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D E C I S I O N
of 19 October 2000

Case Number: T 0291/96 - 3.2.2

Application Number: 91103956.8

Publication Number: 0436501

IPC: A61M 25/10

Language of the proceedings: EN

Title of invention:
Balloons for medical devices and fabrication thereof

Patentee:
Cordis Corporation

Opponent:
Terumo Kabushiki Kaisha Head Office
Schneider (Europe) AG
Guidant Corporation

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 84

Keyword:
"Inventive step (yes) after amendment"
"Public prior use: (no) - insufficient probative value of evidence submitted"

Decisions cited:
T 0021/81

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0291/96 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 19 October 2000

Appellant: (Opponent)
Terumo Kabushiki Kaisha Head Office
44-1, 2-chome Hatagaya
Shibuya-ku
Tokyo (JP)

Representative:
Tiedtke, Harro, Dipl.-Ing.
Patentanwaltsbüro
Tiedtke-Bühling-Kinne & Partner
Bavariaring 4
D-80336 München (DE)

Respondent: (Proprietor of the patent)
Cordis Corporation
14201 N.W. 60th Avenue
Miami Lakes
Florida 33014 (US)

Representative:
Prins, Hendrik Willem
Arnold & Siedsma
Advocaten en Octrooigemachtigden
Postbus 18558
NL-2502 EN Den Haag (NL)

Other party: (Opponent)
Guidant Corporation
111, Monument Circle Tower, 29th Floor
Indianapolis, IN 46204 (US)

Representative:
Witmans, Hermanus Albertus
Vereenigde
Postbus 87930
NL-2508 DH Den Haag (NL)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 29 January 1996 concerning maintenance of European patent No. 0 436 501 in amended form.**

Composition of the Board:

Chairman: W. D. Weiß
Members: R. Ries
R. T. Menapace

Summary of Facts and Submissions

I. European patent No. 0 436 501 was granted on 21 April 1993 on the basis of European patent application 91103956.8.

II. The granted patent was opposed by the present appellant (Opponent I: Terumo K.K.) on the grounds of lack of novelty and lack of inventive step (Article 100(a) EPC. Opponent II (Schneider Europe AG) withdrew its opposition in a letter of 12 September 1995.

III. With its interlocutory decision posted 29 January 1996 the Opposition Division held that, taking into account the amendments made by the patent proprietor during the opposition procedure, the patent and the invention to which it relates meet the requirements of the EPC. In the opposition proceedings, inter alia the following documents were considered:

D2: EP-A-0 349 640

D3: EP-A-0 135 990

D4: EP-A-0 274 411

D11: Cristal balloon brochure January 1989

D12: Letter of Mr Plowiecki

D13: Description of Rilsan polyamide, ATO Chemie 12/1991

D14: "Un polyamide souple LE RILSAN N" Extrait de la Revue "P.M.E: No. 2, March 1974

D18: First Declaration of Mr Plokker

D23: Affidavit of Professor Goodman (Annexes IG1 to IG4)

D24: Second declaration of Mr Plowiecki

D25: Declaration of Mr Jansen

D26: Second Declaration of Mr Plokker

D30: Experiments I and II of Isamu YAMAGUCHI, submitted on 31 May 1996

IV. An appeal against this decision was filed by Opponent I on 27 March 1996 and the appeal fee paid on the same date.

A notice of intervention pursuant to Article 105 submitted on 14 December 1998 was withdrawn with letter of 27 April 2000.

