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D E C I S I O N
of 26 April 2006

Case Number: T 1033/02 - 3.3.10

Application Number: 95913555.9

Publication Number: 0748232

IPC: A61L 29/00

Language of the proceedings: EN

Title of invention:
Block copolymer elastomer catheter balloons

Patentee:
Boston Scientific Scimed, Inc.

Opponent:
Terumo Kabushiki Kaisha

Headword:
Block copolymer elastomer catheter balloons/SCIMED

Relevant legal provisions:
EPC Art. 54, 56, 83

Keyword:
"Sufficiency of disclosure (yes)"
"Novelty (yes)"
"Main and first auxiliary request: inventive step (no) - improvement not credible - unfair comparative tests - arbitrary selection - obvious to try"
"Second auxiliary request: inventive step (yes) - purposive selection"

Decisions cited:
G 0002/98, T 0020/81, T 0301/87

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1033/02 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 26 April 2006

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 28 June 2002 concerning maintenance of European patent No. 0748232 in amended form.**

Composition of the Board:

Chairman: R. Freimuth
Members: J. Schmid
P. Schmitz

Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal on 6 September 2002 against the interlocutory decision of the Opposition Division, posted on 28 June 2002, which found that the European patent No. 748 232 in the form as amended during opposition proceedings according to the then pending main request met the requirements of the EPC.

II. Notice of opposition had been filed by the Appellant requesting revocation of the patent in suit in its entirety on the grounds of Article 100(a) and (b) EPC, in particular on the grounds of lack of novelty, inventive step and sufficient disclosure. *Inter alia* the following documents were submitted in the opposition proceedings:

(1) JP-A-4 144 572, supplemented by its English translation (document (1A)),

(4) EP-A-0 537 069,

(5) EP-A-0 592 870 and

(11) Handbook of Thermoplastic Elastomers, 2nd Edition, 1988, VNR, New York, Chapter 8, Polyamide Thermoplastic Elastomers, pages 258 to 270.

III. The Opposition Division held that the claims in the form as amended satisfied the requirements of the EPC. With regard to Article 100(b) EPC, the Opposition Division considered that the skilled person could determine in view of the working examples which

conditions have been used in the measurement of the objected parameters (hardness and flexural modulus) and thus could reproduce the invention in its whole scope. The Opposition Division acknowledged novelty with respect to documents (1) and (4) since those documents did not mention the hardness of the polymers used in the preparation of the balloons. The Opposition Division further considered that the opponent's argumentation with respect to inventive step was not convincing since none of the cited documents gave the information to the skilled person to use thermoplastic polymers having a hardness shore D and a flexural modulus as set out in the claims for making balloons for catheters.

IV. At the oral proceedings before the Board, held on 26 April 2006, the Respondent (Proprietor of the patent) defended the maintenance of the patent in suit in amended form on the basis of a main request or, subsidiarily, on the basis of auxiliary requests 1 to 3, all requests submitted during the oral proceedings.

The main request comprised a set of twenty two claims and differed from the set of claims considered by the Opposition Division exclusively in that method claims 23 to 29 were deleted. Claims 1 to 22 of that request were identical to the respective claims as granted, independent claim 1 reading as follows:

"A balloon for a medical device formed from a length of polymer tubing by radial expansion of the tubing under pressure, the polymer being a block copolymer thermoplastic elastomer characterized as follows:

the block copolymer comprises two or more hard segments of a polyester or polyamide and two or more soft segments of polyether;

the polyester hard segments are polyesters of terephthalic acid and a C_2-C_4 diol,

the polyamide hard segments are polyamides of C_6 or higher carboxylic acids and C_6 or higher organic diamines or of C_6 or higher aliphatic ω-amino-α-acids, and

the polyether soft segments are polyethers of C_2-C_{10} diols,

the block copolymer has a flexural modulus of less than about 150,000 psi;

the block copolymer has a hardness, Shore D scale, of greater than 60; and

the percentage by weight of the block polymer attributable to the hard segments is between about 50% and about 95%."

Claim 1 of the first auxiliary request differed from that of the main request exclusively in that "the polyamide hard segments" are linked to the polyether soft segments by ester groups.

Claim 1 of the second auxiliary request differed from that of the first auxiliary request exclusively in that the balloon is further characterized by "having a compliant to semi-compliant distension profile whereby as inflation pressure is increased from 6 atm to 12 atm, the balloon expands from a nominal diameter at the 6 atm pressure to an increased diameter at the 12 atm pressure which is at least 7% greater than said nominal diameter".

Claim 1 of the third auxiliary request differed from that of the first auxiliary request exclusively in that "the wall thickness, single wall basis, is no more than 0.0015 inches and said wall strength is greater than 18,000 psi".

V. The submissions of the Appellant can be summarized as follows:

As regards novelty, the Appellant submitted that the claimed subject-matter lacked novelty with respect to documents (1), (4) and

(24) US-A-5 342 386,

the latter cited in the statement of the grounds of appeal.

It nevertheless conceded that if the wording of claim 1 were to be interpreted as the polymer tubing, from which the claimed balloon was obtained by radial expansion, could only consist of one single copolymer, then the claimed subject-matter would be novel over document (1) and over the passage of column 7, lines 7 to 51 of document (24), this passage referring specifically to polymer blends.

It nevertheless submitted that document (24) remained novelty destroying since the passage of column 5, lines 52 to 68 made clear that the balloon member 26 was made of the same material as the thin-walled flexible tube 28. This was confirmed by the example of document (24) where both the thin-walled tube and the balloon were prepared from Huls Vestamid L2101F. Thus, the specific

polyetheramides disclosed on column 6, lines 26 to column 7, line 4 were also disclosed as starting materials for making the balloon.

As regards inventive step, the Appellant held that document (4) represented the closest prior art. The technical problem underlying the patent in suit was to be seen in the provision of further medical balloons. The claimed subject-matter was merely an arbitrary selection of the balloons disclosed in document (4). It furthermore added that document (5) on column 5, lines 31 to 35 and 40 to 42 and document

(26) EP-A-0 592 885

the latter cited in the statement of the grounds of appeal, on page 6, lines 52 to 57 clearly taught how to select the starting polymer depending on the application of the balloon. The Appellant therefore concluded that the claimed subject-matter was the obvious combination of document (4) with documents (5) or (26).

As regards sufficiency of disclosure, the Appellant submitted that neither the measurement methods nor the test condition were disclosed in the patent in suit concerning properties required by the claim and defined in terms of flexural modulus and hardness parameters. It concluded that in view of these two undefined parameters, there was an insufficient information in the patent in suit which had also a bearing on the assessment of claim 1.

The Appellant objected to the fresh set of claims submitted as auxiliary request 2 by the Respondent during the oral proceedings before the Board. This set of claims should not be admitted into the proceedings as it was filed at a very late stage.

VI. As regards novelty, the Respondent submitted that the wording of claim 1 made clear that the polymer tubing consisted of a single copolymer.

As regards inventive step the Respondent held that document (4) could be regarded as the closest prior art. Starting from that document the Respondent defined the technical problem underlying the invention as the provision of better balloons. It stressed that document (5) only dealt with coated balloons and mentioned the commercial product Pebax in a very general way. It put forward that there was no general knowledge that Pebax led to balloons with a good compromise between strength and distensability. It pointed out that document (26) made no suggestion to the use of polyetheresteramide copolymer and that document (4) only disclosed non compliant balloons. The Respondent concluded that the skilled person would therefore not be directed to the claimed balloons.

As regards insufficiency of disclosure the Respondent submitted that Shore D hardness and flexural modulus were standardized features in the art. As the invention was made in the United States, the skilled man would take the corresponding American standards into account, i.e. ASTM D2240 for the Shore D hardness and ASTM D790 for the flexural modulus.

VII. The Appellant requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent requested that the patent be maintained on the basis of the main request, or, subsidiarily, on the basis of auxiliary requests 1 to 3, all requests submitted during the oral proceedings before the Board.

