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**D E C I S I O N**  
**of 13 April 2000**

**Case Number:** T 0941/96 - 3.3.2

**Application Number:** 88908351.5

**Publication Number:** 0380666

**IPC:** A61L 31/00

**Language of the proceedings:** EN

**Title of invention:**

Tool for securing inner diameter of inner cavity of tubular organ

**Patentee:**

TERUMO KABUSHIKI KAISHA

**Opponent:**

Advanced Coronary Technology, Inc.

**Headword:**

Shape memory alloy stent/TERUMO KABUSHIKI KAISHA

**Relevant legal provisions:**

EPC Art. 54, 104(1), 111(1), 123

EPC R. 51(a), 67

**Keyword:**

"Main request - novelty: no - a novel use of the prior art stent does not render the stent novel"

"First auxiliary request - admissibility: yes - restriction of the claimed subject-matter"

"Reimbursement of the appeal fee: no"

"Apportionment of costs: no"

**Decisions cited:**

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**Catchword:**

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**Case Number:** T 0941/96 - 3.3.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.2**  
**of 13 April 2000**

**Appellant:** Advanced Coronary Technology, Inc.  
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**Respondent:** TERUMO KABUSHIKI KAISHA  
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**Decision under appeal:** Interlocutory decision of the Opposition Division  
of the European Patent Office posted 5 August  
1996 concerning maintenance of European patent  
No. 0 380 666 in amended form.

**Composition of the Board:**

**Chairman:** P. A. M. Lançon  
**Members:** J. Riolo  
R. E. Teschemacher

## Summary of Facts and Submissions

- I. European patent No. 0 380 666, based on application No. 88 908 351.5, was granted on the basis of 8 claims comprising a product claim with six dependent claims and a use claim.
- II. Notice of opposition was filed against the granted patent by the appellant.

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of an inventive step and because the use claim concerned a method for therapeutical treatment.

The following documents were cited inter alia during the proceedings.

(1) US-A-4 503 569

(2) US-A-4 665 906

(8) US-A-4 553 545

- III. The interlocutory decision of the Opposition Division posted on 5 August 1996 established that the patent could be maintained on the basis of claim 1 as amended during the oral proceedings on 25 June 1996, of the dependent claims 2 to 7 as granted and of the accordingly adapted description.

Said amended claim 1 reads as follows:

"1. An instrument for retaining a desired inner diameter of a tubular organ lumen (11) comprising a

cylindrical member (10;20;30,40) made of a unidirectional shape memory alloy whose transformation temperature is higher than the temperature of a living body in which the cylindrical member is to be placed, characterized in that said cylindrical member (10;20;30;40) is radially expandable at said desired inner diameter by an external force at said temperature of said living body, and in that the expanded cylindrical member is contractable to its basic phase when heated to said transformation temperature, the outer diameter of said contracted cylindrical member in its basic phase being smaller than said inner diameter of said tubular organ lumen (11)."

The Opposition Division took the view that the patent in suit met the requirements of Articles 52(1), 54 and 56 EPC.

As regards novelty, the Opposition Division was of the opinion that the claimed instrument was novel over document (1) because the outer diameter of the cylindrical member, in its basic phase, was **smaller** than the diameter of the tubular organ lumen whereas it was approximately **equal** to the diameter of the tubular organ lumen in said document.

Accordingly, the compliance of the main claim with Article 54 EPC was acknowledged by the Opposition Division.

The Opposition Division also concluded that it was not obvious for a skilled person to choose the diameter of the cylindrical member and its properties as defined in claim 1 in order to solve the problems of removing and shifting the instrument in a tubular organ.

In fact, the most relevant documents (1) and (2) were silent about these problems.

- IV. The appellant (opponent) lodged an appeal against the said decision.
  
- V. Oral proceedings were held before the Board on 13 April 2000, during which auxiliary requests 1 to 4 were submitted by the respondent.

The main request corresponds to the version of the claims as allowed by the Opposition Division, wherein the wording in claim 1, line 7, "**at** said desired inner diameter" has been corrected to "**to** the desired inner diameter" as agreed by the parties. (Emphasis added).

