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**Datasheet for the decision  
of 14 March 2013**

**Case Number:** T 1069/11 - 3.2.08

**Application Number:** 08151651.0

**Publication Number:** 1961401

**IPC:** A61F 2/90, A61F 2/88

**Language of the proceedings:** EN

**Title of invention:**  
Hyperplasia plaque-preventing stent

**Applicant:**  
Cardiatis S.A.

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 53(c), 54(4)(5), 112(1)(a)  
EPC R. 43(2)

**Keyword:**  
"Main request (plural independent claims in the same category  
- no)"  
"Auxiliary requests (novelty on the base of the medical  
indication - no)"  
"Referral to Enlarged Board of Appeal (no)"

**Decisions cited:**  
G 0002/08, T 0227/91, T 0775/97, T 1172/03, T 1099/09

**Catchword:**  
-



Case Number: T 1069/11 - 3.2.08

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.08  
of 14 March 2013

**Appellant:** Cardiatis S.A.  
(Applicant) Parc Crealys  
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B-5032 Isnes (BE)

**Representative:** Vandenberg, Marie-Paule L.G.  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 17 December 2010  
refusing European patent application  
No. 08151651.0 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** P. Acton  
**Members:** M. Alvazzi Delfrate  
C. Schmidt

## **Summary of Facts and Submissions**

- I. By decision posted on 17 December 2010 the examining division refused European patent application No. 08 151 651.0, on the grounds that the subject-matter of claim 1 of the sole request then on file lacked novelty in view of
- D1: US -A- 2004/0215332.
- II. The appellant (applicant) lodged an appeal against this decision on 17 February 2011, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 22 April 2011.
- III. Oral proceedings before the Board of Appeal took place on 14 March 2013.
- IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims submitted as main request or as auxiliary requests 1 to 3 during the oral proceedings.

Moreover, it requested that the following questions be referred to the Enlarged Board of Appeal:

- 1) "In case that a product X such as stent, which is neither a substance nor a composition, is expended in a process of use and has only a once for all utility as medicament, is the subject-matter of a claim having its format in accordance with Article 54(4) and (5) EPC but wherein "substance or composition" is replaced by "product X such as stent" and the use Y of the product

X is novel over the prior art, can this product X be considered novel in the meaning of Article 53(c)?"

2) "Are all products, except for "substance or composition", excluded from the provisions of Article 54(4) and (5) EPC?"

V. The main request comprises three independent claims (1, 6 and 7) which read as follows:

"1. Stent for use in prevention of restenoses of a wall (3) of a blood vessel having atheromatous plaque consisting of a multilayer braided framework (13) wherein the framework, devoid of any cover layer, comprises a plurality of stabilized layers (14, 15, 16) of biocompatible metal wires (17), which are interlaced, forming a lattice, a plurality of wires (17) of a given layer (14, 15, 16) being integrated in the lattice of at least one of the adjacent layers;

characterized in that:

the mechanical characteristics of the stent are so that, when deployed in the vessel, an outermost layer (14) is able to rest against the vessel wall (3) and the other layers are able to extending [sic] substantially along cylindrical surfaces distinct from the outermost layer (14), so as to form a multi-layer mat so designed that the combined effect of the various layers locally affects the haemodynamic of a flow of blood passing along said mat, the flow of blood being deviated towards an inner face of an innermost layer and and [sic] provoking a drop of the pressure exerted on the vessel wall, thus preventing the growth of

plaques on said vessel wall and promoting the growth of a new layer of endothelial cells."

"6. Stent for use in producing an endothelial cell film on a wall of a blood vessel consisting of a multilayer braided framework (13) wherein:

- the framework, devoid of any cover layer, comprises a plurality of stabilized layers (14, 15, 16) of biocompatible metal wires (17), which are interlaced, forming a lattice, a plurality of wires (17) of a given layer (14, 15, 16) being integrated in the lattice of at least one of the adjacent layers; and

- the mechanical characteristics of an outermost layer (14) are so that, when deployed in the vessel, said layer (14) is able to rest against the vessel wall (3), and the other layers being able to extending [sic] substantially along cylindrical surfaces distinct from the outermost layer (14) so as to form a multi-layer mat so designed that the combined effect of the various layers locally affects the haemodynamic of a flow of blood passing along said mat, the flow of blood being deviated towards an inner face of an innermost layer and and [sic] provoking a drop of the pressure exerted on the vessel wall, thus preventing the growth of plaques on said vessel wall and promoting the growth of a new layer of endothelial cells."

"7. Stent for use in repairing a wall of a blood vessel consisting of a multilayer braided framework (13) wherein:

- the framework, devoid of any cover layer, comprises a plurality of stabilized layers (14, 15, 16) of biocompatible metal wires (17), which are interlaced, forming a lattice, a plurality of wires (17) of a given layer (14, 15, 16) being integrated in the lattice of at least one of the adjacent layers; and

- the mechanical characteristics of an outermost layer (14) are so that, when deployed in the vessel, said layer (14) is able to rest against the vessel wall (3), and the other layers being able to extending [sic] substantially along cylindrical surfaces distinct from the outermost layer (14) so as to form a multi-layer mat so designed that the combined effect of the various layers locally affects the haemodynamic of a flow of blood passing along said mat, the flow of blood being deviated towards an inner face of an innermost layer and and [sic] provoking a drop of the pressure exerted on the vessel wall, thus preventing the growth of plaques on said vessel wall and promoting the growth of a new layer of endothelial cells."

Each set of claims according to auxiliary requests 1 to 3 comprises only one independent claim. Claim 1 of auxiliary requests 1 and 2 is identical to claim 1 of the main request, while claim 1 of auxiliary request 3 is identical to claim 7 of the main request.

VI. The arguments of the appellant can be summarised as follows:

*Main request*

It was true that the main request comprised three independent claims in the same category. However, this was justified in the present case since the independent claims covered different alternative aspects relating to the control of level of shear flow in a blood vessel. Accordingly, the main request complied with Rule 43(2)EPC.

*Auxiliary requests*

D1 related to a stent with a multilayer braided framework. However, D1 did not disclose that, once deployed in the vessel, the stent formed a multi layer mat providing the effects stipulated in the characterising portion of claim 1. These features were the result of mechanical characteristics of the stent which were not disclosed by D1. Hence, the stent according to claim 1 of auxiliary request 1 was novel.

Moreover, D1 did not disclose the use of the stent in the prevention of restenoses in a blood vessel having atheromatous plaque. Hence, novelty was to be acknowledged also on the basis of that medical indication.

It was true that Article 54(4) and (5) EPC, according to which novelty of a product could be acknowledged on the basis of its medical indication, referred solely to substances or compositions. However, in view of the principles set out in decision G 2/08 it was clear that the wording of those articles should be interpreted

widely enough to cover any product used in a method excluded by Article 53(c), first sentence, EPC.

A short indication for medical devices could be found also in the preparatory work on Article 52 EPC 1973, according to which the two new paragraphs proposed stipulated that the provisions of Article 50, paragraphs 1 and 2 [Art. 52 EPC 1973], and paragraphs 1 to 4 of Article 52 [Art. 54 EPC 1973] did not exclude the patentability of substances and compositions intended for use in one of the methods referred to in Article 50, paragraph 2(b) [Art. 52(2)(b) EPC 1973], even if the substances or compositions were already known, insofar as the state of the art did not include their disclosure for any method referred to in Article 50, paragraph 2(b) [Art. 52(2)(b) EPC 1973], and which explicitly stipulated that these rules were not intended to prejudge the patentability of medical equipment.

Decision T 227/91 also provided reasons for acknowledging the patentability of the claimed stent on the basis of its medical indication. That decision dealt with a "Swiss-type claim", i.e. a claim to a use of a known substance X for a known manufacturing process Y of a medicament Z for a novel therapeutic use. According to T 227/91, medicaments are expended in the process of use and have only a once-and-for-all utility. This was also the case for the stent of claim 1 of auxiliary request 1, which was transformed into a different product in a body and was embedded in the vessel wall. Consequently, that stent was analogous to a "substance or composition", and its patentability should also be acknowledged on the basis of its medical



indication in the framework of Article 54(4) and (5) EPC.

As to decisions T 227/91, T 775/97 and T 1172/03, they were concerned with Swiss-type claims and with products different from the stent under consideration. Hence, although those decisions did not recognise the patentability of the products to which they related on the basis of their medical indication, they gave no reason to deny the patentability in the present case.

Accordingly, the stent of claim 1 of auxiliary request 1 was novel by virtue not only of its mechanical characteristics but also of its medical indication.

Novelty of the subject-matter of claim 1 of auxiliary requests 2 and 3 was to be acknowledged on the same grounds.

*Referral to the Enlarged Board of Appeal*

The two questions to be referred to the Enlarged Board of Appeal related to a point of law of fundamental importance. The wording of Article 54(4) and (5) EPC referred solely to substances and compositions, whereas products which were neither substances nor compositions could also be used in a method according to Article 53(c) EPC. Hence, there was a gap concerning the patentability of products different from medicaments to be used in a method referred to in Article 53(c) EPC. The need to fill that gap called for a referral to the Enlarged Board of Appeal.

## Reasons for the Decision

1. The appeal is admissible.
2. Main request
  - 2.1 The main request comprises three independent product claims. However, according to Rule 43(2) EPC a European patent application may contain more than one independent claim in the same category (product, process, apparatus or use) only if the subject-matter of the application involves one of the following:
    - (a) a plurality of interrelated products,
    - (b) different uses of a product or apparatus,
    - (c) alternative solutions to a particular problem, where it is inappropriate to cover these alternatives by a single claim.
  - 2.2 In the present case, all the independent claims concern a stent. Hence, they cannot relate to a plurality of interrelated products within the meaning of Rule 43(2) (a) EPC.

Moreover, being product claims, they are not directed to activities. Therefore, they do not claim different uses of a product or apparatus within the meaning of Rule 43(2) (b) EPC.

Finally, the structural features of the stent of claim 1 are identical to those of the stents of claims

6 and 7. Those independent product claims differ solely in the aim to be achieved by the stent: preventing restenoses of a wall of a blood vessel having atheromatous plaque for claim 1, producing an endothelial cell film on a wall of a blood vessel for claim 6 and repairing a wall of a blood vessel for claim 7. These features represent different aspects of the problem of repairing blood vessels and do not concern solutions to that problem. Accordingly, the subject-matter of claims 1, 6 and 7 does not involve alternative solutions to a particular problem within the meaning of Rule 43(2)(c) EPC.

2.3 Therefore, the main request does not comply with the requirements of Rule 43(2) EPC.

3. Auxiliary request 1

3.1 D1 discloses a stent consisting of a multilayer braided framework (6) wherein the framework, devoid of any cover layer, comprises a plurality of stabilised layers (8, 10, 12) of biocompatible metal wires (14), which are interlaced, forming a lattice, a plurality of wires of a given layer being integrated in the lattice of at least one of the adjacent layers (abstract).

3.2 It is true that D1 does not disclose that, once the stent is deployed in the vessel, its outermost layer rests against the vessel wall and the other layers extend substantially along cylindrical surfaces distinct from the outermost layer, so as to form a multi layer mat so designed that the combined effect of the various layers locally affects the haemodynamic of a flow of blood passing along said mat, the flow of

blood being deviated towards an inner face of an innermost layer and provoking a drop of the pressure exerted on the vessel wall, thus preventing the growth of plaques on said vessel wall and promoting the growth of a new layer of endothelial cells.

- 3.2.1 However, claim 1 is directed to a stent as such. Therefore, these features, which relate to the stent while in use, must be construed as meaning merely that the stent is suitable for realising them once deployed.
- 3.2.2 The appellant submitted that they are the result of mechanical characteristics of the claimed stent which are not disclosed in D1. However, it could not indicate which specific mechanical characteristic or characteristics distinguished it from the prior-art stent.
- 3.2.3 Nor does the application in suit give any indication as to what this characteristic or these characteristics may be. On the contrary, a comparison of Figure 3 and paragraphs [0028] to [0030] of the application in suit and Figure 2 and paragraphs [0017] to [0019] of D1 reveals that the geometry, materials and materials treatment of the stent disclosed as a preferred embodiment in the present application are the same as those of the stent disclosed in D1.

As a matter of fact, the applicant itself acknowledged that the claimed invention is based on the discovery of a completely different field of application of the same structure known from D1 (see amended page 5 of the description filed with letter of 13 July 2009).

3.2.4 Since no difference in terms of mechanical characteristics can be seen between the stent of claim 1 and the stent known from D1, the latter stent must necessarily be intrinsically suitable for satisfying the requirements set out in the characterising portion of claim 1 of auxiliary request 1.

3.3 The appellant submitted that novelty of the subject-matter of claim 1 should be acknowledged also on the basis of its medical indication, i.e. the fact that the stent is "for use in prevention of restenoses of a wall of a blood vessel having atheromatous plaque".

3.3.1 The only provisions of the EPC which foresee that the novelty of a product can be acknowledged on the basis of its medical indication are Article 54(4) and (5) EPC.

According to Article 54(4) EPC, it is possible to acknowledge the novelty of a "... substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art" (emphasis added).

According to Article 54(5) EPC, it is also possible to acknowledge the novelty of a "... substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art" (emphasis added).

Article 53(c) EPC, to which both Article 54(4) and Article 54(5) EPC refer, provides that European patents

are not to be granted in respect of "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods"(emphasis added).

- 3.3.2 It can thus be seen from the text of those articles that there is an explicit difference between the wording chosen by the legislator for Article 53(c) and the wording of Article 54(4) and (5) EPC. First of all, as a consequence of the use of the expression "in particular", Article 53(c) in itself indicates that products are not limited to substances or compositions. Moreover, whereas Article 53(c) mentions products, in particular substances or compositions, Article 54(4) and Article 54(5) only mention substances or compositions.

The legislator has thus made a distinction between products that can qualify as substances or compositions, and which are patentable within the framework of Article 54(4) and (5) EPC, and other products, which do not fall under the exceptions provided by those provisions (see also T 1099/09 of 12 January 2012, point 3.3 of the Reasons for the decision).

- 3.3.3 This finding is not at variance with decision G 2/08 (OJ EPO 10/2010, 456), which deals with the patentability of substances and compositions that are already known as medicaments (see questions referred to the Enlarged Board of Appeal under I.1.2 of the Summary of Facts and Submissions and the corresponding answers

- in the Order) and does not consider the patentability of products which do not qualify as substances or compositions.
- 3.3.4 Nor does the passage of the *travaux préparatoires* of the EPC 1973 cited by the appellant (BR/ 219 e/72 ico/PA/gc, §30, second paragraph) suggest a different interpretation of the provisions of Article 54(4) and (5) EPC. It is true that that passage states that the patentability of medical equipment should not be prejudged. However, it does not stipulate that said patentability can be acknowledged on the basis of the medical indication of those devices.
- 3.3.5 Accordingly, the novelty of the product of claim 1 can be acknowledged on the basis of its medical indication only if that product qualifies as a substance or a composition. However, the claimed product is a stent consisting of a multilayer braided framework devoid of any cover layer. Accordingly it is a finished product having a certain shape and certain dimensions and which does not comprise any active ingredient. Hence, the claimed stent does not qualify as a substance or a composition.
- 3.3.6 Decision T 227/91 (OJ EPO 1994, 491) does not contain any hint to the contrary. That decision is concerned with Swiss-type claims and, though it states that medicaments are expended in the process of use and have only a once-and-for-all utility (point 5.2 of the Reasons for the decision), fails to define all the conditions necessary for a product to qualify as a medicament, let alone a substance or a composition.

3.4 Therefore, the provisions of Article 54(4) and (5) EPC do not apply to the claimed stent. Accordingly, its novelty cannot be acknowledged on the basis of its medical indication (use in the prevention of restenoses in a blood vessel having atheromatous plaque) either.

3.5 Therefore, the subject-matter of claim 1 of auxiliary request 1 lacks novelty with respect to D1.

4. Auxiliary requests 2 and 3

4.1 Claim 1 of auxiliary request 2 is identical to claim 1 of auxiliary request 1. Accordingly, its subject-matter lacks novelty for the reasons already explained.

4.2 Claim 1 of auxiliary request 3 is directed to a stent whose structural features are the same as those of the stent of claim 1 of auxiliary request 1.

The sole difference between those two stents resides in their medical indication, namely the prevention of restenoses of a blood vessel having atheromatous plaque for auxiliary request 1 and the repair of a wall of a blood vessel for auxiliary request 3. However, as already explained, its medical indication cannot impart novelty to the stent. Therefore, the stent according to claim 1 of auxiliary request 3 lacks novelty as well.

5. Referral to the Enlarged Board of Appeal

5.1 Article 112(1)(a) EPC provides that in order to ensure uniform application of the law, or if a point of law of fundamental importance arises, a "Board of Appeal shall, during proceedings on a case and either of its own



motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes".

5.2 Hence, it is within the discretion of the Board to decide whether a referral is necessary or not. Such a need can only exist if the decision to be taken by the Board depends on the question that is to be referred to the Enlarged Board of Appeal and if the Board cannot decide itself without difficulty the question that is to be referred.

5.3 The issue addressed by the first question submitted by the appellant is whether, for a product such as a stent which is neither a substance nor a composition, and which is expended in a process of use and has only a once-and-for-all utility as medicament, novelty can be acknowledged on the basis of its medical use. The second question asks if all products, except for substance or compositions, are excluded from the provisions of Article 54(4) and (5) EPC. Hence, both questions relate to which products can be recognised as patentable on the basis of their use in a method referred to in Article 53(c) EPC.

5.3.1 For the present decision it was indeed necessary to consider this issue. However, as already explained, the Board is of the opinion that it can be derived clearly and explicitly from the provisions of the EPC itself that the patentability of a product to be used in a method referred to in Article 53(c) EPC can be acknowledged on the basis of that use solely for a product which qualifies as a substance or a composition.

5.3.2 Moreover, the Board is not aware of any divergence in the case law concerning this point, so that there is no problem of uniform application of the law.

5.3.3 As to the fact that the appellant perceives the limitation of the provisions of Article 54(4) and (5) EPC to substances and composition as a gap in the law, this is no reason for a referral to the Enlarged Board of Appeal under Article 112(1) EPC.

5.3.4 Under these circumstances the Board sees no need to refer to the Enlarged Board of Appeal the questions submitted by the appellant.

## **Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

P. Acton