In the appeal proceedings, the following further documents were referred to:

D31: WO95/23619 (cited by the patentee)

D32: US-A-4 331 786

D33: JP-A-62-148 669 (cited by the opponent)

D33a: translation of D33

D34: JP-A-62-39 813

D34a: translation of D34

D35: JP-A-64-34 375

D35a: translation of D35

D36: Opinion on Experiments (Japanese experimental report) pages 1 to 13 by Kiyoichi Matsumoto dated 19 September 1997 and submitted on 4 December 1997

D36a: translation of D36 into English

D37: K. Hamaguchi "Lectures on Packaging Film (3) in Food Packaging, January 1988, pages 313 to 330, 364 and translation into English

D38: "Thermoplastic Elastomers, a Comprehensive review", N. R. Legge, G. Holden, H. E. Schroeder ed., pages 218, 225

D39: Handbook of Thermoplastic Elastomers, 2nd edition, van Nostrand Reinhold Company Inc. page 261 (no publication date, not present)

D40: M. Kohno et al., "Properties of Biaxially oriented Nylon 66 Film" in Polymer Engineering and Science, April 1987, vol. 27, No. 8, pages 558 to 561

D41: US-A-4 525 531

D42: Declaration of Mr R. Peura, including documents

D42a: S. B. Levy "Improved Dilation Catheter Balloons",

Journal of Clinical Engineering, volume 11, No. 4, July-August 1986, pages 291 to 296.

D42b: Strength of Materials, Part II; S. Timoshenko, Second Edition, pages 158 to 173

D42c: Mechanics of Materials, F. P. Beer, E. Russel, McGraw Hill 1981, pages 325 to 327

D43: Affidavit of G. Lieber including document

D43a: Resistance of Materials, Fourth Edition, J. Wiley and Sons, 1957, four pages

D44: Affidavit of Mr Trotta including exhibits A to D

D45: Affidavit of D. Berten including Exhibits 1 to 3

D46: Affidavit of G. Lieber

D47: US-A-5 264 260

D48: US-A-5 330 428

D49: Affidavit of P. Hendrick

V. Oral proceedings were held before the Board on 19 October 2000.

The appellant (opponent I) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the decision under appeal be set aside and that the patent be

maintained in amended form

- with claim 1 as submitted at the oral proceedings as main request and first auxiliary request, further claims and description to be adapted accordingly, or

- as second auxiliary request, with the following documents:

  Claims: 1 to 7

  Description: pages 2a, 2b, 2c, 3 as submitted at the oral proceedings, page 5 as underlying the decision under appeal, pages 6 to 10 and

  Figures: 1 to 7 as granted.

Claim 1 of the main request reads as follows:

"1. A biaxially oriented balloon for a medical device, which balloon is made of a nylon or another polyamide material; and said balloon has a non-distended working profile having a predetermined size to which the balloon inflates without significant stretching thereof, and said balloon has an expansion profile having a maximum inflated size to which the balloon stretches without bursting during use, said maximum inflated size being greater than said predetermined size of the non-distended working profile; and said balloon has a calculated tensile strength of at least about 103.4 MPa (15,000 psi);

which balloon is obtainable by a process comprising mechanically stretching a length of tubing in the radial and longitudinal directions wherein said length of tubing having been formed into said balloon 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 wording of claim 1 of the first auxiliary request differs from the main request by the restriction that "the balloon is made of nylon 12" in line 2 of the claim.

Claim 1 of the second auxiliary request reads as follows:

"1. A process for tailoring expansion properties of a balloon for a medical device, the process comprising:

longitudinally stretching a length of tubing having an initial diameter made of nylon or another polyamide material capable of being tailored by the steps hereof to provide drawn tubing;

radially expanding the thus drawn tubing to a balloon member, said balloon member having a non-distended working diameter and having a hoop expansion ratio, which hoop expansion ratio is an approximate ratio of said non-distended working diameter to said initial diameter of the tubing;

said radially expanding step including selecting said hoop expansion ratio to be 3 to 6 such that the balloon member exhibits a maximum inflated size to which the balloon stretches without bursting during

use, said maximum inflated size of the balloon member having a range of expansion profile maximum inflated sizes of at least about 10 percentage points of radial expansion and said balloon has a calculated tensile strength of at least about 103.4 MPa (15000 psi)."