Independent claim 1 of the first subsidiary request reads:

"1. An instrument for retaining a desired inner diameter of a tubular organ lumen (11) comprising a cylindrical member (10;20;30,40) made of a unidirectional shape memory alloy whose transformation temperature is higher than the temperature of a living body in which the cylindrical member is to be placed, characterized in that said cylindrical member (10;20;30;40) is radially expandable to said desired inner diameter by an external force at said temperature of said living body, and in that the expanded cylindrical member is contractable to its basic phase when heated to said transformation temperature, the outer diameter of said contracted cylindrical member in its basic phase being smaller than the inner diameter of said tubular organ lumen (11), **in combination with an indwelling balloon catheter (50) having an**

expandable balloon (51) at its distal end capable of applying said external force to said cylindrical member (10;20;30;40) fitted thereon in a contracted state and causing said radial expansion of said cylindrical member, said balloon (51) communicating with a path (23) for a balloon expanding solution." (Emphasis added).

The dependent claims 2 to 7 correspond to claims 2 to 7 as granted.

VI. The submissions of the appellant both in the written procedure and at the oral proceedings can be summarised as follows:

The appellant first argued that the oral proceedings during the opposition procedure suffered from a substantial procedural violation. It further maintained the grounds of opposition under Article 100(a) EPC as to the lack of novelty and inventive step of the patent in suit.

As regards the alleged procedural violation, the appellant stated that it was surprised by the intermediate decision of the Opposition Division because the claims which it was decided were inventive were not the subject-matter which had been discussed before the proceedings were closed for deliberation. It therefore requested the reimbursement of the appeal fee.

As regards the question of novelty under Article 54 EPC, the appellant took the view that all the features of claim 1 of the patent in suit were disclosed by document (1).

As regards the assessment of inventive step, the appellant contended that the subject-matter of claim 1 of the patent in suit was obvious over the teaching of document (1), taken alone or in combination with document (2) or document (8), as well as over the combination of document (8) with document (2).

In its view, the skilled person, knowing from his general knowledge that coils were mechanically expandable, would without any inventive step choose a cylindrical member of shape memory alloy as described in (1), which in its memorised shape had a diameter such that it could be inserted into the organ lumen and removed therefrom.

In that respect, the skilled person would moreover clearly learn from document (2) that medical instruments made of shape memory alloys were heated in order to deform them back to a removable shape.

As an alternative argument, the appellant maintained that, having regard to the teaching in document (8) disclosing that instruments for retaining the inner diameter of a tubular organ lumen with a diameter smaller than the blood vessel were mechanically expanded in order to be placed within the blood vessel and mechanically reduced in order to be removed therefrom, the skilled person would without an inventive step choose a cylindrical member of shape memory alloy as described in (1), which in its memorised shape had a diameter such that it could be inserted into the organ lumen and removed therefrom.

The appellant argued finally that, starting from document (8), the skilled person would moreover clearly



learn from document (2) that medical instruments made of shape memory alloys were heated in order to deform them back to a removable shape.

VII. The respondent's arguments submitted both in the written procedure and at the oral proceedings can be summarised as follows:

In the respondent's view, the subject-matter of claim 1 of the patent in suit was novel over document (1) because the outer diameter of the cylindrical member, in its basic phase, was **smaller** than the diameter of the tubular organ lumen, whereas it was approximately **equal** to the diameter of the tubular organ lumen in said document. In addition, it argued that the stent of document (1) had a memory to expand whereas the stent of the contested patent had a memory to retract. It contended that these different physical properties implied that the alloys were different as regards their constitution.

The contested subject-matter also involved an inventive step over documents (1), (2) and (8) because the problems solved by the subject-matter of the patent in suit, ie the problems relating to the provision of an easily removable and displaceable instrument for retaining the inner diameter of a tubular organ, had not been identified in this prior art.

The respondent further pointed out that nothing in document (1) suggested using a unidirectional shape memory alloy as defined in claim 1 of the contested patent and that the skilled person would not be prompted to combine that document either with document (2), as it taught a contraceptive device which was

completely different from the cylindrical stent of the contested patent, or with document (8), as this latter document did not disclose devices using shape memory alloys.

Moreover, the respondent contended that the combination of document (1) with document (2) would not result in the features of the subject-matter of claim 1 since none of these documents disclosed a cylindrical element which was expandable at the desired inner diameter **by an external force**. The same applied to the combination of document (1) with document (8) since the latter document would not suggest removing the stent by heat application.

VIII. The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

In case the Board was prepared to allow the respondent's main request, the appellant requested that the question of law, which it submitted during oral proceedings before the Board, be referred to the Enlarged Board of Appeal ie "is a product claim which defines by functional language a behaviour of a product at different conditions, which allow a new use of this product, novel even if the product per se was known?". In the case of remittal to the departement of first instance, it requested a decision in its favour on the apportionment of costs. In addition, it requested that the appeal fee be reimbursed.

The respondent requested that the appeal be dismissed and that the patent be maintained in the version allowed by the Opposition Division with the amendment in claim 1, line 7 as submitted during the oral

proceedings before the Board.

Alternatively, it was requested that the case be remitted to the departement of first instance for further prosecution on the basis of the four subsidiary requests submitted during the oral proceedings.

## **Reasons for the Decision**

1. The appeal is admissible.
2. *Main request*
  - 2.1 Article 123 EPC

There are no objections on the basis of Article 123(2) and (3) EPC to the set of claims of the main request since the amendments to the claims are adequately disclosed in the original description and do not extend the protection conferred when compared to the claims as granted. This was not contested by the appellant.

- 2.2 Novelty
  - 2.2.1 Since document (1) has been cited as prejudicial to the novelty of the subject-matter of the patent in suit it is necessary to discuss this matter in detail.

Document (1) discloses a graft prosthesis useful for placement within the body passageway, which is a tubular shaped coil of wire made of a shape memory Nitinol® alloy with a transition temperature in the

range of 115-125 degrees Fahrenheit (46-52°C)  
(Figure 2, column 2, lines 36 to 38, and column 3,  
lines 17 to 24).

Accordingly, an instrument for retaining a desired inner diameter of a tubular organ lumen comprising a cylindrical member made of a unidirectional shape memory alloy whose transformation temperature is higher than the temperature of a living body in which the cylindrical member is to be placed is known from this document.

It remains therefore to examine whether the cylindrical member described in (1) can be radially expanded to said inner diameter by an external force at said temperature of said living body, and whether the expanded cylindrical member is contractable to its basic phase when heated to said transformation temperature, the outer diameter of said contracted cylindrical member in its basic phase being smaller than said inner diameter of a tubular organ lumen.

The Board notes that the material of the cylindrical member of the contested patent is also a stent of Ni-Ti alloy having the same transformation temperature and the same shape as the one used in (1) (Figure 1B, column 6, lines 6 to 12).

The Board is therefore convinced that the stent of document (1) is also radially expandable to said inner diameter by an external force at said temperature of said living body. To a certain extent, this feature is moreover *a priori* inherent to any cylindrical member of a shape memory alloy which has a coil-like body under normal temperature and expansion conditions.

As regards the last feature, it is also clear that the shape memory alloy stent of document (1), which has been mechanically deformed to an expanded state exceeding the diameter of its basic phase, will contract back to its basic phase when heated to its transformation temperature as this is precisely the very property of these alloys. It also goes without saying that, for a given stent as described in (1), there are many tubular organs having an inner diameter larger than the diameter of said stent in its phase.

Accordingly, the stent disclosed in document (1) has all the features required by claim 1 of the main request.

The Board agrees that, in relation to a particular tubular organ, the stent of the prior art is used differently. A novel use of a known device cannot however, as a rule, provide novelty of the device per se.

- 2.2.2 The Board cannot agree with the respondent's view that the stent of the contested patent was novel because it had a diameter in its basic phase smaller than the inner diameter of the tubular organ lumen whereas the stent of (1) had a diameter which was equal to the organ lumen.

As a matter of fact, this relative feature depends merely on the choice of the tubular organ. As it is clear that a given cylindrical stent according to document (1) can also be placed in a tubular organ having an inner diameter larger than the diameter of the stent in its basic phase, the prior art stent cannot be distinguished from the stent of the contested

patent on the basis of its diameter in its basic phase.

Nor can the Board accept the argument that the prior art stent and the stent of the contested patent must be chemically different because they have opposite memories, ie a memory to expand and a memory to retract respectively.

According to document (1) the stent is prepared so as to return to a single predetermined memorised structural configuration when heated to its transformation temperature (column 3, lines 44 to 51). This phenomenon, which is the very property of the memory shape alloys, is obviously independent of the type of structural deformation which the stent made of such an alloy might have undergone before being heated to said temperature.

In other words, when the diameter of the cylindrical stent is expanded above its memorised shape, it will retract to said shape upon heating at the transformation temperature, whereas when it is shrunk below said shape, it will expand. Accordingly, the prior art stent and the stent of the contested patent do not have opposite memories. Rather, the memory status of the stent when used for a specific purpose depends on the manner in which it was treated before. Such treatment does not destroy the stent's ability to return to the other status of its memory.

Finally, the Board does not share the respondent's allegation that document (1) may also concern a bidirectional shape memory alloy possessing a second memorised shape instead of a unidirectional one, because it mentioned that the stent retained its basic

shape unless it was cooled below a certain temperature (column 3, lines 61 to 66).

As a matter of fact, it is clear from the method of preparation of the stent and from many other passages of the description that the shape memory alloy of document (1) has a single transformation temperature and that it is therefore a unidirectional shape memory alloy (column 3, lines 44 to 54 and eg, column 2, line 44, column 3, line 21, column 4, line 30, and line 66, and column 5, line 17).

In fact, the passage referred to by the respondent means merely that the basic shape of the stent can only be changed at a temperature below the transformation temperature, ie at a temperature at which the specific basic phase crystalline structure of the memory alloy changes.

In conclusion, the subject-matter of claim 1 of the main request lacks novelty under Article 54 EPC.

Under these circumstances, there is no need to refer the question of law submitted by the appellant to the Enlarged Board of Appeal.

### 3. *First auxiliary request*

#### 3.1 Admissibility

The subject-matter of independent claim 1 of the first auxiliary request differs from claim 1 of the set of claims of the main request in that the functional means producing the external force necessary to expand the cylindrical member as recited in the claims are now

specified as being an indwelling balloon catheter.

The Board notes that this subject-matter, ie the combination of a cylindrical member with an indwelling balloon catheter, is still within the scope of the preamble of claim 1 as maintained, because this claim was directed to an instrument **comprising** a cylindrical member and because the combination of the cylindrical member with an external tool for expanding its diameter was implicit from its wording, ie "said cylindrical member (10,20,30,40) is radially expandable to said desired inner diameter by an external force".

In addition, the subject-matter of claim 1 of the first auxiliary request, claiming the combination of the cylindrical member with a very specific means for applying an external force, constitutes a limitation of the scope of the claims of the patent as amended according to the interlocutory decision. The Board accepts that this limitation is a consequence of the novelty objection and therefore, does not agree with the respondent's view that this set of claims could only be allowed if the respondent had himself filed an appeal.

Accordingly, the Board judges that this set of claims fulfils the requirements of Rule 57a EPC.

### 3.2 Article 123 EPC

There are no objections on the basis of Article 123(2) and (3) EPC to the set of claims of the first auxiliary request since the additional features are adequately disclosed by the original description and do not extend the protection conferred when compared to the claims as



granted. This was not contested by the appellant.

3.3 Remittal to the departement of first instance

3.3.1 Although Article 111(1) EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, that may well be appropriate as regards essential issues. Hence, cases are often referred back, if essential questions regarding the patentability of the claimed subject-matter have not been examined and decided by the department of first instance.

In the present case, the subject-matter examined during the grant proceedings and during the opposition proceedings related to a single device, ie a cylindrical member having the properties as defined in the product claim.

The relevance of the combination of this device with a specific means for expanding it has therefore never been assessed.

