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**D E C I S I O N**  
**of 18 March 1994**

**Case Number:** T 0783/91 - 3.2.2

**Application Number:** 89202699.8

**Publication Number:** 0355937

**IPC:** A61M 25/00

**Language of the proceedings:** EN

**Title of invention:**  
Balloon and manufacture thereof

**Applicant:**  
C.R. Bard, Inc.

**Opponent:**

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**Headword:**

-

**Relevant legal norms:**  
EPC Art. 76(1)

**Keyword:**  
"Divisional application - extension beyond the content of the  
parent application (no)"

**Decisions cited:**  
T 0201/83, T 0514/88, T 0288/92

**Catchword:**

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Boards of Appeal

Chambres de recours

**Case Number:** T 0783/91 - 3.2.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.2**  
**of 18 March 1994**

**Appellant:** C.R. Bard, Inc.  
730 Central Avenue  
Murray Hill  
New Jersey 07974 (US)

**Representative:** Jones, Alan John  
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London, WC1A 2RA (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office dated 15 May 1991 refusing  
European patent application No. 89 202 699.8  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** H. Seidenschwarz  
**Members:** P. Dropmann  
J. Van Moer

## Summary of Facts and Submissions

I. The Appellant (Applicant) lodged an appeal against the decision of the Examining Division to refuse the application No. 89 202 699.8, which was divided out from the application No. 84 304 570.9, publication No. 0 135 990.

The Examining Division had expressed the view that the divisional application did not meet the requirements of Article 76(1) EPC.

II. Following a telephone conversation between the Appellant's Representative and the Rapporteur, the Appellant filed an amended set of Claims 1 to 11 with its letter dated 14 March 1994.

III. The Appellant requested that the decision under appeal be set aside, that the appeal be allowed on the basis of the amended set of claims, and that the application be remitted to the Examining Division for a continuation of the examination proceedings.

IV. Claims 1 to 11 read as follows:

"1. High molecular weight, biaxially oriented, flexible polymeric balloon, the tensile strength of the wall of said balloon being at least 218.66 MPa (31,714 psi).

2. Balloon of Claim 1 wherein the polymer is a polyethylene terephthalate homopolyester having an intrinsic viscosity of 0.8 to 1.1.

3. Balloon of Claim 1 or Claim 2 having a wall thickness of 0.028 to 0.045 mm.

4. Dilatation balloon catheter comprising the balloon of any one of Claims 1 to 3.

5. Process for forming a polymeric balloon according to Claim 1, the polymer of said balloon having first order and second order transition temperatures, the process comprising, at a temperature within the range extending from the second order transition temperature to the first order transition temperature, drawing a polymeric tubing having a finite length ( $L_1$ ) and an internal diameter (ID) which is about one-half the outer diameter (OD) to a length ( $L_2$ ) which is 3 to 6  $L_1$ , and thereafter expanding the drawn tubing of internal diameter ( $ID_1$ ) and outer diameter ( $OD_1$ ) by expanding means to an internal diameter ( $ID_2$ ) which is 6 to 8 (ID) and an outer diameter ( $OD_2$ ) which is 3 to 4 (OD), followed by cooling the drawn and expanded tubing to less than its second order transition temperature.
6. Process of Claim 5 wherein the expanding means is pressurized fluid applied to the inside of the tubing.
7. Process of Claim 6 wherein the pressurized fluid is a pressurized gas.
8. Process of any one of Claims 5 to 7 wherein the polymeric tubing is formed by extrusion of polyethylene terephthalate homopolymer resin having an intrinsic viscosity of 1.0 to 1.3 and a density of 1.35 to 1.45.
9. Process of any one of Claims 5 to 8 wherein the tubing drawing temperature is different from the tubing expanding temperature.
10. Process of any one of Claims 5 to 9 wherein the ratio  $(ID_2)/(ID)$  to  $(OD_2)/(OD)$  is in the range 1.5 to 2.67.
11. Dilatation balloon catheter comprising the balloon produced by the process of any one of Claims 5 to 10."

**Reasons for the Decision**

1. The appeal is admissible.

2. *Article 76(1) EPC - Claim 1*

2.1 According to Article 76(1) EPC, a divisional application may be filed only in respect of subject-matter which does not extend beyond the content of the earlier (or parent) application as filed.

2.2 Claim 1 of the parent application as originally filed reads:

"Polymeric balloon having a burst pressure of at least 200 psi (1.4 MPa) and a radial expansion of less than 5% at 200 psi (1.4 MPa)."

2.3 Claim 1 of the divisional application differs from said Claim 1 of the parent application in the following respects:

(i) The features "high molecular weight, biaxially oriented, flexible" have been added,

(ii) the feature "having a burst pressure of at least 200 psi (1.4 MPa)" has been replaced by the feature "the tensile strength of the wall of said balloon being at least 218.66 MPa (31,714 psi)", and

(iii) the feature "having a radial expansion of less than 5% at 200 psi (1.4 MPa)" has been deleted.

