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D E C I S I O N
of 3 April 2001

Case Number: T 0775/97 - 3.2.2

Application Number: 93300047.3

Publication Number: 0551179

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Method and apparatus for bilateral intra-aortic bypass

Applicant:
EXPANDABLE GRAFTS PARTNERSHIP

Headword:
-

Relevant legal provisions:
EPC Art. 52(4), 54(5), 112(1)

Keyword:
"Constructions which are only arrived at in the human body following a surgical method step, are not allowable under Article 52(4) EPC".
"Purpose-related use claims in the second medical indication format not applicable to surgical devices"

Decisions cited:
G 0005/83, T 0009/81, T 0227/91, T 0035/99, T 0019/86, T 0438/91, T 0820/92, T 0329/94, T 0385/86, T 0024/91, T 0182/90, T 0082/93

Catchword:
No European patent can be granted with claims directed to a new and even possibly inventive way of using materials or

devices, in particular endoprotheses, involving a treatment by surgery. This is equally true for product claims defined by a construction which is only arrived at in the human or animal body following a surgical method step.

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Case Number: T 0775/97 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 3 April 2001

Appellant: EXPANDABLE GRAFTS PARTNERSHIP
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 13 February 1997 refusing European patent application No. 93 300 047.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. European patent application No. 93 300 047.3 was refused on 13 February 1997 by the Examining Division on the grounds that the independent claims did not meet the requirements of clarity (Article 84 EPC) and of novelty (Article 54(1) EPC) vis-à-vis the state of the art represented, in particular, by document

D1: EP-A-0 461 791.

II. The grounds of refusal were that the configuration with two grafts was not a true combination but the positioning side-by-side within a body lumen of two known grafts (in particular from D1), that are not linked in any way to each other before use. Furthermore the use of the device did not impose any restriction on the device itself since any two of these known grafts were suitable for the same use. The second configuration, however, with two grafts lodged within a third graft of a larger diameter was not disclosed and could form the basis of an allowable claim.

III. The appellant (applicant) lodged an appeal on 11 April 1997 against this decision. A statement of grounds received on 13 June 1997 was accompanied by amended claims according to a main request and an auxiliary request.

IV. In a communication sent on 29 January 2001, the Board took the view that the new claims still lacked clarity and conciseness and also contained features which could be regarded as unallowable steps of a surgical method under Article 52(4) EPC. Further, following the opinion of the Examining Division, the first configuration with

two tubular members placed side-by-side appeared to represent a mere juxtaposition, without any synergistic effect, of two identical grafts each known *per se* from document D1, whereas the second configuration seemed to be allowable as being structurally distinguished from the prior art solutions.

V. Oral proceedings, held on 3 April 2001, started with the discussion of a set of claims which contained the following three independent claims 1, 29 and 31:

"1. A device for forming a bilateral passageway (150) in a body passageway (152) to repair the body passageway, the device comprising:

a first tube (160A), having first and second ends and a wall surface disposed between the two ends, at least a portion of the first tube adapted to be disposed within the body passageway, and means, including a first tubular member (166A) having first and second ends and connected to the first end of the first tube (160A), for securing the first end of the first tube in the body passageway; and

a second tube (160B), having first and second ends and a wall surface disposed between the two ends, at least a portion of the second tube adapted to be disposed within the body passageway, and means, including a second tubular member (166B) having first and second ends and connected to the first end of the second tube (160B), for securing the first end of the second tube in the body passageway;

wherein:

each tubular member has a first diameter which permits intraluminal delivery of the tubular members and tubes into the body passageway to be disposed therein substantially even and on the same level as each other and each tubular member has a second, expanded and deformed diameter which is variable and dependent upon the amount of a radially outwardly extending force applied to the tubular member from the interior thereof, and the tubular members are capable, when so disposed in the body passageway in the said first diameter condition, of being simultaneously expanded and deformed, upon the application from the interior of the tubular members of a radially outwardly extending force, from the first diameter to the second, expanded and deformed, diameter, with portions of the first and second tubular members in the said second diameter condition being in a substantially flat adjacent relationship, whereby the adjacent portions are substantially flattened towards each other to substantially close off and substantially remove any gaps that may otherwise be present within the body passageway between the tubular members."

"29. Use of a mutually connected first tube (160A) and first tubular member (166A) and a mutually connected second tube (160B) and second tubular member (166B), as defined in any one of claims 1 to 26, for the manufacture of a device for use in a surgical method in which the tubular members and tubes are intraluminally delivered in the first diameter condition of the tubular members into a body passageway (152) to be repaired, to be disposed therein substantially even and on the same level as each other, and the tubular members are subsequently expanded and deformed, by the application from the interior of the tubular members of

a radially outwardly extending force, from the first diameter to the second, expanded and deformed, diameter with portions of the first and second tubular members being in a substantially flat adjacent relationship, whereby the adjacent portions are substantially flattened towards each other to substantially close off and substantially remove any gaps that may otherwise be present within the body passageway between the tubular members; to form a bilateral passageway in the body passageway to repair the body passageway."

"31. A bilateral surgical bypass graft, comprising:

a first tube (160A), having first and second ends and a wall surface disposed between the two ends, at least a portion of the first tube adapted to be disposed within a body passageway (152), and means, including a first tubular member (166A) having first and second ends and connected to the first end of the first tube (160A), for securing the first end of the first tube in the body passageway; and

a second tube (160B), having first and second ends and a wall surface disposed between the two ends, at least a portion of the second tube adapted to be disposed within the body passageway, and means, including a second tubular member (166B) having first and second ends and connected to the first end of the second tube (160B), for securing the first end of the second tube in the body passageway; wherein:

the tubular members are disposed substantially even and on the same level as each other, portions of the first and second tubular members being in a substantially flat adjacent relationship whereby the adjacent

portions are substantially flattened towards each other to substantially close off and substantially remove any gaps that may otherwise be present between the tubular members;

the graft being obtainable by simultaneously expanding and deforming the tubular members disposed substantially even and on the same level as each other from a first diameter suitable for permitting intraluminal delivery of the tubular members and tubes into the body passageway to be so disposed therein, to the said adjacent condition upon the application from the interior of the tubular members of a radially outwardly extending force."

VI. When, after intermediate deliberation, the Board considered these claims to be unallowable on grounds of Article 52(4) EPC, the appellant formulated the following two questions to be referred to the Enlarged Board of Appeal:

(1) Are purpose-related use claims in the "second indication" format, which is standard for inventions relating to therapeutic products and functional combination's thereof, applicable to surgical products and functional combinations thereof?

(2) Are product *per se* claims, limited to a construction which is only arrived at in the human or animal body following a surgical method step, allowable in view of Article 52(4) EPC?

VII. The appellant at the oral proceedings also filed an amended set of 24 claims the independent claim 1 of

which reads as follows:

"1. A device for forming a bilateral passageway (150) in a body passageway (152) to repair the body passageway, the device comprising:

a first tube (160A), having first and second ends and a wall surface disposed between the two ends, at least a portion of the first tube adapted to be disposed within the body passageway, and means, including a first tubular member (166A) having first and second ends and connected to the first end of the first tube (160A), for securing the first end of the first tube in the body passageway; and

a second tube (160B), having first and second ends and a wall surface disposed between the two ends, at least a portion of the second tube adapted to be disposed within the body passageway, and means, including a second tubular member (166B) having first and second ends and connected to the first end of the second tube (160B), for securing the first end of the second tube in the body passageway;

wherein:

each tubular member has a first diameter which permits intraluminal delivery of the tubular members and tubes into the body passageway to be disposed therein substantially even and on the same level as each other and each tubular member has a second, expanded and deformed diameter which is variable and dependent upon the amount of a radially outwardly extending force applied to the tubular member from the interior thereof, and the tubular members are capable, when so

disposed in the body passageway in the said first diameter condition, of being simultaneously expanded and deformed, upon the application from the interior of the tubular members of a radially outwardly extending force, from the first diameter to the second, expanded and deformed, diameter, with portions of the first and second tubular members in the said second diameter condition being in a substantially flat adjacent relationship, whereby the adjacent portions are substantially flattened towards each other to substantially close off and substantially remove any gaps that may otherwise be present within the body passageway between the tubular members;

the device including a further, expandable and deformable, tubular member (166C) which is capable of being intraluminally delivered into the body passageway (152) before the remainder of the device and there expanded and deformed to force the further tubular member (166C) radially outwardly into contact with the body passageway to secure the further tubular member within the body passageway; the further tubular member (166C) being adapted to be so disposed within the body passageway that, after the intraluminal delivery and expansion and deformation of the first and second tubular members (166A, 166B), the first and second tubular members are disposed within the further tubular member in an adjacent relationship with each other and with the further tubular member, whereby the first and second tubular members may be secured within the body passageway and within the further tubular member."

VIII. At the end of the oral proceedings, the appellant's requests were that:

- the decision under appeal be set aside

- the two questions as formulated during the oral proceedings (point VI above) be referred to the Enlarged Board of Appeal (main request)

- a patent be granted on the basis of the set of claims 1 to 24 as submitted during the oral proceedings (auxiliary request, point VII above).

IX. The appellant argued as follows:

- Claim 1 as cited under point V above defines the product/device per se, before the expansion/deformation. The novelty lies in the purposive or functional juxtaposition of two individually known stent/graft composites, analogously to a claim to a new therapeutic substance or composition.

- Following decision T 9/81, an indication of purpose in claims is generally regarded as technically meaningful if the skilled person is thereby made aware of further, not expressly specified characteristics of the product. Further, "insofar as the individual components of the claimed device cannot attain the advantageous effects according to the invention independently of each other, their joint effect justifies the unity of the combined product as a result of the limitation by the indication of purpose of the area of protection of the claim under the conditions laid down in Article 54(5) EPC, even if the components are presented side-by-side and not as a union. In the present case the subject-matter

of claim 1 fulfils these conditions."

- Moreover, the present case relates to a surgical device in which products known individually are combined for the purpose of a new medical use. The device (the graft) being consumed in the medical use without the possibility of repeated use, the second indication claiming format is appropriate and allowable, in line with decision T 227/91. Once the stent part of each graft prosthesis has been expanded into the deformed "mirror-D" configuration created intraluminally, in accordance with claims 29 and 31, it cannot be contracted again and re-used.

- Therefore, purpose-related product and use claims in surgical cases should be treated analogously to purpose-related product and use claims in therapeutic cases, provided that the essential characteristics of the surgical use correspond to the essential characteristics of a therapeutic administration of a medicament. If the Board is doubtful as to the allowability of such claims, it is requested that the two questions above (section VI) be referred to the Enlarged Board of Appeal under Article 112(1) EPC.

- Claim 1 according to the auxiliary request is now limited to the second configuration with three tubular members, although it is felt that broader protection would be fair to the applicant. Moreover, its subject-matter is not disclosed in the prior art documents.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 The appellant's main request, which explicitly mentions only the referral of two questions (those set out in section VI, above) to the Enlarged Board of appeal, implicitly also includes the grant of a patent at least also with the claims 29 and 31 according to the former main request (see point V above). This is clear from the context, and including the fact that this implied request is a pre-requisite for a substantive answer, either by the Technical Board or the Enlarged Board, to those two questions. The appellant had unambiguously made clear his wish to get such an answer and the Board had accepted it. Under these circumstances it would be inappropriate to reject the Appellant's request for referral for formal reasons (questions not related to subject-matter of the claims according to the auxiliary request) and the Board's reasoning on the merits of the issues raised by the Appellant's questions does not constitute a mere *obiter dictum*; rather, the following considerations are indispensable for a complete and proper decision of the present case.