In view of the Board's decision to reject the main request for lack of novelty of the cylindrical member, the combination of this cylindrical member with an indwelling balloon catheter now falls to be considered as an essential substantive issue in the present case.

It should be added that the respondent had already presented this first auxiliary request to the Opposition Division as an auxiliary request during the opposition proceedings.

3.3.2 In view of the above the Board has reached the

conclusion that, in the circumstances of the present case, it is appropriate to remit the case to the Opposition Division.

4. *Apportionment of costs*

In support of the request for apportionment of costs it was submitted that it was unfair for the appellant to have to bear additional expenses arising from the remittal of the case, which resulted from the amendments made by the respondent. Such a line of argument is not sufficient to justify an apportionment of costs. According to the general rule, each party to opposition proceedings must meet its own costs. An exception to this principle in the form of an apportionment of costs is made if costs arise from culpable actions of an irresponsible nature (see the decisions cited in Case Law of the Boards of Appeal of the EPO, 3rd ed. 1998, VII.C.13.3). Such a case has not even been alleged by the appellant. The fact that the auxiliary requests have not yet been examined by the Opposition Division is not due to a negligent course of action by the respondent. Although the auxiliary requests were filed in their present form in appeal proceedings, similar requests had already been filed in the proceedings at first instance.

5. *Reimbursement of the appeal fee*

5.1 The request for reimbursement of the appeal fee was based on the appellant's allegation that in the oral proceedings before the Opposition Division there was no opportunity to comment on the question of inventive step concerning claim 1 in the version as allowed before the decision was taken.

- 5.2 This allegation is not confirmed by the facts apparent from the file.
- 5.2.1 The claim in question was filed as an auxiliary request in response to the communication accompanying the summons to the oral proceedings. In its written response, the appellant submitted that the novelty objection to claim 1 in the version of the main request also applied to claim 1 in the version of the auxiliary request without adding anything in respect of inventive step relating to the auxiliary request.
- 5.2.2 The minutes of the oral proceedings report that the chairman of the Opposition Division announced that claim 1 in the versions of the main request and of the auxiliary request would be dealt with together, in respect of novelty and inventive step, in the course of the proceedings. This was not contested by the appellant. Furthermore, the minutes reflect the discussion on novelty and the conclusion of the Opposition Division that claim 1 in the version of the main request was considered novel. The minutes then reflect the discussion on inventive step without distinguishing between the main request and the auxiliary request. After deliberation, the Division announced in its decision that claim 1 according to the main request did not involve an inventive step, whereas claim 1 in the version of the auxiliary request did.
- 5.2.3 The decision under appeal deals with the question of inventive step in point 4 of the grounds for the decision. Having considered the respective arguments of the parties, it concludes that claim 1 in the version of the main request does not involve an inventive step. Referring to the additional feature in claim 1 in the

version of the auxiliary request, namely that " the expanded cylindrical member is contractable to its basic phase when heated to said transformation temperature", it quotes the opponent's arguments in point 4.4.1, deals with them and comes to the conclusion that the subject-matter of claim 1 in this version involves an inventive step (point 4.4.4).

5.3 It follows therefrom that the Opposition Division took account of arguments submitted by the appellant in the oral proceedings concerning the inventive step of claim 1 of the auxiliary request. The Opposition Division was not obliged in the oral proceedings to discuss inventive step for both requests separately so long as the envisaged structure of the discussion was clear to the parties. Taking account of the initial announcement of the chairman (point 5.2.2 above), the appellant had to reckon with the possibility that after the discussion on inventive step was closed for deliberation by the Division, the discussion would not be reopened. If there was anything more which the appellant wished to add in respect of inventive step, it should have asked for an opportunity to do so before the discussion was closed.

5.4 Hence, it has not been established that the appellant's right to be heard was violated.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.

2. The respondent's main request is rejected.
3. The case is remitted to the department of first instance for further prosecution.
4. The appellant's request for apportionment of costs is refused.
5. The appellant's request for reimbursement of the appeal fee is refused.

The Registrar:

The Chairman:

M. Dainese

P. A. M. Lançon