is radially expanded by operation of an expander tool 18 introduced into the sleeve. However, a variety of expanding devices may also be used to set the fixation sleeve in place (cf. column 3, lines 56 to 57) so that a balloon catheter is not excluded for other applications. According to the radial force exerted by the expander tool from the interior of the sleeve, the expansion is made variable and can be controlled to a predictable amount (cf. column 3, lines 72 to 73 and column 4, lines 5 to 7).

Thus, having regard to the general wording of claim 1 in suit (no specification of a particular use or particular expansion means), all features mentioned in the precharacterising portion of claim 1 are known from document (1).

The Appellant's assertion that the fixation device described in document (1) cannot be regarded as an expandable intraluminal vascular graft to be inserted in a lumen of a human body is not accepted. In the Board's

judgement, because of its expansion capabilities, the prosthetic sleeve disclosed in document (1) is also suitable for enlarging a lumen or reinforcing the internal wall of a body passageway such as an artery, a vein or a blood vessel as examplified in the contested patent. The fact that balloon dilation may be critical for certain body passageways such as the left main coronary artery (cf. patent specification, column 2, lines 41 to 51), does not mean that the expandable sleeve disclosed in document (1), which is concerned with such a critical application, cannot be set in place and subsequently expanded by a balloon catheter technique in other applications.

The tubular-shaped prosthetic implant illustrated in Figure 2 of document (1), is made from a metal sheeting by forming at first a series of staggered parallel slits in a metal sheet. Therefore, document (1) discloses in a first stage a plurality of integrally formed intersecting elongate members having a uniform, thin rectangular cross-sectional configuration, to take up the same terminology as used in claim 1 in suit. Then, the metal sheet is stretched in a direction perpendicular to the slits to cause the slits to open in diamond-shaped apertures uniformly sized and distributed. The stretching operation imparts a twist to the ribbon-like portions 22 (elongate members) separating the diamond-shaped apertures 23 (cf. column 2, lines 56 to 75). The expanded metal sheeting is desirably **not** flattened prior to forming into a sleeve, with the result that the ribbon-like portions extend angularly relative to the perimeter of the sleeve to provide, as shown in Figure 5, a plurality of projecting edges with the view to facilitating anchoring of the sleeve into the tissue wall upon subsequent expansion. The expanded metal sheet is then formed into a sleeve which is spot welded to form a

longitudinal seam (cf. column 3, lines 1 to 9). From this resting state, the sleeve may be still further expanded by about 50% beyond its original diameter (cf. column 3, lines 14 to 16).

It is of particular importance to notice at this stage that the prosthetic sleeve illustrated by Figure 2 of document (1), which represents a ready-for-use prosthesis, i.e. in an unexpanded state, has been in fact already subjected to pre-expansion during its fabrication since the diamond shaped apertures are already formed. Therefore, the configuration of the sleeve before use according to Figure 2 of document (1) is actually comparable with the configuration of the graft after use (and after expansion) according to Figure 2B in the contested patent.

4.3 With respect to the embodiment disclosed in document (1), the subject-matter of claim 1 in suit differs by the following characterising features:

(a) each second bar (79) extends only between said pair of first bars (78), and

(b) each second bar (79) extends on the circumference of a circle whose plane is perpendicular to the longitudinal axis of said tubular shaped member (71).

In feature (a) "said pair of first bars" refers to the "adjacent first bars" mentioned in the preceding feature of the characterising portion of claim 1, so that through the expression "only between said pair of first bars" it is meant that the connection between two adjacent first bars by means of a second bar is interrupted when passing to the next pair of adjacent first bars. In other words, the successive

interconnections by the second bars extending on a circumference of the tube are offset when passing from a pair of first bars to the next one as shown in Figure 2A of the patent. In contrast, in the embodiment according to Figure 2 of document (1) and also Figure 1 of the patent, the tubular-shaped member is made of continuous (not offset), obliquely oriented elongate members woven in a cris-crossed tubular pattern to form a wire mesh tube.

From the simultaneous consideration of features (a) and (b) it can be further derived that all successive second bars extending on the same circumference of a given cross section of the tubular member form spaced apart segments in the manner of a curved broken line. Since, in addition, each group of first and second bars is formed by a plurality of similar elongate members and each pair of adjacent first bars is interconnected by at least two second bars, it results that all first bars are parallel, extend along the generating lines of the tube and define together with the second bars a series of axially shifted rectangular openings as shown in Figure 2A of the patent. In contrast, the wire mesh illustrated in Figure 2 of document (1), and also in Figure 1 of the patent, is made of diamond-shaped openings.

