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Datasheet for the decision of 23 August 2012

Case Number: T 1550/06 - 3.2.02

Application Number: 89118420.2

Publication Number: 362826

IPC: A61M 25/10

Language of the proceedings: EN

Title of invention:
Balloons for medical devices

Patent Proprietor:
Cordis Corporation

Opponent:
Biotronic SE & Co. KG
Terumo Kabushiki Kaisha Head Office

Headword:
-

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
"Insufficiency of disclosure (no)"

Decisions cited:
T 1139/00, T 0291/96

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1550/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 23 August 2012

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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 18 August 2006 revoking European patent No. 362826 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: E. Dufrasne
Members: P. L. P. Weber
M. Stern

Summary of Facts and Submissions

I. The appeal by the patent proprietor is against the decision of the Opposition Division posted on 18 August 2006 to revoke the patent because it did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

The appeal was filed on 5 October 2006 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 22 December 2006.

II. The Appellant requests as main request the maintenance of the patent as granted. The auxiliary requests are not relevant for the present decision.

Respondent III (Opponent III) requests dismissal of the appeal and remittal of the case if the Board considers the requirements pursuant to Article 100(b) EPC to be fulfilled. It also requests oral proceedings as an auxiliary measure.

There are no requests on file from Respondent I (Opponent I).

Respondent II (Opponent II) withdrew its opposition unconditionally (letter of 19 October 2009).

III. Claim 1 according to the main request reads as follows:

"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)."

Claim 2 according to the main request reads as follows:

"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)."

IV. A patent (EP-B-0436501) was granted in 1993 on the basis of a divisional application of the present application, opposed and the corresponding decision appealed (T 0291/96). The independent claim as accepted to be maintained by the Board, i.e. the then 2nd auxiliary request, included the feature that the balloon has a calculated tensile strength of at least about 103.4 MPa (15 000 psi). The originally filed description and drawings were identical to those in the patent in suit.

In T 0291/96 the Board summarised one argument relative to the tensile strength feature of the then Appellant (Opponent III) in the following way under point VI of the Facts and Submissions:
"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."

Under point 4.2 of the Reasons, the Board then established that claim 1 of the 2nd auxiliary request met the requirements of Article 84 EPC.

V. The wording of present independent claims 1 and 2 comprises a disclaimer: "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".

In a first decision the Opposition Division revoked the patent because it considered that the claims violated Article 123(2) EPC.

In a first appeal (T 1139/00) following that first decision the Board found Article 123(2) EPC to be fulfilled (in particular the disclaimer allowable, point 4.1 of the Reasons) and remitted the case for further prosecution.

VI. During the further prosecution of the case the Opposition Division took the decision presently under appeal to revoke the patent under Article 100(b) EPC.

The Opposition Division considered the requirements of sufficiency of disclosure essentially not fulfilled for two reasons:

i) the patent was silent about the method to be used to reach the calculated tensile strength of at least 103.4 MPa (15 000 psi) so that the person skilled in the art was unable to carry out the invention. The Opposition Division based its opinion in this respect mainly on the declaration (D51) of Mr Meier (point 2.4 of the Reasons).

ii) the disclaimer excluded from the claims all the balloons formed according to the sole process described in the description so that the person skilled in the art was unable to manufacture a balloon according to claim 1. More particularly, balloons manufactured by first axially elongating the parison and then radially expanding the parison were no longer claimed so that only balloons manufactured either by simultaneously elongating and expanding or by first expanding and then elongating the parison were covered by the wording of the claim. However no such latter process was described in the patent (point 2.2 of the Reasons).

VII. Following a communication of the Board posted on 13 October 2010 in which the Board asked the parties, in accordance with Rules 84 and 100(1) EPC, to confirm their interest in the prosecution of the case, the Appellant (patent proprietor) confirmed that it wished the proceedings to continue. Respondent III informed the Board that it did not wish to withdraw the opposition but that it would not take part any further in the procedure, and Respondent I informed the Board

that it did not wish to withdraw the opposition but that it was no longer interested in the procedure.