2.2 Both questions concern the scope of the exclusion from patentability pursuant to Article 54(2) EPC, first sentence and, in the Board's view, raise an important point of law. However, as can be seen from what is set out below, the issues in question can be decided upon on the basis of and in conformity with the comprehensive and uniform jurisprudence, including that of the Enlarged Board of Appeal. Therefore, there is no

reason for allowing the request for referral to that Board (Article 112(1) EPC).

2.3 An appropriate starting point for approaching the questions formulated by the Appellant has been provided by the Enlarged Board of Appeal in its decision G 5/83 (OJ EPO 1985, 64):

In the first part of the order the Enlarged Board of Appeal categorically excluded the grant of claims directed to "the use of a substance or composition for the treatment of the human or animal body by therapy" on the ground that such a claim is in no way different in essential content from a claim directed to "a method of treatment of the human or animal body by therapy with the substance or composition". The difference between the two claims being one of form only and the second form of claim being plainly in conflict with Article 52(4) EPC, no European patent can be granted including any such claim (point 13 of the reasons for the decision).

In contrast thereto, the Enlarged Board of Appeal held in the second part of its order that a European patent may be granted with claims directed to "the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application". As it is not only expressly made clear in Article 52(4) EPC, last sentence, but may also be deduced from the definition of "susceptible of industrial application" in Article 57 EPC, claims of this second type are unquestionably directed to inventions which are susceptible of industrial application within the meaning of Article 52(1) EPC (point 14 of the reasons for the decision). The same

must then be true for claims directed to "the use of a substance or composition for the preparation of a pharmaceutical product" (point 16 of the reasons) .

2.4 The reason why claims in the second format of claims ("Swiss type claims") qualify as representing an "industrial" activity outside the scope of the exclusion from patentability under Article 52(4) EPC is simply the fact that the mere manufacturing of a product, irrespective of whether that product is (also) a "medicament" because of its capacity to produce certain effects on or in the human or animal body when administered to it, does not necessitate or comprise any action on an individual human or animal body and, therefore, does not constitute a treatment of such body by surgery or therapy. Such treatment would, by definition, require that the product be actually used on an individual human or animal body for bringing about a certain effect on that body; but this is clearly a further and quite different activity of a therapeutical nature because it is directed to the maintenance or restoration of health (e.g. decisions T 19/86, T 438/91 and T 820/92). The difference between the two is also exhibited in real life, where the manufacturing and distribution of medicaments is a matter of industry and commerce which is performed by persons who need not and normally do not have a medical qualification, whereas the exercise of therapeutical activities including those involving the treatment by medicaments is reserved for medical practitioners or other persons having a medical knowledge (cf. T 385/86, T 24/91 and T 329/94).

2.5 It is the intention of Article 52(4) EPC to free from restraint non-commercial and non-industrial medical and

veterinary activities (see e.g. G 05/83, cited above, point 22 of the reasons), and said provision, in respect of the exclusion from patentability of methods for treatment of the human or animal body, in no way differentiates between therapy and surgery - for good reasons, in that both serve the same purpose, namely maintaining or restoring the health of the body, on which they are performed, and very often a successful treatment requires the combined use of methods of both kinds. The criteria for deciding whether a certain format of claims is *per se* allowable in view of Article 52(4) EPC or not, must be the same for both surgical and therapeutical methods. It is thus not surprising that the jurisprudence regarding "treatment by surgery" as excluded from patentability pursuant to Article 52(4) EPC relies on whether what is claimed comprises or implies a (physical) intervention on a human or animal body (cf. recent decision T 35/99, OJ EPO 2000, 447), the presence of one such "surgical" step being sufficient for rendering a claim unallowable (e.g. T 820/92, OJ EPO 1995, 113 and T 82/93, OJ EPO 1996, 274).

2.6 When comparing the subject-matter of claim 29 of the set of claims discussed first during the oral proceedings with that of a "Swiss type claim" directed to the preparation of a medicament having a certain effect on a living body, an essential difference is immediately evident: A medicament is a finished product, i.e. it has the composition and shape in which it is ready to perform its therapeutical function without further modification, as a result of an industrial ("non-medical") manufacturing process. By contrast, the device according to claim 29 (and 31), in order to perform its intended function, namely "to form

a bilateral passageway in the body passageway to repair the body passageway", is assembled and brought into its final form and position inside the body by a surgical method (sic!) "in which the tubular members and tubes are intraluminally delivered ... into a body passageway (152) to be repaired ... whereby the adjacent portions are substantially flattened towards each other to substantially close of and substantially remove any gaps that may otherwise be present within the body passageway between the tubular members".