2.4 ad(i): The incorporation into Claim 1 of the features "high molecular weight, biaxially oriented, flexible" is admissible in the light of the statements at page 6, line 30, page 8, line 33, page 9, lines 1 and 2 and page 2, line 8 of the parent application as originally filed.

ad(ii): The value of the tensile strength  $\bar{\sigma}$  of 218.66 MPa (31,714 psi) can be calculated, using the membrane equation  $\bar{\sigma} = pr/h$ , from the burst pressure  $p$  of 480 psi of balloon C having a radius  $r$  of 1.85 mm and a membrane wall thickness  $h$  of 0.028 mm (cf. page 4, lines 30 and 32, page 9, line 10 and Figure 2 of the parent application). It should be borne in mind that the value of the burst pressure of the balloon depends upon the geometry (radius, wall thickness) and material strength of the balloon, whilst the tensile strength provides a measure of the inherent strength of the material, independent of geometry.

The use of the calculated figure of 218.66 MPa as the minimum tensile strength of the wall of the polymeric balloon is considered to be justified in view of decision T 201/83 (OJ EPO 1984, 481).

ad(iii): Thus the only question to be answered under Article 76(1) EPC is whether or not, after deletion of the feature "having a radial expansion of less than 5% at 200 psi (1.4 MPa)", the subject-matter of the divisional application extends beyond the content of the parent application as originally filed. This question will be dealt with in the following points 2.5 and 2.6.

2.5 According to the decision T 514/88 (OJ EPO 1992, 570, in particular point 2.7), broadening of a claim before grant by abandoning a feature does not contravene the provisions of Articles 76(1) or 123(2) EPC if there is a basis for the broadened claim in the original or parent application. The basis need not be presented in express terms but it must be sufficiently clear to a person skilled in the art to be directly and unambiguously recognisable as such and not of a vague and general character. In this context, reference is also made to the unreported decision T 288/92 (cf. in particular points 3.1 to 3.4).

2.6 The Board takes the view that the disclosure of the parent application as filed is not restricted to balloons having a **combination** of a minimum burst pressure (or minimum tensile strength) and a maximum radial expansion under pressure. Rather, the invention in its broadest terms is disclosed, **without any mention of the feature of a maximum radial expansion**, in the following passages of the parent application as filed:

At page 2, lines 6 to 10 the first object of the invention is stated: "It is an object of this invention to provide balloons which exhibit physical properties, for example, toughness, flexibility and tensile strength, superior to those exhibited by balloons known in the art."

Page 4, lines 14 to 16 reads: "The balloon prepared by the process of this invention exhibits an unusual combination of film properties, such as toughness, flexibility and tensile strength."

Also at page 6, line 34 to page 7, line 1 it is stated: "..., provided the resultant balloon exhibits the desired film properties, such as toughness, flexibility and tensile strength."

It is true that one of the large number of objects of the invention, which are described from page 2, line 6 to page 3, line 3, is "to provide such balloons which exhibit very little elongation or creep radially, collectively referred to herein as radial expansion, when inflated to the pressure necessary to perform the desired medical procedure" (page 2, lines 16 to 20). However, the Board considers that, as is normally the case, not all of the objects enumerated in the application are to be achieved by the broadest aspect of the invention set out in Claim 1, but that some of the objects represent advantageous or alternative characteristics. The above-mentioned object concerning the limited radial expansion represents such a characteristic which may be advantageous when the balloon is used in medical procedures as set out at page 2, lines 16 to 20. The mentioning of the burst pressure in combination with the radial expansion at pages 4 and 5 is therefore to be seen in this context.

When deciding on the admissibility of omitting the parameter of limited radial expansion from Claim 1, the Board took into consideration furthermore that, similar to the burst pressure (cf. point 2.4, ad(ii) above), the radial expansion of a balloon depends not only on the properties of the material of the wall but also on the geometry (membrane wall thickness) of the balloon, whereas the tensile strength represents the strength of the material and is independent of the geometry. The linking of the invention with the geometry of the balloon is not justified in the light of the wide aspect of the disclosure of the parent application.



2.7 It follows from the preceding statements that there is a clear basis as required in point 2.5 above for abandoning the feature concerning the radial expansion from Claim 1 of the parent application.

Hence, the subject-matter of Claim 1 of the divisional application does not extend beyond the content of the parent application as filed. Claim 1 of the divisional application thus complies with the provisions of Article 76(1) EPC.

3. *Article 76(1) EPC - Claims 2 to 11*

The basis for the subject-matter of Claims 2 to 11 of the divisional application is to be found in the following parts of the parent application as originally filed:

Claims 2, 4, 5, 6, 7, 8, 9 and 11:

See Claims 4, 12, 5, 6, 7, 8, 11 and 12 respectively, of the parent application.

Claim 3: See page 4, lines 31 to 33 of the parent application.

Claim 10: The range of 1.5 to 2.67 follows from the ratios  $ID_2/ID = 6$  to 8 and  $OD_2/OD = 3$  to 4 disclosed in Claim 5 of the parent application. This claim appears to be superfluous in view of Claim 5 of the divisional application.

The subject-matter of Claims 2 to 11 thus meets the requirements of Article 76(1) EPC.

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 on the basis of Claims 1 to 11 set out in point IV above.

The Registrar:



N. Maslin

The Chairman:

  
H. Seidenschwarz