VI. The arguments put forward by the appellant can be summarized as follows:

As to the calculated tensile strength (TS) of 15,000 psi featuring in claim 1 of all requests, no information whatsoever can be found anywhere in the patent specification showing the reader a method to determine this value accurately. Moreover, the tensile strength has to be calculated rather than measured on the basis of specific parameters which can be measured. The physical and mechanical parameters of the polymers to be measured are, however, strongly dependent e.g. on the temperature, the degree of humidity and/or the inflation rate, and various standard methods (DIN or ASTM) are at the disposal of the expert. Since a bi-axially oriented material exhibits different tensile strengths in the axial and radial direction, it remains also unclear which type of the TS should be 15,000 psi. Given this situation, this mechanical property claimed in the patent cannot be regarded as representing a clear technical feature which distinguishes the claimed subject matter from the subject matter of the prior art.

A percutaneous transluminal coronary angioplasty catheter comprising a so-called "Cristal Balloon" was marketed before the priority date of the patent at issue. The Cristal Balloon has been made of RILSAN N ever since 1987 which is a polyamide material

exhibiting the mechanical properties called for by claim 1 of the patent. Evidence for this public prior use of the claimed balloon is found in documents D9 to D18 and D24 to D26. The Cristal Balloon, therefore, anticipates the subject matter of claim 1 of the main and the first auxiliary request.

As to the question of novelty further reference is made to documents D2, D33a and D34a. Document D2 discloses an expansible member or balloon made of a polyamide elastomer (cf. D2, page 20, second paragraph). The balloon is formed by axially elongating and radially expanding a heated tube and is, therefore, biaxially oriented (cf. D2, Figures 23 to 25). Furthermore, document D33a discloses a medical balloon formed by stretch blow moulding a polyamide type resin and document D34a specifically mentions an endoscopic catheter including a therapeutic balloon which inflates to a predetermined size and which is formed of EEA, EVA or nylon (cf. claims 13, 14; Example 4). Taking the view that every nylon or polyamide material after a stretching treatment always exhibits a TS >15,000 psi, the subject matter of claim 1 of the main and first auxiliary request lacks novelty.

Even if novelty were acknowledged, the claimed subject matter would lack an inventive step. As shown above, a plethora of evidence exists (documents D2, D33a, D34a) disclosing polyamides or nylon as a material suitable for forming a therapeutic balloon. As set out in decision T 21/81, Headnote II, it belongs to the normal activities of a skilled person to select from the materials which are known to him as suitable for a certain purpose the most appropriate one. Consequently, it does not involve an inventive step to select nylon,

or more preferably nylon 12, for forming the balloon. As confirmed by the patentee, the two-step process of bi-axially stretching the balloon material within specific limits to improve its mechanical properties merely represents a conventional standard method which taken per se is well known in the art, as disclosed for instance in document D2. The subject matter of claim 1 of all requests, therefore, does not involve an inventive step.

VII. The respondent (patentee) argued as follows:

As to the technical feature of a calculated TS > 15,000 psi claimed in the patent, a person skilled in this field of technology knows that he or she has to use the well known "pressure vessel equation" for calculating the tensile strength in the circumferential (radial) direction. This position is confirmed by the statements given in documents D42, D43, D3, D4 and D30 and by the fact that many prior art documents refer to a TS or burst pressure strength without specifying a particular test method. Regarding the testing conditions, it is self-explanatory from the patent specification and its context that the testing of the balloon is to be done under doctor/patient conditions, i.e. at 37° within water (see also Figures 4 to 7 of the patent specification). Moreover, the experts elaborating the experimental data given in D36 the appellant relied upon had no problems to determine accurately the tensile strength of the tested material in spite of the fact that the patent at issue does not specify a particular test method. Hence, the calculated TS > 15,000 psi featuring in claim 1 of all requests is a clear and distinguishing technical feature.

Turning to the public prior use, it is noted that document D11 disclosing the BALT Cristal Balloon made of polyamide materials is published after the priority date of the patent at issue. In documents D12 and D24, Mr Plowiecki declares that since November 1987 the Crystal Balloon has been made of RILSAN N and that the material has remained unchanged ever since. However, the melting point of the Crystal balloon material (sterilisation date 1993) tested twice by Mr Trotta (D44) was different from the melting point reported for Rilsan N by ATO Chimie in 1974 (D14), thus proving that a material different from Rilsan N had been used in 1993. Consequently, it has not been proven beyond any possible doubt which type of polymeric material was actually used at the priority date of the patent at issue.

As to the novelty of the claimed subject matter, none of the documents discloses a balloon exhibiting a calculated TS >15000 psi. Although document D2 mentions "polyamide elastomers" together with various chemically different polymers, the list given on page 50/51 fails to mention "polyamide elastomer" as a material preferred for the expansible member. Also the teaching given in document D33a is not novelty destroying for claim 1 since inter alia polyamide type resin among many other resins is disclosed as a material appropriate for the balloon. However, no specific example is given. Besides, stretch blow moulding does not result automatically in a biaxially stretched material exhibiting the required tensile strength. Turning to document D34a, this document remains silent about the method of how the balloon which can be made of ethylene ethylacrylate (EEA), ethylene vinyl acetate (EVA) or nylon has been actually formed.

Regarding inventive step, the problem underlying the patent at issue resides in a better controlled and improved distensibility of the balloon. The material commonly used in the art heretofore for the balloon had been non-distensible polyethylene terephthalate (PET) or, alternatively, distensible low-tensile strength polyvinyl chloride (PVC), but nothing in any of the cited documents would lead a skilled person to note that by specifically selecting polyamide or even nylon a high tensile strength in combination with a controlled distensibility of the balloon could be achieved, while maintaining the strength and flexibility and without pin-holing or rupture. Thus, the opponent's allegations are purely based on hindsight. The subject matter claimed in the patent at issue, therefore, involves an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. *Prior use*

2.1 In order to determine whether an invention has been made available to the public by prior use, the following facts must be provided:

(a) the date of the prior use

(b) the precise object of the prior use

(c) the circumstances of the prior use.

In the present case, the Board has to consider whether

an unbroken chain of evidence relating to the nature of a balloon made of RILSAN N and its method of manufacturing was presented by the appellant.

2.2 According to the statements of Mr Plowiecki (documents D12 and D24) RILSAN N has been the only material ever used from 1986 up to the present time (i.e. 25 November 1994) to manufacture the balloon of the "Balt Cristal Balloon" catheter. According to his declaration (D18), Mr Plokker, in 1987, discussed with Mr Plowiecki a new product called "Cristal Balloon" and performed burst pressure tests with Cristal balloons available at that time. The high balloon strength was attributed by Mr Plokker to the polyamide material the balloon was made of, and the test results were presented to Mr Plowiecki (cf. D18, points 2 and 3).

2.3 However, the allegation of public prior use is not sufficiently founded. Firstly, it is noted that the only document D11 which mentions a Cristal balloon made of polyamides has a publication date of January 1989 which is after the first priority date of the patent at issue. Secondly, Mr Plowiecki failed to present the burst pressure test results he had obtained from Mr Plokker in 1987, and it is further uncertain whether the balloon material actually had been biaxially stretched. Thus, no positive evidence was produced in the form of test results concerning a Cristal balloon that had been produced **before** the priority date of the patent at issue.

Thirdly, the tests performed by Mr Trotta (cf. document D44, page 7) on a Cristal Balloon bearing a sterilisation date of October 1993 (i.e. 5 years after the priority date of the patent at issue) reported a

melting point of 172°C of the balloon material. It is noted in this context that the melting point represents a "fingerprint" of the investigated polymeric material and remains unchanged by forming the polymer. However, the melting point of 172°C significantly differs from the melting point of 150 to 155°C attributed to RILSAN N in 1974 by ATO Chimie (document D14). This temperature complies with the melting point reported for RILSAN N in document D23, annex IG4, "Non plasticized polyamide with flexibility", Table 1. It thus appears that either there has been a change in the material of the Balt Cristal balloon or that the composition of RILSAN N has been modified by ATO Chimie over the years. In view of these considerations, it must be concluded that the precise nature of the "Cristal balloon" material marketed in 1987 is uncertain.

Given this situation, the probative value of the various affidavits and documents produced by the appellant is in no way sufficient to prove up to the hilt and with such a high degree of certainty which is beyond all reasonable doubt that a catheter balloon exhibiting the technical features given in claim 1 was made available to the public before the priority date of the patent at issue.

3. *Main request and first auxiliary request*

3.1 The closest prior art

Among the cited documents, only document D34a deals with an endoscope catheter comprising a balloon which inflates to a predetermined size and which definitely is formed of EEA, EVA **or nylon** (cf. D34a, claims 13 and

14). Moreover, also Example 4 identifies nylon as a suitable material for the therapeutic balloon that is adapted to expand a stenosis in a blood vessel. Given that document D34a (i) discloses the same polyamide (nylon) which is the most preferred material for the claimed balloon and (ii) that the balloon is intended for the same therapeutic use, this document represents the closest prior art. However, document 34a remains silent about the mechanical properties of the balloon and about the method of its production.

3.2 The problem to be solved

Starting from this prior art, the problem underlying the patent at issue, therefore, resides in providing a balloon which exhibits a specific tensile strength in the radial direction in combination with a controlled distensibility so that a limited expansion beyond the fully expanded but non-distended dilatation profile is possible. The solution to this problem consists in the biaxially stretching step by which the mechanical parameters and expansion characteristics of the nylon balloon are tailored to the application in a particular environment.

3.3 Inventive step

The above mentioned solution would, however, be obvious for a medical engineer. The expert is aware of the fact that the dilatation characteristics of a catheter balloon are dependent on

(i) the selected material,

(ii) the tubing extrusion and

(iii) the biaxial orientation process (cf. D2, page 46 to page 47, line 6; D42a, page 292, right hand column, paragraph 2, page 293, paragraph "Orientation", Figures 4a to 4d).

From document D34a, nylon or EEA or EVA are known to him as suitable balloon materials. Based on this professional knowledge, it forms part of the normal activities of a skilled person to test the required mechanical properties of the materials proposed by document D34a and - in order to meet a specific user's needs - to select the most appropriate one from three materials which are known as being suitable for producing therapeutic balloons. In the present case the first choice has been nylon or, among the various nylon types, even nylon 12. Moreover, biaxial stretching merely represents a standard method for making catheter balloons to tailor the properties of the balloon according to the needs of the client. Thus, the biaxial orientation is typical for balloons made of polymeric material. This position is unchallenged by the respondent and is confirmed by the affidavit of its own expert (cf. document D43, points 25, 26). The calculated tensile strength and the controlled distensibility are a consequence of the stretching process of the selected balloon material, since they are an inherent property of nylon.

Hence, the subject matter of claim 1 of the main request and of the first auxiliary request lacks an inventive step.

4. *Second auxiliary request*

4.1 Amendments (Article 123(2), (3) EPC)

Claim 1 of the second auxiliary request derives from a combination of claims 19, 20, 3 and 4 of the claims as granted. The addition of the word "**another** polyamide" and replacing the word "inflated **diameter**" by "inflated **size**" are editorial amendments which do not affect the scope of the claim. Dependent claims 2 to 7 correspond to claims 21 to 26 in form as granted. Hence, there is no formal objection to claims 1 to 7 of the second auxiliary request. The description has been suitably adapted to the amended wording of claim 1 and equally satisfies the requirement of Article 123(2), (3) EPC.

4.2 Clarity (Article 84 EPC)

In particular with respect to the tensile strength of 15000 psi, the appellant alleged that it is unclear which tensile strength in claim 1 exactly is meant and how it should be calculated. The Board is, however, convinced that the expert skilled in designing dilation balloons will know that he has to apply the well known "pressure vessel equation" to determine the burst pressure, diameter and wall thickness of the balloon for arriving at the calculated tensile strength. This estimation is confirmed by document D3, page 4, lines 33 to 37; D4, page 4, lines 55 to 60 D43, page 1, point A.; D42a, page 296, Figure 6. Furthermore, the skilled reader appreciates from the patent specification as a whole that realistic test conditions are to be chosen, i.e. the doctor/patient situation at which the balloon will be used. Hence, there is no need, although it would have been desirable, to specify in detail all the test conditions and formulae that should be used for calculating the TS.