VIII. The following documents are cited in the present decision :

D3: EP-A-0135990
D4: EP-A-0274411
D32: Declaration of Mr Robert E. Peura dated 25 November 1998,
D51: Declaration of Prof. Meijer dated 2 November 1998 and English translation,
D58: Affidavit of Mr Glen Lieber dated 7 July 2000.

IX. The arguments of the Appellant can be summarised as follows:

The description of a patent is for the person skilled in the art, not for a layman. Accordingly there is no need to give details of well-known features or tests. The crux of the invention is the selection of new materials for a balloon subjected to a biaxial orientation process as rightly understood by the Board in T 1139/00. Two main requirements have to be fulfilled: the material should be nylon or polyamide and the balloon should have a calculated tensile strength of at least 15 000 psi. It is correct that the patent description does not provide further information in relation to the test and that the person skilled in the art has to consult the common general knowledge. However for the person skilled in the art having knowledge of manufacturing of medical balloons it is obvious that the balloon burst test is to be used and that more particularly the tangential stress has to be

used for calculation as such tangential stress is larger by factor 2 than the axial stress, in other words it is the first stress which will lead to bursting of the balloon.
Quite clearly such a test has to be performed under realistic test conditions namely the same conditions (temperature, humidity, etc.) as those existing during a medical procedure on a patient.
It is further to be noted that documents D3 and D4 also mention this well-known pressure equation for the calculation of the tensile strength.

Concerning the formation of the balloon, a disclaimer was introduced into claims 1 and 2 in order to avoid double patenting in relation to the corresponding divisional patent EP-B-0436501 (earlier granted). By decision T 1139/00 the Board allowed this disclaimer. This disclaimer does not, however, have a limitative effect on the technical information in the specification in relation to the whole invention.
As already mentioned, the crux of the invention is the choice of the material and not the provision of a new or different biaxial orientation process. Such processes are known in the art.

Hence, the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art.

X. The arguments of Respondent III can be summarised as follows:

The Respondent agrees with the Opposition Division that the patent does not provide sufficient technical

information in relation to the way elongation and expansion should be mixed or follow each other in the biaxial elongation process and under which conditions that process should be performed in order to arrive at the specific dilatation profile claimed. The granted patent only explains the way to manufacture a balloon which is now excluded from the claimed subject-matter by the disclaimer. For the other embodiments it is only under undue burden that the person skilled in the art might be able to find out the technical details of a proper manufacturing process.

The burst pressure method and the respective vessel equation calculation can only be applied for cylindrical balloons to which the claims are not limited.

For these reasons the appeal should be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Background of the invention.

The introductory passages of the specification describe prior-art medical balloons made of polyethylene terephthalate (PET) and PVC material and mention 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. PVC materials have low tensile strength, for example, whereas PET materials have undesirable

properties, for example an excessively high Young's modulus.

The disadvantages of the prior-art balloons made from PET and PVC materials are overcome by the choice of nylon or polyamide material. The selection of these materials forms the technical essence of the claimed invention. Thus, the balloons according to the invention are made of nylon or polyamide tubing that has been biaxially oriented into the desired balloon configuration.

3. The ground for revocation invoked by the Opposition Division was that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

The Opposition Division essentially based its decision on two reasons (point VI above):

i) the patent was silent about the method to be used to reach the calculated tensile strength of at least about 103.4 MPa (15 000 psi) so that the person skilled in the art was unable to carry out the invention;
ii) the disclaimer excluded from the claims all the balloons formed according to the sole process described in the description so that the person skilled in the art was unable to manufacture a balloon according to claim 1. However no such process as now encompassed by the claims was described in the patent.

4. Concerning the first argument i) the Opposition Division mainly referred to D51.

4.1 In the opinion of the Board, the declaration D51 merely enumerates different ways (pull-strip test and burst-pressure test) of calculating tensile strength for a balloon and the problems associated therewith. It does not establish that it would not be possible to calculate such tensile strength. It merely notices that in the patent specification there is no specific method indicated, that the person skilled in the art can however establish the calculated tensile strength of a balloon in different manners, but that depending on the method used the results would be different (paragraphs 15 and 16).