VIII. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Priority Right (Article 87(1) EPC)*

2.1 The Appellant submitted that documents (5), (24) and (26) disclosed and/or suggested a balloon as defined in claim 1 of the patent in suit. Those documents are intermediate documents having publication date between the priority date claimed by the patent in suit and the filing date thereof. Since the question arises whether documents (5), (24) and (26) are to be considered state of the art according to Article 54(2) EPC, the matter of whether or not claim 1 of the patent in suit as amended is entitled to the claimed right of priority has to be decided by the Board.

2.2 Pursuant to Article 87(1) EPC, a right of priority may only be enjoyed in respect of the same invention. Therefore, in deciding whether claim 1 of any request is entitled to the claimed priority, it needs to be

decided whether in the priority document the same invention is disclosed as in present claim 1.

The requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent (application) in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole (see decision G 2/98, OJ EPO 2001, 413).

The priority document aims at balloons for medical devices which possess a unique combination of physical properties including non compliant, semi-compliant and compliant distension attributes, good flexibility and high tensile strength. This is achieved by balloons formed from a length of polymer tubing by radial expansion of the tubing under pressure, the polymer being a polyamide/polyether polyester. Suitable copolymers exemplified in the priority document include the commercially available polyamide/polyether polyesters Pebax® 33 series with shore D hardness 25 or above.

However, there is no disclosure in the priority document that the copolymer has a hardness, Shore D scale, of greater than 60 and a flexural modulus of less than 150 000 psi.

2.3 Claim 1 of all the requests includes those features not disclosed in the priority document and being mandatory for performing the invention. As the person skilled in

the art cannot derive the subject-matter of those claims directly and unambiguously, using common general knowledge, from the previous application as a whole, it follows that the priority based on that previous application cannot be acknowledged.

2.4 For these reasons, the Board concludes that independent claim 1 of each request is not entitled to the claimed priority right. The effective date for claim 1 of all requests is then the filing date of the patent in suit.

Consequently, documents (5), (24) and (26) are prior art documents pursuant to Article 54(2) EPC for the subject-matter of claim 1 of the main and auxiliary requests 1 to 3.

Main request

3. *Novelty*

3.1 Claim 1 of the patent in suit is directed to a balloon for a medical device which is defined by its process of preparation (product-by-process claim).

Thus, the claimed balloons are formed by radial expansion under pressure of a length of polymer tubing, the polymer being a block copolymer thermoplastic elastomer. This copolymer, from which the tubing is made, is further structurally and mechanically characterized in the claim.

Thus the subject-matter of this claim only covers balloons made from a tubing consisting of a block copolymer thermoplastic elastomer as structurally

defined in claim 1, excluding therefore the presence of other polymers therein.

3.2 Document (1) discloses a balloon (3) for a medical device which includes an inner layer (31) made of a crystalline plastic material and an outer layer (32) made of an elastic material (see document (1A), figure 3 and page 20, lines 5 to 8). Furthermore document (1) discloses that the balloons can be fabricated by radial expansion of a tube. In that case, the inner layer and the outer layer are formed as a two-layered tube, followed by blow molding (see document (1A) page 22, lines 1 to 3). Accordingly, the balloons disclosed in document (1) are not formed by radial expansion of a length of polymer tubing made of one same polymer.

Consequently, the subject-matter of claim 1 is novel with respect to document (1).

3.3 Document (4) discloses a balloon for a medical device which is prepared by inflating a tube in its radial direction by applying an elevated pressure (page 6, lines 50 to 51). The tube is made of a material which comprises an aromatic polyamide. The aromatic polyamide may be used either alone or as the main constituent (see page 6, lines 14 to 16 and 42 to 43). The term aromatic polyamide as defined in document (4) designates a polyamide produced by polycondensing a diamine and a dicarboxylic acid, at least a part of the diamine or the dicarboxylic acid containing an aromatic ring. The aromatic polyamide may be produced by polycondensing two or more types of diamines and dicarboxylic acids (see page 4, lines 29 to 36). The

aliphatic diamines or dicarboxylic acids mentioned in document (4) include those comprising a polyether block moiety (see page 5, lines 48 to 52; formulae (3), (4) and (5)).

However, though comprised within the general disclosure of document (4), there is no specific disclosure of a block copolymer comprising two or more hard segments of a polyamide and two or more soft segments of a polyether.

The subject-matter of claim 1 is therefore not anticipated by document (4).