The subject matter of claim 1 of the second auxiliary

request, therefore, meets the requirements of Article 84 EPC.

5. *Novelty*

None of the cited documents discloses a process for tailoring the expansion properties of a therapeutic balloon made of nylon or another polyamide material comprising the step of radially expanding the balloon with a hoop expansion ratio between 3 and 6. The subject matter of claim 1, therefore, is novel. This issue not being in dispute, it is not necessary to give detailed reasons for this finding.

6. *Inventive step*

6.1 The closest prior art

Also for the subject matter covered for in claim 1 of the second auxiliary request, document D34a represents the closest prior art for the reasons set out in point 3.1.

6.2 Problem to be solved and solution

Starting from document D34a as closest prior art, the problem underlying the claimed process consists in providing a reproducible method which results in a balloon member that

(i) exhibits the ability to be expanded to a first non-distended working size upon the application of a given pressure and,

(ii) in addition thereto, has the ability to be

inflated further so as to be stretched beyond that point **in a controlled and limited manner.**

The solution to this problem consists in radially expanding the polyamide balloon material with a hoop expansion ratio in the range of 3 to 6. By working within this hoop expansion ratio, the balloon exhibits an additional radial expansion of at least 10 percentage points. It is clearly evident from Figure 7 and the accompanying text in column 16 of the patent, lines 20 to 29 that the balloon expansion tailorability is a function of the hoop expansion ratio (cf. also column 15, lines 31 to 34 and 39 to 42 of the patent specification). Hence, the problem specified above is successfully solved by the process set out in claim 1 of the second auxiliary request.

The problem of tailoring the therapeutic balloon by a specific treatment so that in practice it covers values within a span of at least 10 percentage points of radial expansion beyond the non-distended condition without running the risk of overinflation or bursting is not addressed in any of the cited documents. Although document D2 discloses on page 46 axially and radially stretching to produce a balloon, it remains silent about the degree of radial stretching, and it is doubtful whether polyamide materials actually were envisaged as a balloon material. Documents D3 and D4 both relate to balloons preferably made of PET rather than polyamides or nylon. More specifically, document D3 states that a balloon of higher strength can be produced from polymeric tubing by operating at high stretch ratios i.e. at the upper ends of the draw and expansion ratios, while document D3 discloses radially expanding the drawn tubing to an internal diameter

which is six to eight times the initial diameter of the parison to achieve a high degree of orientation and tensile strength values of more than 35000 psi (cf. D3, page 5, lines 13 to 17; D4, claim 10). These balloons should, however, exhibit dimensional stability in storage as well as under inflation conditions (cf. p. 3, lines 79/80) which means that a certain degree of distensibility is not envisaged. The balloons described in D33a are produced by stretch blow moulding without, however, giving any details about the radial expansion ratio. Document D34a completely fails to give any information about the method of how the therapeutic balloons made of EEA, EVA or nylon have been produced. The remaining documents are more remote in that they either relate to different balloon material or, if polyamides or nylon are mentioned, a non-medical application different to that claimed is envisaged. Thus, the man skilled in the art had no incentive based on these documents to choose the claimed hoop expansion ratio in order to achieve a balloon exhibiting a controlled distensibility. Consequently, given that the problem addressed by the patent in suit is not realized in any of the above mentioned documents, they are far from giving any suggestion towards the problem solved by the patent at issue.

6.3 In view of these considerations, the subject matter of claim 1 of the second auxiliary request involves an inventive step within the meaning of Article 56 EPC.

7. The dependent claims 2 to 7 relate to preferred embodiments of the process given in claim 1 and are, therefore, equally allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form with the following documents:

Claims: 1 to 7 submitted as 2nd auxiliary request at the oral proceedings

Description: pages 2a, 2b, 2c and 3 as submitted at the oral proceedings;
page 5 as underlying the decision under appeal;
pages 6 to 10 as granted;

Figures: 1 to 7 as granted.

The Registrar: The Chairman:

V. Commare W. D. Weiß