Therefore, the subject-matter of claim 1 is regarded as novel over the disclosure of document (1), since novelty within the meaning of Article 54(1) EPC has to be understood strictly. As a consequence, the lack of novelty alleged by the respondent is not accepted, the more because the latter contradicts itself in its letter dated 18 January 1996, page 20, second paragraph, where it is stated that in document (1) "the second bars which

extend on the circumference of the tubular member are not explicitly shown to extend along a circle whose plane is perpendicular to the longitudinal axis of the tubular member".

4.4 The Board also considered the other available documents and found that the disclosures thereof are more remote from the subject-matter of claim 1 in suit than the disclosure of document (1) discussed above.

4.4.1 Document (2) is a report i.a. by the inventor J. C. Palmaz, which was published (July 1985) shortly before the priority date of the contested patent and which corresponds to Exhibit 12 cited in document (17) under item 23. Document (2) relies on the same invention as that proposed in the patent under consideration. Besides, it can be noticed that Figures 1(a) to 1(d) in this document correspond, respectively, to Figures 1(a), 1(b), 3 and 4 of the priority document US-A-4 733 665 (application number 796 009), the first two Figures being identical to Figures 1A and 1B of the patent in suit.

Document (2) describes an expandable intraluminal vascular graft having all features contained in the precharacterising portion of claim 1. However, the description in document (2) is confined to the first embodiment with respect to Figure 1A and 1B of the present patent, that is to a prosthetic graft made of a wire mesh of elongate members soldered at intersecting points. Therefore, the subject-matter of claim 1 in suit differs from the disclosure made in document (2) by all its characterising features.

4.4.2 Document (3), by the same author as document (2), was published (October 1985) shortly after the latter. It also describes an expandable tubular stent made of woven mesh wire with soldered cross points, as seen on Figure D of this document. However, document (3) discloses nothing more than document (2).

4.4.3 Document (19) describes memory metals generally used as drivers in mechanical pipe couplings, internally as well as externally with respect to pipes. Since the inherent recovery capability of a memory metal is limited (in the range of 4 to 9%), it provided a sheet of memory metal having a specific perforation pattern for enhancing recoverability beyond the inherent recovery of the memory metal comprising said sheet. Thus, the pattern illustrated by Figure 1 of document (19) allows for a memory metal structure to expand some 50 to 300% in direction of arrow 14 so as to obtain the pattern illustrated in Figure 2. To this end, the sheet of memory metal is provided with a plurality of perforations of particular shape and pattern and then formed into a cylindrical configuration, which also necessarily implies subsequent junction of the sheet edges.

Figure 1 of document (19) illustrates a perforated metal sheet in a first geometric, non-expanded state, having rectangular, offset perforations according to a pattern similar to that shown in Figure 2A of the contested patent. Upon application of heat the metal expansion causes the pattern to change from the first to the second geometric state illustrated in Figure 2, in which the perforations are deformed from rectangular into diamond-shaped configuration. Depending on the alloy used, which manifests the required recovery properties a reverse effect can be obtained, i.e. to pass from the pattern of Figure 2 to that of Figure 1, upon heating.

Although document (19) shows a pattern having a clear similarity to the pattern according to Figures 2A and 2B of the contested patent and discloses all characterising features of claim 1 in suit considered in isolation, if it is assumed that in document (19) the arrow 14 illustrating the expansion direction extends in the cross-section of the cylindrical shape obtained after forming the metal sheet, this document, however, is distinguished from the precharacterising portion of claim 1 in suit in that expansion is not caused by application from the interior of the tubular shaped member of a radially, outwardly extending force, but instead by application of heat. Since recovery capability is predetermined by the composition of the alloy being used, there is no possibility of controlling the amount of expansion for a given alloy. Moreover, document (19) makes no mention as to the use of the device described therein as expandable graft to be inserted into a body passageway.

Therefore, the Board does not accept either the respondent's objection of lack of novelty of the subject-matter of claim 1 in suit vis-à-vis the disclosure made in document (19).

4.4.4 Document (4) describes a prosthetic stent which may be collapsed for insertion into a blood vessel via a catheter and then expanded to provide internal support. The stent is made of a series of helically interwoven fiber filaments which are braided into a generally flexible tubular body having means for biasing it to an expanded configuration. The biasing means are of two types.

In the embodiment according to Figure 3 the braided filaments are annealed while in a radially expanded configuration. After insertion of the stent in a radially contracted configuration to fit within the catheter, the latter is retracted so that the stent will return automatically to its original expanded configuration thus providing internal support for the blood vessel. In the embodiment according to Figure 4, a plurality of warp filaments are longitudinally woven into the braided filaments to provide a frictional interface therebetween so as to maintain the prosthetic stent in whatever configuration and also resist radial contraction of the stent after insertion and expansion. Alternatively, the warp filaments may be elastically shrinkable or heat recoverable to axially shorten the tubular body to the radially expanded configuration.

Therefore, the stent described in document (4) differs from the subject-matter of claim 1 in suit in that it is not made of bars formed integrally and arranged in a pattern such as that claimed and in that the expansion is not controlled by application of a radially, outwardly extending force from the interior of the tubular body. Instead, biasing characteristics are imparted to the braided filaments.

4.4.5 Document (11) relates to a method for etching arcuately shaped metal sheets, in particular for producing cylindrical shaped articles in which rectangular apertures are etched through by conventional mechanical stripping or chemical etching process. Although the integral structure disclosed in this document presents some resemblance with the pattern of the graft illustrated in Figure 2A and 2B of the contested patent, however, the cylindrical perforated shape disclosed by document (11) would not be capable of being radially expanded. Clearly, the rectangular apertures could not

be deformed into a diamond-shaped configuration since the transverse bars (second bars in the contested patent) are not connected half-way of the longitudinal bars (first bars in the patent), i.e. the adjacent transverse bars are not off-set with respect to one another. Consequently, the structure described could not be used for the fabrication of an expandable graft.

4.5 Since none of the cited prior art documents discloses all the features contained in claim 1 in suit, its subject-matter must be regarded as novel within the meaning of Article 54(1) EPC.

5. *Inventive step*

5.1 A drawback of the expandable prosthetic sleeve proposed in document (1) resides in the presence of projecting edges on the periphery of the sleeve, which makes more difficult and hazardous its delivery at a desired location within a body passageway if a protective sheath, which is to be pulled away from the sleeve before expansion, is not provided.

Also, the fact that the prosthetic sleeve according to document (1) was already subject to pre-expansion before use results in the possibilities of subsequent additional expansion being reduced in the same proportion. Furthermore, the force required to pursue expansion of the sleeve beyond its original diameter will be necessarily greater than the force required for a sleeve that has not been previously deformed at the time it is used.

5.2 With respect to the closest embodiment disclosed in document (1), the objective problem underlying the present patent is, therefore, to provide an expandable graft having a wide expansion capability, which can be

easily inserted and delivered in place and, in the same time, which can be expanded to a variable and controlled size to prevent migration of the graft away from the desired location.

In this respect, the Board observes that it matters little whether the specific problem related to expansion control was already solved in document (1) since, for the assessment of the inventive nature of the solution, the technical problem either considered partly or in its entirety need not be new.

Furthermore, a reformulation of the problem which then may become necessary is not precluded by the Convention if the problem could be deduced by the person skilled in the art from the application as filed when considered in the light of the prior art which is nearest to the invention (cf. decision T 13/84, OJ EPO 1986, 253). Therefore, it is sufficient if the reformulated problem can be subsequently derived from the comparison of the application with the closest prior art.

Even more if the problem is to be reformulated on the basis of features taken only from the drawings, it cannot be required that the advantages and technical effects produced by such features should be mentioned in the application as originally filed. As features taken from the drawings can be validly included in the claims and in the description as well in order to give the latter support (cf. decision T 169/83, quoted before, point 3.5), the effects and advantages generated by these features can also serve as basis to substantiate reformulation of the problem, provided that it be clearly derivable from the comparison.

In the case of decision T 386/89 (24 March 1992, unpublished) cited by the Respondent, reformulation of the technical problem was not allowed because the alleged unexpected effect could not be deduced from the application as filed and was regarded by the Board merely as a "bonus effect" without inventive significance. Instead, in the present case where the effects and advantages set forth by the Appellant clearly represent the counterpart of the drawbacks suffered by the expandable sleeve described in document (1) as explained above (cf. point 5.1), these effects and others developed thereafter (cf. point 5.3) result from the direct comparison of the present application with the nearest prior art, in line with the principle laid down in decision T 386/89.

5.3 The problem as defined above is solved by the characterising features of claim 1 mentioned before (cf. point 4.3). It is of the first importance to notice at this stage that the expandable graft as defined in claim 1 in suit corresponds actually to the configuration illustrated in Figure 2A of the patent in suit, i.e. before expansion and, hence, before use. In such an unexpanded state the graft provides an integral bar structure having a smooth outer surface, i.e. provides minimal resistance to sliding. This advantage is not to be found in the application as filed but it is stated in document (10) (cf. page 6, second paragraph) that the smooth structure allows an easier introduction and positioning of the graft within the body passageway before the inflation. As already explained, document (10) is not part of the state of the art, however, it can be used as evidence to supplement and interpret the description of the present invention.

During expansion of the prosthesis, the rectangular openings are deformed into a diamond-shaped configuration. As also confirmed in the above-mentioned paragraph of document (10), the connecting bars will be subject to a twisting of the same nature as the one imparted to the ribbon-like portions of the sleeve described in document (1). However, the twist will be considerably less in the case of the invention because the graft has not been pre-expanded and, hence, not deformed before use. Even if, in document (1), the metal sheet were flattened prior to forming the sleeve, a residual inherent undulation will continue to exist. Instead, in the present invention, the twist, if any, will not be so detrimental because it will appear only at the time the expansion by the balloon catheter takes place, that means after the positioning of the prosthesis into the lumen at desired location.

5.4 Starting from the sleeve described in document (1) the skilled person would not be prompted to the claimed structure since, as already explained, the known sleeve was already expanded before use and the apertures were already deformed into a diamond-shaped configuration due to the previous stretching operation of the slitted metal sheet prior to forming the sleeve.

The Affidavit by Mr A. Mische (document (21)), which comprises twenty one Exhibits, is aimed at comparing, by way of illustrating photographs, the claimed graft with the sleeve according to document (1) at different stages of fabrication and expansion. In particular, Exhibit 2 refers to the known device and shows different steps of fabrication from a sheet of metal after stretching (photograph 2a) to a sleeve definitively formed and in a state ready for use (photograph 2d) comparable to that shown in Figure 2 of document (1).

The shape of the apertures prior to the stretching operation cannot be drawn from these photographs. But a comparison between Exhibit 5 showing in an enlarged size the stent of document (1) before expansion, in particular the connections between two adjacent rhombus, and Exhibits 9 or 15 showing the graft according to the invention in the same state, lead to the conclusion that in the known stent the second bars (in the sense of the present patent) simply do not exist. They are reduced to connecting points similar to welding spots.

Instead, the second bars of the claimed graft are clearly in the form of elongate members interconnecting the apexes of adjacent rhombus as better shown on photographs (electron microscope) according to Exhibits 12 or 17. It results from the comparison that the two stents are fundamentally different in their structure and, hence, provide necessarily different expansion characteristics. Therefore, the skilled person could not arrive at the claimed structure by making use of the production technique described in document (1).

5.5 From the foregoing, it also results that the embodiments according to Figure 1 and Figure 2 of the contested patent cannot be regarded as equivalent. Although both embodiments function generally in the same way and are generally referred to in the patent as "wire mesh tubes", this common terminology obviously used for simplification, does not actually overcome the structural differences set out by the wording of claim 1, which, again, is confined to the second embodiment according to Figure 2A of the patent.

As a matter of fact, the elongate members according to Figure 2 of the patent are integrally formed from a thin tube of uniform thickness so as to realize a plurality of off-set rectangular openings, all delimited by pairs

of first and second bars, whereas in Figure 1 the openings are diamond-shaped from the very beginning and made from continuous wires arranged in a criss-crossed pattern and soldered or welded at intersecting points.

These constructional differences made the integral bar structure according to Figure 2 more resistant to breakage and smoother than that according to Figure 1, in particular due to the fact that in the invention the second bars contained on a given cross-section form a broken line on a circle extending perpendicularly to the direction of expansion by the radial forces and thus are not subjected to the deformation caused by said expansion. As a consequence, the second bars are practically invariable, i.e. not deformed during expansion as can be observed from the comparison between Figures 2A and 2B of the patent and also from the photographs according to Exhibits 14 and 17 of document (21).

Furthermore, the bending forces applied to the first bars are distributed at both ends of each second bar approximately in the middle of the respective first bars, whereas in the embodiment of Figure 1 each intersecting point supports the deformations of two adjacent rhombus connected by opposite angles. Consequently the stress will be better supported in the embodiment of Figure 2 and the twisting effect will be less than in the case of Figure 1 in which the wire-mesh structure is stiffer and harder to expand. Moreover, resistance to collapse will be greater in the case of Figure 2 due to the presence of the incompressible second bars.

Since, as demonstrated, the structural differences generate different technical effects, the embodiments illustrated by Figures 1 and 2 of the contested patent are not equivalent (cf. also T 697/92, 15 June 1994, unpublished, point 5.3).

5.6 The skilled person would not have considered document (19) since this prior art refers to recovery memory metals that expand or retract upon heating, which the present patent seeks to avoid. As a matter of fact, it is stated in the introduction part of the description of the contested patent that heat sensitive materials are not satisfactory. They do not allow for efficient expansion control of the graft because the amount of expansion is predetermined by the heat expansion characteristics of the particular alloy used (cf. patent specification, column 1, lines 30 to 53). Indeed, it is known that heating of the material is generally provided by electrical resistance heating after the graft has been inserted at the desired location, with the risks that surrounding sensitive tissue may be damaged during heating and that blood may be subjected to undesirable coagulation. Such considerations were, in the Board's judgement, sufficiently dissuasive for the skilled person to set aside document (19) as inappropriate and to disregard the possibility of using the structure disclosed therein, the more because using said structure in conjunction with other metals than alloys exhibiting recovery characteristics is neither envisaged nor suggested in this document.

Even in the hypothetical event that the person skilled in the art were to replace the wire-mesh structure disclosed in any of documents (1) to (3) by a perforated metal sheet as described in document (19), he would not have arrived at an expandable graft according to the subject-matter of claim 1 because the particular pattern

described in document (19) functions as an amplifier, i.e. only provides for amplifying the available recovery motion inherent to the alloy used (cf. column 3, lines 56 to 57). Instead, in the patent embodiment no inherent displacement is induced by the metal itself. An additional expanding force is still necessary.

5.7 The previous considerations also exclude the relevance of document (4) according to which (cf. Figure 3) braided filaments are annealed in the radially expanded configuration to impart permanent biasing characteristics to the tubular member, with the result that any control of the expansion is quite impossible.

Also in the alternative embodiment illustrated in Figure 4 the biasing means are made of shrinkable or heat recoverable warp filaments longitudinally interwoven in the braided filaments. Besides the fact that the structure described therein has nothing in common with the graft as claimed, it suffers from the same deficiencies as those recited with respect to document (19). The use in document (4) of heat sensitive materials, presented in the contested patent as undesirable is sufficient, in the Board's judgement, to act as a deterrent and to set aside also document (4).

5.8 In the present case, in the Board's view, the invention resides in the application of a known structure to the making of an expandable prosthesis that can be expanded in a controlled way i.e. in the combination of all features recited in claim 1. It is generally admitted that in a combination invention all features may be known per se. Rather, the invention resides in the way they are inter-related structurally and functionally as well. Therefore, when assessing the inventive step of the present combination it is of no consequence that a suitable structure was already known for instance from

document (19), provided its use and application in the conditions and circumstances as disclosed in the patent were not suggested by this document or any other cited prior art.

Stated another way, in the case of a new application of known means the assessment of an inventive step has to take account of the problems to be solved in the known embodiment and in the case in suit (cf. decision T 39/82, OJ EPO 1982, 419,point 7.3). As was explained before, the main problems are different (controlling the expansion in the graft according to the patent; enhancing recovery capabilities in the device comprising a sheet of memory metal according to document (19)). Hence, the solutions also diverge (expansion controlled by a radially inner force in the patent; uncontrolled expansion by application of heat in document (19)). Therefore the teaching of document (19) would not suggest the same measure for a different purpose. It results that this new application is also not obvious.

5.9 For all the forgoing reasons, the subject-matter of claim 1 according to the main request is not obvious over the state of the art and thus is inventive within the meaning of Article 56 EPC.

5.10 Independent claim 3 according to the main request which relates to an apparatus for reinforcing or expanding the lumen of a body passageway, includes all features contained in claim 1 as far as the prosthesis is concerned. Its combination with a balloon catheter for mounting the same inside the lumen is therefore inventive for the same reasons as stated beforehand.

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 grant the patent with claims 1 to 4 according to the main request (submitted at the begining of the oral proceedings as the first auxiliary request - see item V of the present decision) and a description to be adapted thereto.

The Registrar: The Chairman:

S. Fabiani H. Seidenschwarz