3.4 Document (24) is prior art under Article 54(2) EPC since claim 1 is not entitled to the priority date (see point 2 above).

This document discloses a medical device balloon which is prepared from a nylon or from a polyamide parison which is subjected to radial expansion under pressure (see column 5, lines 4 to 13 and 52 to 55). The term polyamide being very broad, the disclosure of an article made from this general class of polymer cannot take away the novelty of an article made from a specific polyamide polyether block copolymer, such as that specified in claim 1.

The claimed balloons made from the specific polyamide polyether block copolymer as set forth in claim 1 are therefore novel with respect to the balloon disclosed in document (24).

The specific polyamide material disclosed on column 6, line 26 to column 7, line 51 of document (24) and referred to by the Appellant is that one from which the thin-walled flexible tube 28 is made (see column 6, line 1 to 4 and 18 to 21). It is, however, not the material from which the balloon is made. The Board does not concur with the Appellant's interpretation that the fact that the balloon is prepared from a parison, which is subjected to similar processing to that used to form the thin-walled flexible tube, results necessarily in the conclusion that the balloon and the thin-walled flexible tube are made from the same material. The materials for the balloon and for the thin-walled tube are separately disclosed in document (24) in two independent sections, namely in column 5, lines 52 to 54 for the balloon and in column 6, line 1 to column 7, line 51 for the thin-walled tube. There is an overlap between the materials disclosed for the preparation of the balloon and the thin-walled tube. Accordingly, the balloon and the thin-walled tube may be made from the same material, as shown in the example of document (24) and addressed by the Appellant, but they need not, as is clear from the disclosure of document (24) that the materials for the balloon and the thin-walled tube are to be chosen from two separate and independent lists of materials.

Thus, the subject-matter of claim 1 is novel with respect to document (24).

4. *Inventive step*

4.1 In accordance with the "problem-solution approach" applied by the Boards of Appeal to assess inventive

step on an objective basis, it is in particular necessary to establish the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art.

4.2 The patent in suit is directed to a balloon for medical devices which possess a unique combination of physical properties including non compliant, semi-compliant and compliant distension attributes, good flexibility and high tensile strength. This is achieved by balloons formed from a length of polymer tubing by radial expansion of the tubing under pressure, the polymer being a specific block copolymer.

4.3 Document (4) discloses balloons for medical devices having a burst pressure higher than 10 kg/cm^2 with sufficient softness and flexibility and without compromising the strength (see page 7, lines 43 to 46; page 9, lines 37 to 39). The balloons disclosed in document (4) are formed from aromatic polyamides inter alia comprising polyether blocks (see point 3.3 above).

The Board considers, in agreement with the Parties, that document (4) represents the closest state of the art, and, hence, the starting point in the assessment of inventive step.

4.4 In view of this state of the art, the Respondent submitted during the oral proceedings that the technical problem underlying the patent in suit consisted in providing a balloon for a medical device having improved burst strength and distension profile.

4.5 The patent in suit proposes as the solution the balloon according to claim 1 which is characterized by the preparation from a polymer tubing, the polymer being selected from particular polyamide polyether block copolymers as defined in claim 1 (see point IV above). These polyamide polyether block copolymers overlap with the polyamides embraced by the general disclosure of document (4) (see point 3.3 above).

4.6 The Appellant and the Respondent were divided as to whether or not the evidence presented, namely comparative examples A to G of the patent specification, convincingly showed that the technical problem defined in point 4.4 above was successfully solved by the claimed balloons.

4.6.1 The balloons described in comparative example A to G were prepared from Pebax® materials having a Shore D hardness of below 60.

These comparative examples do not reproduce the balloons disclosed in the closest prior document (4), since the material used in the preparation of the balloons of those comparative examples are aliphatic block copolymers and not aromatic polymers, as required by document (4).

Therefore, the comparative examples do not truly reflect the closest prior art and do not allow a fair comparison with the claimed invention. Consequently, those tests do not allow any conclusion with regard to the technical benefits of the claimed balloons vis-à-

vis the balloons disclosed in the closest prior art document (4).

The Respondent argued that the claimed technical effects were properly demonstrated, since the comparative data have been provided using polymer materials being even closer to the claimed invention than the balloon material disclosed in document (4).

However, the Board is not convinced by the Respondent's argument. Claim 1 covers balloons made from aromatic polyamides disclosed in document (4). Accordingly, in order to convincingly show an improvement with respect to document (4), comparative examples would have been necessary using balloons made from the polyamide material disclosed in document (4), in particular from an aromatic material which is the structurally closest.

4.7 Since the Respondent did not present a fair and convincing comparison between the closest prior art and the claimed invention, the purported technical benefits are devoid of corroborating evidence.

According to the jurisprudence of the Boards of Appeal, alleged but unsupported advantages cannot be taken into consideration for the determination of the problem underlying the claimed invention (see e.g. decision T 20/81, OJ EPO 1982, 217, point 3, last paragraph of the reasons). Since in the present case the alleged advantages, i.e. improvement of burst strength and distension profile, lack the required experimental support, the technical problem as defined above (see point 4.4) needs to be redefined in a less ambitious way, and in view of the teaching of document (4) can

merely be seen in providing alternative balloons for medical devices.

4.8 It remains to be decided whether or not the proposed solution to that objective technical problem, namely the balloon according to claim 1 of the patent in suit, is obvious in view of the state of the art.

The balloons disclosed in document (4) are formed from a polymer tubing made from aromatic polyamides optionally comprising polyether blocks (see point 3.3 above). Thus any polymer so covered, including therefore polyamide polyether block copolymers as specified in claim 1, are taught to be suitable for the preparation of balloons for medical devices.

Consequently, the choice of a particular block copolymer within the ambit of document (4) such as those specified in claim 1 cannot be treated as either critical or as a purposive choice for solving the objective problem underlying the patent in suit, but merely as an arbitrary restriction of no technical significance.

On this basis, the arbitrary choice of copolymers within the ambit envisaged by the general teaching of document (4) can only be seen as lying within the routine activity of the skilled person faced with the objective problem of providing alternative balloons for a medical device and thus cannot provide the claimed balloons with any inventive ingenuity.

4.9 The Respondent, at the oral proceedings before the Board, submitted in support of inventive step that

document (4) did not point the skilled person to select the block copolymer as specified in claim 1 of the patent in suit and that the examples of document (4) were only made with polyamides, i.e. which are outside of the scope of present claim 1.

However, the teaching of a document is not confined to its examples but embraces any information contained therein. It is true, that document (4) specifically describes only polyamide which do not contain polyether blocks. That fact is merely a reason for accepting that it does not anticipate the claimed subject-matter.

The Respondent's objection that there is no pointer to the specific block copolymers according claim 1 cannot convince the Board because this is asking for a condition to be met which is meaningless in a situation where the claimed solution merely consists in picking out block copolymers at random within the ambit of document (4), as no improvement is attributable to the specific polymers of claim 1 over those defined in document (4).

4.10 For these reasons, the subject-matter of claim 1 is obvious in the light of document (4).

4.11 As a result, the Respondent's main request is not allowable for lack of inventive step pursuant to Article 56 EPC.

Auxiliary request 1

5. *Amendments Article 123 EPC*

Claim 1 of the first auxiliary request differs from that of the main request exclusively in that the polyamide hard segments are linked to the polyether soft segments by ester groups. This amendment is supported by page 5, lines 5 to 7 of the application as filed and thus satisfies the requirement of Article 123(2) EPC.

As this amendment results in a restriction of the claimed scope, the requirement of Article 123(3) is consequently also satisfied.

6. *Novelty*

In view of the findings of the Board with respect to the main request indicated in point 3 above, the Board considers the requirement of Article 54 EPC to be satisfied also with respect to claim 1 of the first auxiliary request which is narrower in scope than claim 1 of the main request.

7. *Inventive step*

7.1 Document (4) remains to be the closest prior art while the technical problem is still the provision of further balloons for medical devices.

The solution proposed is the balloon made from the block copolymers defined in claim 1 which differ from those disclosed in document (4) additionally in that

there is an ester group linking the polyamide segments to the polyether segments. Due to this amendment there is no longer an overlap between the claimed balloons and those disclosed in document (4).

When starting from the balloons known from document (4), it is a matter of course that the person skilled in the art seeking to provide further balloons for medical devices would turn his attention to that prior art in this field just dealing with the same technical problem. As a skilled person he would be struck by document (5) which teaches that material typically used to form expanded products such as dilatation balloons include thermoplastic material such as polyether polyamide block copolymers, e.g. Pebax® (see column 5, lines 5 to 7, 21 and 22). Pebax® are commercially available polyetheramide block copolymers having an ester group linking the polyamide segments to the polyether segments (see document (11), table 8-1 on page 260) and are qualified in the patent specification as being suitable for the claimed invention (see page 4, lines 18 to 20).

The Board concludes from the above that the state of the art represented by document (5) gives the person skilled in the art a concrete hint as to how to solve the problem underlying the patent in suit as defined in point 4.7 above of providing further balloons, namely by using polyetheresteramide block copolymers, thereby arriving at the claimed balloons, i.e. the solution proposed by the patent in suit. In the Board's judgment, it was obvious to try to follow the avenue indicated in the state of the art with a reasonable expectation of success without involving any inventive ingenuity, all

the more since suitable thermoplastic material are commercial products. Thus a skilled person would find in document (5) a hint to use the thermoplastic material as set forth in claim 1 to obtain balloons for medical devices.

Therefore, a person skilled in the art would solve the technical problem by known means and without inventive activity.

7.2 For the following reasons the Board cannot accept the Respondent's arguments designed to support an inventive step.

The Respondent submitted that not all Pebax® materials are suitable for preparing balloons with suitable properties and referred to the comparative examples of the patent in suit where is apparent that balloons made with Pebax® having Shore D hardness lower than 60 do not possess suitable distension profile and wall strength.

The Board cannot accept this argumentation since claim 1 of that request - in contrast to claim 1 of auxiliary request 2 - is not restricted to balloons having particular properties and since the technical problem is merely the provision of further balloons for medical devices.

7.3 Therefore, in the Board's judgement, the subject-matter of claim 1 represents an obvious solution to the problem underlying the patent in suit and does not involve an inventive step.

8. In these circumstances, the Respondent's auxiliary request 1 is not allowable for lack of inventive step pursuant to Article 56 EPC as well.

Auxiliary request 2

9. *Admissibility*

The second auxiliary request was filed during the oral proceedings before the Board. The sole amendment in this set of claims was that dependent claim 14 as granted was incorporated into claim 1.

Thus, the Respondent has merely restricted the subject-matter of the patent in suit to claims the Appellant was familiar with and which the Appellant opposed according to the notice of opposition. Therefore, the claims of the Respondent's auxiliary request 2 do not give rise to any fresh issue.

For these reasons, the Board exercises its discretion to admit the Respondent's second auxiliary request into the proceedings.

10. *Amendments (Article 123 EPC)*

The incorporation of granted claim 14, which is identical to original claim 14, into claim 1 neither generates added subject-matter nor extends the protection conferred.

Amended claim 1 therefore satisfies the requirement of Article 123 (2) and (3) EPC.

11. *Insufficiency of disclosure* (Article 100(b) EPC)

11.1 In the Notice of Opposition, the Appellant challenged the claimed invention on the ground of insufficient disclosure in view of the fact that the measuring method of two parameters recited in claim 1 was flawed: the patent did not specify according to which standard and how the skilled person should perform the measurement of the flexural modulus and of the hardness.

It is the Appellant's point that, owing to this insufficient information with respect those critical, but unreliable parameters to define the balloon, the skilled person could not assess whether a balloon falls within or outside the scope of claim 1.

11.2 According to Article 100(b) EPC, the European patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person.

With respect to sufficiency of disclosure, the relevant question is whether the patent in suit provides sufficient information which enables the skilled person when taking into account common general technical knowledge to reproduce the claimed balloons.

11.3 Shore D hardness and flexural modulus are properties conventional in the art. There exist standardized methods to measure these mechanical properties. Accordingly the skilled person has no difficulty to determine the values of the Shore D hardness and the flexural modulus of the block copolymers recited in claim 1.

Furthermore the mechanical properties objected to do not define the balloons as such. They refer to the starting block copolymer from which the polymer tubing is made. Claim 1 is a product-by-process claim wherein the claimed balloons are formed under pressure by radial expansion of this polymer tubing which is prestretched (patent specification, paragraphs [0031] and [0036]. The initial mechanical properties of the block copolymer, including hardness and flexural properties, however, are modified by this preparation process comprising subjecting the polymer to stretching, i.e. mechanical strain. The exact mechanical properties, such as hardness Shore D and flexural modulus of the starting block copolymer cannot therefore be detected with certainty on the claimed balloon *per se*.

11.4 The Appellant's objection rather refers to determining the limits of the subject-matter claimed. Accordingly, that objection is thus related to the question whether the claims clearly define the matter for which protection is sought, which is a matter of Article 84 EPC. The Board observes that Article 84 EPC is not a ground for opposition within the sense of Article 100 EPC. Nor does Article 102 (3) EPC provide a proper basis in the present case for objecting to this matter since that provision does not allow objections to be based upon Article 84 EPC if such objections do not arise out of the amendments made in opposition(-appeal) proceedings (see decision T 301/87, OJ EPO 1990, 335, point 3.8 of the reasons). For these reasons and since the claims as granted already contained those features, the Appellant's objection cannot be taken into consideration.

11.5 Consequently, the Appellant's challenge to the sufficiency of the disclosure of the patent in suit under Article 100(b) EPC is rejected.

12. *Novelty*

In view of the findings of the Board with respect to the main request indicated in point 3 above, the Board considers the requirement of Article 54 EPC to be satisfied also with respect to claim 1 of the second auxiliary request which is narrower is scope than claim 1 of the main request.

13. *Inventive step*

Document (4) remains the closest prior art while the technical problem is still the provision of further balloons for medical devices.

The solution proposed, i.e. the balloons of claim 1, differs from the balloons of document (4) not only by being made from a different material (see point 7 above), but additionally differ in that they have a compliant to semi-compliant distension profile, that is, when the inflation pressure is increased from 6 atm to 12 atm, the claimed balloons expand from a nominal diameter at the 6 atm pressure to an increased diameter at the 12 atm pressure which is at least 7% greater than said nominal diameter.

When starting from the balloons known from document (4), the person skilled in the art seeking to provide further balloons for medical devices would not find any

hint in the cited prior art leading to the claimed balloons.

Document (5), which addresses the polyetheresteramides Pebax® in general on column 5, lines 22 for making dilatation balloons, does not specifically refer to balloons having a compliant to semi-compliant distension profile. As is apparent from the comparative examples of the patent in suit, particular Pebax® materials, such as Pebax® 3533 or Pebax® 5533 which have a hardness, shore D, of 35 and 55 respectively, do not result in (semi) compliant balloons as defined in claim 1 since the burst pressure is lower than 12 atm (see patent specification, comparative examples A to D on page 8, line 41 to page 9, line 20). Accordingly, there is no suggestion in document (5) to pick out a particular polyetheresteramide (Pebax®) material to arrive at balloons having a compliant to semi-compliant distension profile.

Nor does document (26) suggest the claimed balloons. Document (26) discloses distensible dilatation balloons i.e. compliant balloons (see claim 5). The polymers which may be used as starting materials for the preparation of the balloons are block copolymers, in particular polyurethane block copolymers (see page 7, lines 15 to 18 and examples), polyetheresteramide block copolymers being not described.

Accordingly, there is no suggestion in this document towards the use of polyetheresteramide block copolymers having at least two polyester or polyamide hard segments and at least two or more soft segments of

polyether, which is however the solution proposed by the claimed invention.

14. For these reasons the Board concludes that the subject-matter of claim 1, and by the same token, that of dependent claims 2 to 20 involves an inventive step within the meaning of Articles 52(1) and 56 EPC.

Auxiliary Request 3

15. Since the preceding auxiliary request 2 is allowable for the reasons set out above, there is no need for the Board to decide on the lower ranking auxiliary request 3.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of auxiliary request 2 submitted during the oral proceedings before the Board and a description yet to be adapted.

The Registrar The Chairman

C. Moser R. Freimuth