The substance - and that is what counts for the purpose of Article 52(4) EPC, and not the form of the claim (see above) - of claim 29 is directed to a method for placing in a blood vessel two tubular members in a specific position to each other ("mirror-D configuration"). Clearly, this constitutes a surgical treatment within the meaning of Article 52(4) EPC (for its definition see decision T 182/90, cited above, points 2 to 4 of the Reasons) and it is only by this step that the "device" is given all the properties which are necessary for the intended functionality. As stated on page 2 of the applicant's letter dated 2 March 2001: "Without both "Ds" being substantially present, an effective leak-resistant bi-lateral passageway could not be constructed, and the patient's life would be in great danger".

2.7 This means that claims of the sort under consideration are actually directed to a surgical method which is characterized by the use of known endoprotheses in a new way. This use of a known material as, so to say, starting material for a medical activity, is quite different from the use of a known composition for manufacturing a medicament, which is an industrial

process (see above). Thus, as regards the exclusion under Article 52 (4) EPC, no analogy can be made between the use of materials or devices in a surgical method and the use of substances or compositions within the "second medical indication" in the meaning of decision G 05/83. Thus, decisions T 227/91 and T 9/81, on which the appellant relied, are not relevant in this context.

2.8 It follows that no European patent can be granted with claims directed to a new and even possibly inventive way of using materials or devices, in particular endoprotheses, involving a treatment by surgery. This is equally true in the case of product claims defined by a construction which is only arrived at in the human or animal body following a surgical method step.

3. *Auxiliary request*

3.1 Claims 1 to 24 of the auxiliary request are based on previous claims 1 to 25 according to the version of 30 March 2001 (sixth auxiliary request), after the deletion of the device and use claims which comprised features related to placing or forming the graft *in situ*, i.e. including one or more steps of a surgical method.

The current independent claim 1 is now based on the second configuration regarded favourably by the Board and directed to a device for forming a bilateral passageway, comprising essentially a first and a second expandable tubular member to be disposed within a third expandable tubular member of a larger diameter.

The claims are at present clear, fairly supported by

the application as filed and do not fall any more into the area excluded by Article 52(4) EPC. Therefore, they are allowable as regards formal aspects.

3.2 Document D1 is regarded as the closest prior art document. It originates from the applicant/appellant itself and discloses only one expandable aortic graft comprising a tubular member similar in its structure and its function to each of the tubular members used in the present invention. But as explained in the introductory part of the application as filed (column 2, line 54 to column 3, line 12), because of the relatively large diameter of the catheter and associated graft, some difficulties such as spasms, kinking and/or twisting of the flexible collapsible graft during or after implantation have been encountered.

The solution to this problem is given by the subject-matter of claim 1, comprising two identical expandable tubular members of reduced diameter placed within a third expandable tubular member of larger diameter, with a view to securing them in a body passageway and to each other, successively. This second configuration is new, contrary to the first configuration with only two identical tubular members, each of them known separately from document D1 and existing independently without any link or relationship to each other before expansion.

The second configuration also involves an inventive step since no prior art discloses or suggests this particular arrangement with a view to solving the above mentioned difficulties. Therefore, patent protection must be granted, after adequate adaptation of the

description by mentioning the closest prior art and revision for consistency with the new main claim, by the first instance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The request for referral of questions to the Enlarged Board of Appeal is rejected.

3. The case is remitted to the first instance with the order to grant a patent on the basis of the set of claims 1 to 24 submitted as (auxiliary) request at the oral proceedings, Figures as originally filed and the description to be adapted.

The Registrar: The Chairman:

V. Commare W. D. Weiß