This means that the concern expressed in D51 is in fact a clarity problem, not a sufficiency problem.
The clarity problem has been dealt with by this Board for the divisional application on the basis of the same description and with the same feature present in the claims as in the patent in suit.
The Board agrees with the analysis made under point 4.2 of the Reasons in decision T 0291/96:

"In particular with respect to the tensile strength of 15 000 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."
D3 and D4 are the same as in the present proceedings, D43 corresponds to D58 and D42a is reproduced in D32.

For sufficiency of disclosure, it is only required, in the absence of a explicit disclosure, that a method for calculating the tensile strength be known to the person skilled in the art. As explained above this is established from D51 and from the analysis relative to clarity made in T 0291/96. Even the Opposition Division acknowledges in its decision that for a given medical balloon it is possible to determine a calculated tensile strength (point 2.4 of the Reasons, pages 15, 16).

On that basis, the Board cannot share the first line of argument i) developed by the Opposition Division in its decision.

4.2 Additionally the Board cannot agree with the argument of Respondent III that the claim was not limited to cylindrical balloons.
As agreed by the Appellant (points 47 to 49 of its statement setting out the grounds of appeal) the balloons are obtained by axial elongation and radial expansion of a tube. Such balloons can only be cylindrical in shape.

5. Concerning the second argument ii) the Board refers to some passages of point 4.1 of the Reasons of decision T 1139/00 concerning the compliance of the patent in suit as granted with Article 123(2) EPC examined there. These passages appear to be relevant for the sufficiency of disclosure as well (emphasis added by the Board).

5.1 "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. [...]

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."

5.2 As highlighted above, numerous passages in the description point to the fact that several known biaxial elongation processes may be used for the manufacturing of the balloons. The Board sees no reason to doubt that such processes are well known to the person skilled in the art and that the person skilled in the art will be able to determine without undue burden what are the specific technical conditions (temperature, pressure, elongation ratio, etc.) under which the processes have to be run in order to obtain the desired balloons.

In this context the Board considers that, even though the manufacturing conditions (temperature, elongation

ratio, expansion ratio, setting temperature, etc.) mentioned in the patent in suit relate to a process in which the radial expansion is meant to take place after the axial elongation, these manufacturing conditions also give helpful initial technical indications to the person skilled in the art who wishes to use another manufacturing process, for instance one in which the axial elongation and radial expansion take place simultaneously.

In this respect the Board disagrees with the Opposition Division and Respondent III that the disclaiming of an embodiment in a claim would have the effect of taking away the specific description of this particular embodiment from the description of the patent and that consequently no aspect of this specific description would be usable anymore to give the person skilled in the art technical information on the way the claimed invention can be carried out.

Article 100(b) EPC requires the invention to be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
In order to make a decision on whether or not the requirements of Article 100(b) EPC are met, the whole patent specification has to be scrutinised and it has to be assessed in relation to all the parts of the patent specification whether they contain technical information relevant for carrying out the invention or not. In particular, parts of the specification not precisely relating to the subject-matter claimed cannot be completely ignored for formal reasons only. It has to be examined whether they contain technical

information relevant for carrying out the claimed invention or not.

In the present case the Board has no doubt that a manufacturing process of a balloon with a particular material in which an axial elongation takes place before a radial extension, as described in the description, is basically similar to another process for manufacturing the same balloon with the same material in which e.g. both axial and radial elongations take place simultaneously, and hence, the technical details of the described process are helpful indications for the person skilled in the art when adapting known processes to the new starting material claimed.

On that basis the Board cannot agree with the second line of argument ii) of the Opposition Division either.

6. In conclusion, the Board considers that the requirements of sufficiency of disclosure are fulfilled and that the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Therefore, the ground of opposition under Article 100 (b) EPC raised against the main request cannot succeed and the impugned decision is to be set aside.

7. The Respondents have declared that they will not take part any further in the proceedings or are no longer interested in the proceedings. These declarations can only be interpreted as implicit withdrawals of any request for oral proceedings, such as the request of Respondent III.

8. Since the objection upon which the impugned decision is based has been dealt with and the grounds of opposition under Article 100(a) EPC have not yet been decided upon by the Opposition Division, remittal of the case to the department of first instance for further prosecution pursuant to Article 111(1) EPC is, in the Board's opinion, appropriate.

Order

For these reasons it is decided that:

1. The decision is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne