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**D E C I S I O N**  
**of 10 February 2005**

**Case Number:** T 1139/00 - 3.2.2

**Application Number:** 89118420.2

**Publication Number:** 0362826

**IPC:** A61M 25/10

**Language of the proceedings:** EN

**Title of invention:**  
Balloons for medical devices

**Patentee:**  
Cordis Corporation

**Opponent:**  
Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro  
Berlin  
Boston Scientific International BV  
Terumo Kabushiki Kaisha Head Office

**Headword:**

-

**Relevant legal provisions:**  
EPC Art. 100(c), 123(2)

**Keyword:**  
"Disclaimer allowable under Article 123(2) (yes)"

**Decisions cited:**  
G 0001/93, G 0001/03

**Catchword:**

-



Case Number: T 1139/00 - 3.2.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.2**  
**of 10 February 2005**

**Appellant:** Cordis Corporation  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted 22 September 2000  
revoking European patent No. 0362826 pursuant  
to Article 102(1) EPC.**

**Composition of the Board:**

**Chairman:** S. S. Chowdhury  
**Members:** R. Ries  
E. J. Dufrasne

## Summary of Facts and Submissions

I. The appellant (patent proprietor, Cordis Corporation, USA) lodged an appeal against the decision of the opposition division to revoke the European patent No. 0 362 826. The decision was dispatched on 22 September 2000.

The notice of appeal and the fee for the appeal were received on 22 November 2000. The statement setting out the grounds of appeal was received on 23 January 2001.

Oppositions were filed against the whole patent and based on Article 100(a) to 100(c) EPC. The opposition division decided that claims 1 and 2 did not meet the requirement of Article 100(c) EPC and revoked the patent, accordingly. The decision further noted, by way of obiter dictum, that the claims also did not meet the requirement of Article 100(b) EPC.

II. Of the several documents cited during the opposition procedure, the following are of interest for the present decision:

D3: EP-A-0 135 990

D4: EP-A-0 274 411

D18: Fundamentals of Plastic Processing, High Polymer Association Corporation, Tokyo, 1982.

III. A first oral proceedings before the Board took place on 5 February 2004 and a second oral proceedings on 10 February 2005, at the end of which the following requests forming the basis of the decision were put forward:

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or alternatively according to the claims of the auxiliary requests I or II filed with its letter dated 5 January 2004. In case the patent should comply with the requirements of Article 123(2) EPC, remittal to the first instance for further processing is requested.

The respondents (opponents Biotronik Meß- und Therapiegeräte GmbH & Co (hereinafter respondent OI), Boston Scientific International BV (respondent OII), and Terumo K. K. (respondent OIII) requested that the appeal be dismissed.

IV. The independent claims 1 and 2 of the main request read as follows:

"1. A balloon for a medical device, comprising: a length of tubing made of a nylon material or of a polyamide material, said length of tubing having been formed into said balloon by axial elongation and radial expansion, disclaiming a balloon having been formed during a first step of axially elongating said tubing and a second step of inflating at least a section thereof with a pressurized fluid in order to radially expand said length of tubing to at least double its outer diameter, the balloon being such that said balloon has a non-distended working profile having a predetermined size to which the balloon inflates without significant stretching thereof, an expansion profile having a maximum inflated size to which the balloon stretches without bursting during dilatation,

said maximum inflated size being greater than said predetermined size of the non-distended working profile, and a calculated tensile strength of at least 103.4 MPa (15,000 psi).

2. A balloon for a medical device, comprising: a length of tubing made of a nylon material or of a polyamide material, said length of tubing having been formed into a biaxially oriented balloon, disclaiming a balloon having been formed during a first step of axially elongating said tubing and a second step of inflating at least a section thereof with a pressurized fluid in order to radially expand said length of tubing to at least double its outer diameter, the balloon being such that said balloon has a non-distended working profile having a predetermined size to which the balloon inflates without significant stretching thereof, an expansion profile having a maximum inflated size to which the balloon stretches without bursting during dilatation, said maximum inflated size being greater than said predetermined size of the non-distended working profile and a calculated tensile strength of at least 103.4 MPa (15,000 psi)."

Claims 3 to 19 are dependent on claims 1 and/or 2.

Auxiliary requests

In auxiliary request I claim 1 as granted has been cancelled, and in auxiliary request II claim 2 as granted has been cancelled.

V. The parties argued as follows:

Appellant

Column 1, lines 16 to 19 of EP-A2-0 362 826 gave the broadest disclosure of the invention, and the following parts of the description discussed the prior art, which used PET and PVC materials to make medical balloons. The application indicated that these balloons were made by biaxial orientation and the prior art materials had disadvantages which the application set out to overcome (column 3, line 41 onwards). The invention lay in the selection of materials and not in the biaxial method used to form the balloons, since any appropriate axial elongation, radial expansion and heat treatment procedures could be used (column 4, lines 5 to 10). The description with reference to the Figures only gave an example of a possible process.

G 1/03 was not limitative, it went beyond the referred questions and said that a disclaimer could be used for removing specific legal obstacles so long as the technical content of the application was not changed.

Moreover, G 1/03 said that the use of a disclaimer was the solution to a problem that could not be foreseen at the application date, such as the question of double patenting which applied to the present case. Moreover, the appellant had not gained any advantage by use of the disclaimer since this only limited the protection and did not breach the rights of third parties or lead to legal uncertainty, nor did it make any technical contribution to the disclosure of the patent.

Respondent OI

The question was not whether the steps of simultaneously stretching and radially expanding a tube were within the scope of the original claims, but whether a method containing the simultaneous steps was new as compared with the application as originally filed. This question was independent of the category of the claims and must be answered in the positive.

An amendment must be directly and unambiguously derivable from the original disclosure, and there was no such disclosure of simultaneous steps for producing a biaxially oriented balloon. The word "appropriate" in column 4, line 9 was unclear and could not be used to support a broad claim, only a two or four step sequential method as described with reference to Figures 2 and 3 was supported. If the apparatus of Figure 3 were to be used to carry out the steps simultaneously then the balloon would be non-uniform and susceptible to tearing. There was also no disclosure of balloons made by a general biaxially orienting procedure which had a tensile strength of at least 103.4 MPa (15,000 psi), the disclosure in column 14, lines 38 to 43, owing to the use of the words "as discussed herein", referred to the particular example only.

G 1/03 was limiting regarding the situations in which a disclaimer was allowable, and double patenting was not one of these. There were, moreover, no unforeseen circumstances justifying a disclaimer since the shape of the claims of the parent and divisional applications was entirely within the power of the appellant.



Moreover, the use of a disclaimer led to a fuzzy situation as foreshadowed in point 2.3.3 of G 1/03.

Respondent OII

The arguments of respondent OI were correct. In addition, the application as originally filed did not disclose a biaxially oriented balloon formed during a first step of axially elongating a tubing and a second step of inflating at least a section thereof to less than double its outer diameter, and which had a tensile strength of at least 103.4 MPa (15,000 psi).

A disclaimer may not be used to repair a mistake that occurred in the divisional application. If the disclaimed subject-matter were to be removed from the present application then all that would remain would be a vague description, and the requirement of Rule 27(1)(c) EPC would also not be met.

There were no external influences that created any unforeseen problems, the whole situation was the creation of the appellant itself. G 1/03 listed only three circumstances in which disclaimers were allowable and double patenting was not one of them. Moreover, the disclaimer made a huge difference to the technical content since the entire basis of the patent disappeared with the disclaimer.

Respondent OIII

There was no disclosure originally that the process in which a balloon was formed during a first step of axially elongating a tubing and a second step of

inflating at least a section thereof to at least double its outer diameter was not intended, so there was no support for the disclaimer in the application as originally filed. The four-step method was merely a variation of and came under the heading of a two-step method, and was for overcoming a different problem (column 8, line 20 onwards).

The paragraph in column 14, lines 33 to 43 meant that the process was important to the final properties of the balloon, and the required tensile strength was obtained only with the specific two-step method described with reference to the Figures, and this was what was meant by "appropriate" in column 4, line 9. The totality of the original disclosure did not support the fact that any biaxial orienting method would give the required tensile strength. In particular if the two steps were carried out simultaneously the process could not produce the required tensile strength.

The scope of the divisional patent had been restricted so the question of double patenting did not even arise and, therefore, the entire basis of the appellant's argument vanished. G 1/03 discussed only earlier and later applications and the question of novelty, but not the present type of situation. The scope of the claims had been changed arbitrarily by the disclaimer, whose further effect was to change the technical content of the application, and also to lead to lack of clarity.

## Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Use of a disclaimer in light of G 1/03*

- 2.1 The respondents consider the use of the "disclaimer" in independent claims 1 and 2 to be unallowable having regard to decision G 1/03 (OJ 2004, 413) of the Enlarged Board of Appeal.

- 2.2 The questions referred to the Enlarged Board of Appeal were:

"1. Is an amendment to a claim by the introduction of a disclaimer unallowable under Article 123(2) EPC for the sole reason that neither the disclaimer nor the subject-matter excluded by it from the scope of the claim have a basis in the application as filed?

2. If the answer to question 1 is no, which criteria are to be applied in order to determine whether or not a disclaimer is allowable?" [followed by a list of criteria].

The Enlarged Board answered as follows (see the Order):

"1. An amendment to a claim by the introduction of a disclaimer may not be refused under Article 123(2) EPC for the sole reason that neither the disclaimer nor the subject-matter excluded by it from the scope of the claim have a basis in the application as filed.

2. The following criteria are to be applied for assessing the allowability of a disclaimer which is not disclosed in the application as filed:

3.1 A disclaimer may be allowable in order to:

- restore novelty by delimiting a claim against state of the art under Article 54(3) and (4) EPC;
- restore novelty by delimiting a claim against an accidental anticipation under Article 54(2) EPC; an anticipation is accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention; and
- disclaim subject-matter which, under Articles 52 to 57 EPC, is excluded from patentability for non-technical reasons.

3.2 A disclaimer should not remove more than is necessary either to restore novelty or to disclaim subject-matter excluded from patentability for non-technical reasons.

3.3 A disclaimer which is or becomes relevant for the assessment of inventive step or sufficiency of disclosure adds subject-matter contrary to Article 123(2) EPC.

- 3.4 A claim containing a disclaimer must meet the requirements of clarity and conciseness of Article 84 EPC."
- 2.3 It follows both from the questions put to the Enlarged Board as well as from the Order of G 1/03 that this decision concerns only the situation where the subject-matter excluded from the scope of a claim did not have a basis in the application as filed. Thus, Point 2. of the Reasons states "the Enlarged Board of Appeal has to deal with the allowability of disclaimers which have not been disclosed in the application as filed. In this context, the term "unsupported" disclaimer is used in T 451/99, the President's comments and third parties' observations. The expression "unsupported" is avoided in the following reasons, since the term "support" in Article 84 EPC has a different meaning. Instead, the expression undisclosed is used."
- 2.4 An undisclosed disclaimer arises, for example, when the applicant was unaware of the existence of a document falling under the terms of Article 54(3) EPC at the time of filing, and upon subsequent revelation of this document the applicant restricts the scope of the claims using a disclaimer, in order to avoid a novelty objection. At the filing date of the application the applicant could not know which subject-matter would later have to be disclaimed and consequently did not disclose this subject-matter explicitly.
- 2.5 In the present case, by contrast, the subject-matter excluded by the disclaimer is supported by the application as filed. The situation is, as expressed by

respondent OII in its letter dated 29 September 2004, the opposite to that considered in G 1/03. Therefore, the present disclaimer is not one covered by the decision G 1/03. In the present case, instead of the term "disclaiming" the claims could equally have used "excluding" as a synonym since the claims intend to exclude part of the subject-matter that was originally disclosed.

- 2.6 Moreover, G 1/03 confined itself to the consideration of those cases where a disclaimer is employed in order to restore novelty in cases where documents under Article 54(3) and 54(4) are revealed after the application date, or to disclaim subject-matter excluded from patentability for non-technical reasons. G 1/03 did not consider the case of conflicting applications having the same applicant and the same application date, e.g. the case of parent and divisional applications. For these reasons the Board is of the opinion that the conclusions of G 1/03 do not apply to the present case.
3. The present Board has based its decision as to the allowability of the "disclaimers" in the present case on the basis of whether the patent proprietor gains an unwarranted advantage by its use, whether the use of a "disclaimer" could be damaging to the legal security of third parties, and whether it provides a technical contribution to the subject-matter of the claimed invention.

These are important considerations since the present decision must be compatible with G 1/93 (OJ 1994, 541), which is referred to in G 1/03. The latter decision

places considerable importance on whether a disclaimer changes the technical content of an application (see Reasons 2. third paragraph, 2.1.3 second paragraph, 2.2.2 last sentence of the last paragraph, and 2.4.1 penultimate sentence), or whether it affects the question of inventive step or sufficiency of the disclosure (points 2.5.2 and 2.5.3 of the Reasons). The same constraints must apply in the present case, even though this does not fall within the scope of G 1/03.

As set out in G 1/93, an applicant may not gain an unwarranted advantage by an amendment, and so damage the legal security of third parties (point 9 of the reasons). G 1/93 considers that the main purpose of Article 123(2) EPC is to create a fair balance between the interests of applicants and patentees, on the one hand, and competitors and third parties, on the other hand (point 8. of the Reasons). It then concludes that "A feature which has not been disclosed in the application as filed but which has been added to the application during examination and which, without providing a technical contribution to the subject-matter of the claimed invention, merely limits the protection conferred by the patent as granted by excluding protection for part of the subject-matter of the claimed invention as covered by the application as filed, is not to be considered as subject-matter which extends beyond the content of the application as filed within the meaning of Article 123(2) EPC. The ground for opposition under Article 100(c) EPC therefore does not prejudice the maintenance of a European patent which includes such a feature" (point 2. of the Order).

- 3.1 The only effect of the introduction of the disclaimers in the present case is to remove one embodiment from the scope of protection without providing any technical contribution to the invention as claimed. As discussed in point 4.1 below, the original claims envisaged a dilation balloon made of tubing which was biaxially oriented using one of a group of known processes, from which group one particular process (forming a balloon during a first step of axially elongating a tubing and a second step of inflating at least a section thereof with a pressurized fluid in order to radially expand the tubing to at least double its outer diameter) has now been removed to leave a more limited group. The patent proprietor gains no advantage from this limitation, nor does limiting the scope of the original claims affect the rights of third parties.
- 3.2 The respondents argued that the disclaimers in the present case do change the technical content of the patent since only one embodiment was originally disclosed and removing this drastically alters the technical teaching. However, that this is not the case is demonstrated in points 4.3 and 4.4 below.
- 3.3 The respondents further argued that the use of a disclaimer leads to lack of clarity since the subject-matter can and, therefore, should be expressed in positive terms. The Board does not share this opinion since, although the application as filed did envisage various methods of biaxially expanding a tube, it did not explicitly mention any of these except the one now excluded. The application as filed did not contain any disclosure encompassing in general and positive terms any but the presently claimed embodiment. To express



the subject-matter in positive terms in the claims would have led to an objection under Article 123(2) EPC and was avoided for this reason.

3.4 For the above reasons the use of the "disclaimer" in the claims is not objectionable.

4. *Article 123(2) EPC*

4.1 Disclosure of the application as originally filed

The opening paragraph of the description describes the invention in general terms as relating to balloons for medical devices, having certain expansion properties, ie expansion beyond a non-distended inflated size, and states that "Balloons which are especially suitable in this regard are made of nylon or polyamide tubing that has been biaxially oriented into the desired balloon configuration." The subsequent introductory passages of the description describe prior art medical balloons made of polyethylene terephthalate (PET) and PVC material and their drawbacks. Non-distensible prior art balloons were made of PET material, whereas PVC and cross-linked polyethylenes were used to make distensible balloons.

Both these materials have associated technical problems, as set out in column 2, line 38 (of the A2 publication) onwards. PVC materials have low tensile strength, for example, whereas PET materials have undesirable properties, for example too high a Young's modulus.

The disadvantages of balloons made from PET and PVC materials are overcome by the choice of nylon or

polyamide material for the balloons, and the selection of these materials forms the technical essence of the claimed invention (column 1, lines 16 to 19, column 4, lines 5 to 10, claim 1, etc). The balloons of the invention, made of nylon or polyamide material and using an appropriate method, should have the controlled distensibility and flexibility of PVC balloons, and the strength of PET balloons. The application as originally filed does not place any importance on the method of manufacture of the balloon.

It was known in the prior art to make PET balloons using different bi-axial orientation processes. In this respect D4 states (page 3, lines 39 to 41) that the PET parison preferably is drawn axially and while being so drawn, is expanded radially within the mold. This is a disclosure of a simultaneous axial and radial expansion. D18 (page 12) discloses two different biaxial orientation procedures, a method involving successive steps of stretching in the vertical and horizontal directions, and a simultaneous stretching method. The first method is described for PET and polypropylene materials. The person skilled in the art who wants to make a medical balloon would also consider employing such known processes, together with combinations and variations thereof, if the material was nylon or polyamide instead. Variations of the basic process are described in D3, page 7, lines 23 to 26, for example.

According to the application, column 4, lines 8 to 10, the material is "formed into a biaxially oriented balloon by appropriate axial elongation, radial expansion and heat treatment procedures". In the context, this passage means that the nylon or polyamide

material is subjected to any known and appropriate biaxial orientation processes in order to form the balloon, such as disclosed in D3, D4, D18, etc.

The particular description from column 4, line 48 onwards describes one way of carrying out the invention and in particular describes, with reference to Figures 2 and 3, a process and apparatus for making balloons, which involves a first step of axially elongating a tubing and a second step of inflating a section thereof in order to radially expand the tubing to at least double its outer diameter. However, this illustrates an example only, nowhere is it stated that balloons according to the invention may only be obtained using this two-step method.

Claim 1 of the application as originally filed claims a "balloon for a medical device, the balloon comprising: a length of biaxially orientable tubing made of a nylon material or of a polyamide material, said length of tubing having been formed into the balloon during a biaxial orienting procedure including inflating at least a section thereof with a pressurized fluid in order to at least double its outer diameter.....". Original independent claim 13 relates to a catheter but mentions tubing that had been biaxially oriented, and original independent claim 18 relates to a dilation balloon and also mentions tubing that had been biaxially oriented.

Thus the person skilled in the art would understand that the intention at the time of filing was to claim, by means of a product-by-process claim, a balloon made by subjecting a tubing to a biaxial orientation process,

which is to say any biaxial orientation processes, and not necessarily the two-step process described with reference to the Figures. Only original process claim 23 is restricted to making a balloon by successive steps of longitudinally stretching a length of biaxially orientable tubing to provide drawn tubing and radially expanding the thus drawn tubing to a balloon member. However, the radial expansion step of this claim need not expand the length of tubing to at least double its outer diameter.

Claiming the product made by a broader process than that illustrated with reference to the Figures was originally justified since the crux of the invention was the selection of the new materials nylon or polyamide in preference to the known materials PET and PVC, rather than in the biaxial orientation process, which was already known in the prior art and could also be applied to nylon or polyamide materials.

Thus, original claim 19 broadly claims, as the invention, a dilatation balloon comprising a length of thermoformable material tubing that had been biaxially oriented to a predetermined diameter and which has a calculated tensile strength of at least about 15,000 psi. The balloon may be biaxially oriented using an appropriate biaxial orientation process, as stated in column 4, lines 5 to 10, and not necessarily the biaxial orientation process described with reference to Figures 2 and 3, ie which involves a first step of axially elongating a tubing and a second step of inflating a section thereof in order to radially expand the tubing to at least double its outer diameter.

In summary, having knowledge of the prior art, a variety of biaxial orienting processes would occur to the person skilled in the art for making a balloon, such as that which involves a first step of axially elongating a tubing and a second step of inflating a section thereof in order to radially expand the tubing to at least double its outer diameter, or simultaneously elongating a tubing and inflating a section thereof, or combinations and variations of these processes, etc. Therefore, original claim 18 envisaged a dilation balloon made of tubing which was biaxially oriented using one of a group of processes.

The effect of the "disclaimer" in the claims is to exclude one particular process from the group of processes, to leave a more limited group, which merely narrows the scope of the claims.

#### 4.2 Amendments

Apart from the disclaimer the following amendments to granted claim 1 (i.e. the main request) are controversial:

- (i) Granted claim 1 uses the wording "said length of tubing having been formed into said balloon by axial elongation and radial expansion" instead of "said length of tubing having been formed into the balloon during a biaxial orienting procedure" in original claim 1.
- (ii) Granted claim 1 includes the feature "a calculated tensile strength of at least 103.4 MPa (15,000 psi)".

Claim 2 relates to a balloon for a medical device, comprising a length of tubing made of a nylon material or of a polyamide material, said length of tubing having been formed into a biaxially oriented balloon. This claim also incorporates amendment ii).

The opposition division found that amendment i) was objectionable since the original application disclosed only the sequence of steps whereby the tube was first axially elongated and then radially expanded, whereas the new claim encompasses other sequences of the axial and radial expansion steps. Moreover, the tensile strength of 103.4 MPa was strictly bound with the two-step process disclosed, ie axial elongation followed by radial expansion.

#### 4.3 Allowability of the new claims

Amendment i)

As explained in point 4.1 above, the person skilled in the art would understand that the intention at the time of filing was to claim, by means of a product-by-process claim, a balloon made by subjecting a tubing to a biaxial orientation process, which is to say any biaxial orientation processes, and not only the two-step process described with reference to the Figures. Therefore, the amendment i) in the claims of the main request meets the requirement of Article 123(2) EPC.

Amendment ii)

As stated above, original claim 19 claims a dilatation balloon tubing that had been biaxially oriented to a predetermined diameter and which has a calculated tensile strength of at least about 15,000 psi. The balloon may be biaxially oriented using any appropriate biaxial orientation process. This claim, therefore, provides support for amendment ii).

4.4 In summary the disclaimer in the claims does not alter the technical teaching of the application, and claims 1 and 2 meet the requirement of Article 123(2) EPC.

5. *Article 100(b) EPC*

It appears from the minutes of the oral proceedings before the opposition division that the chairman set out the provisional opinion of the opposition division at the outset of the oral proceedings, that the patent was objectionable under Article 123(2) EPC and also under Article 100(b) EPC.

However, the debate at the oral proceedings before the opposition division was confined only to the matter of Article 123(2) EPC, and the position under Article 100(b) EPC was not discussed further, so that the patent proprietor and the opponents did not have the opportunity to argue their case under Article 100(b) EPC orally.

In order not to deprive the parties of their opportunity of pleading their respective cases orally

before two instances, it is appropriate to remit the case to the first instance for a reconsideration of this point. In this respect a reference to the decision T 291/96 of this Board may be helpful to all parties. The ground of opposition under Article 100(a) EPC is also to be considered.

## **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 for further prosecution.

The Registrar

The Chairman

V. Commare

S. S. Chowdhury