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Datasheet for the decision of 25 April 2023

Case Number: T 0825/20 - 3.2.02

Application Number: 12835108.7

Publication Number: 2762191

IPC: A61M25/10, A61L29/00

Language of the proceedings: EN

Title of invention:
CATHETER BALLOON AND BALLOON CATHETER

Patent Proprietor:
Terumo Kabushiki Kaisha

Opponent:
Höhfeld, Jochen

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 12(6)

Keyword:
Inventive step - (no)
Late-filed request - should have been submitted in first-instance proceedings (yes) - admitted (no)

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Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0825/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 April 2023

Appellant: (Patent Proprietor)	Terumo Kabushiki Kaisha 44-1 Hatagaya 2-chome Shibuya-ku Tokyo 151-0072 (JP)
Representative:	Casalonga Casalonga & Partners Bayerstraße 71/73 80335 München (DE)
Respondent: (Opponent)	Höhfeld, Jochen Jagdweg 15 82041 Deisenhofen (DE)
Representative:	Klunker IP Patentanwälte PartG mbB Destouchesstraße 68 80796 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 January 2020 revoking European patent No. 2762191 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	Y. Podbielski

Summary of Facts and Submissions

I. This appeal was filed by the proprietor (appellant) against the Opposition Division's decision to revoke the contested patent.

II. In its decision, the Opposition Division held, *inter alia*, that the subject-matter of claim 1 of the patent as granted did not involve an inventive step over the document US 2010/0130926 A (D10).

III. The appellant requested, as its main request, that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of claims 1 to 5 as granted and an amended description. As auxiliary measures, the appellant requested that the patent be maintained on the basis of one of the first to fourth auxiliary requests filed with the statement of grounds of appeal.

IV. The respondent (opponent) requested that the appeal be dismissed.

V. The Board summoned the parties to attend oral proceedings on 17 March 2023 and provided its preliminary opinion in a communication under Article 15(1) RPBA 2020.

In its letter dated 8 March 2023, the appellant declared that it would not attend the oral proceedings and withdrew its request for oral proceedings.

The Board thus cancelled the oral proceedings.

This decision relies on the parties' written submissions filed on appeal.

VI. Reference is also made to the following documents:

D4 R. S. Stein and F. H. Norris, Journal of Polymer Science, vol. 21, 1956, pages 381-396

D5 WO 2009/112369 A1

ANNEX 1 filed by the appellant on 29 October 2018, entitled "*Why do pipes burst they way they do?*"

ANNEXES 1 to 22, 14a, 18a, 19a and 20a filed with the appellant's statement of grounds of appeal, listed on page 17 of that statement

VII. Claim 1 as granted (main request) reads as follows:

"*A cylindrical catheter balloon (11) formed of a membrane (2) as a laminate of at least two or more layers which include a polyamide elastomer layer (8) and a polyamide layer (9), wherein the polyamide elastomer layer (8) is disposed at the inner side of the polyamide layer (9), a refractive index n_{r1} in the circumferential direction of a cross-section perpendicular to the axis in the surface of inner side of the polyamide layer (9) is greater than a refractive index n_{r2} in the circumferential direction of a cross-section perpendicular to the axis in the surface of inner side of the polyamide elastomer layer (8), and a difference between the refractive index n_{r1} and the refractive index n_{r2} is 0.01 or greater.*"

In the following, polyamide and polyamide elastomer are referred to as PA and PAE respectively.

VIII. The appellant's arguments relevant for this decision can be summarised as follows.

Main request – inventive step starting from D10

It was well established in polymer physics, as reflected for example in the Lorentz-Lorenz equation, that there was a correlation between the refractive index measured in a given direction in a polymer material and the orientation of the polymer chains in that material (ANNEXES 1 to 16, 20 and 20a). More specifically, the refractive index in the direction of the polymer chain alignment was higher than the refractive index in a perpendicular direction.

Therefore, the relationship $n_{r1} - n_{r2} \geq 0.01$ defined in claim 1 as granted implied that the polymer chains in the inner PAE layer with the lower refractive index n_{r2} were on average less oriented in the circumferential direction than the polymer chains in the outer PA layer with the higher refractive index n_{r1}. Accordingly, the polymer chains in the inner PAE layer had more freedom to rotate and align in response to the stress caused by balloon inflation. This increased the ability of the inner layer to withstand high internal pressure, and therefore the burst resistance of the balloon.

Indeed, as explained in ANNEX 1 filed on 29 October 2018 and ANNEX 17, 18, 18a, 19 and 19a, the highest stress caused by inflating a balloon built up in the innermost wall of the balloon, in the circumferential direction. This was where cracks would begin to appear, and therefore where the greatest resistance to the effects of internal pressure increase was required to improve the burst resistance of the balloon.

Examples 1 to 9 and comparative examples 1 and 2 discussed in the description of the patent and compiled in ANNEXES 21 and 22 provided experimental support for the influence of the criterion $n_{r1} - n_{r2} \geq 0.01$ on the burst pressure. In particular, these results indicated that the outermost layer had no direct effect on the burst pressure and that the observed increase in burst pressure was not due to the hardness of the PAE material used. Moreover, this criterion was independent on any additives added to the materials because the presence of such additives would not influence the anisotropy resulting from the polymer chain orientation.

Starting from D10, the objective technical problem to be solved was therefore not merely to provide an alternative to the catheter balloon disclosed in that document but to provide a catheter balloon with improved burst resistance. It followed that the subject-matter of claim 1 as granted involved an inventive step over D10.

First to fourth auxiliary requests - admittance

In the first to fourth auxiliary requests, the subject-matter of claim 1 was limited in comparison with claim 1 as granted, essentially by further specifying that the catheter balloon was biaxially stretched, in particular by being formed from a parison which had been caused to stretch in the axial direction and to expand in a radial direction. The appellant did not comment on the admittance of these requests in the appeal proceedings.

IX. The respondent's arguments relevant for this decision can be summarised as follows.

Main request - inventive step starting from D10

It was not credible that the criterion $n_{r1} - n_{r2} \geq 0.01$ defined in claim 1 as granted led to an increased burst pressure of the balloon as alleged by the appellant. As a consequence, the subject-matter of claim 1 of the main request did not involve an inventive step in view of the catheter balloon disclosed in D10.

First to fourth auxiliary requests - admittance

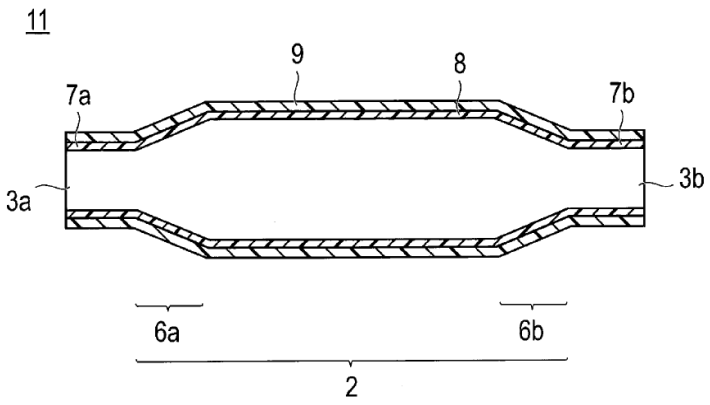
The first to fourth auxiliary requests, which differed from the requests on which the decision under appeal was based, had been filed for the first time on appeal. They could and should have been filed in the first-instance opposition proceedings. Consequently, they should not be admitted into the appeal proceedings.

Reasons for the Decision

1. Subject-matter of the contested patent

The patent in suit relates to a cylindrical catheter balloon as illustrated, for example, in Figure 1A, reproduced below. This balloon (11) is made of a laminate comprising at least a PA layer (9) and a PAE layer (8) disposed at the inner side of the PA layer.

[FIG. 1A]



Each layer is characterised by its refractive index n_r "in the circumferential direction of a cross-section perpendicular to the axis" of the balloon (i.e. tangentially to the cylinder, according to paragraph [0036] of the description) and "in the surface of inner side" of the layer (i.e. measured in an area of the layer which starts from the inner surface of the layer and extends up to one third of the thickness of the entire PA layer and up to half of the thickness of the entire PAE layer, according to paragraphs [0043] and [0044]).

Claim 1 as granted requires that the refractive indices n_{r1} for the outer PA layer and n_{r2} for the inner PAE layer satisfy the relationship

$$n_{r1} - n_{r2} \geq 0.01$$

According to the patent specification (paragraphs [0008], [0009], [0032] to [0035], and [0041]), this criterion would ensure a particular orientation of the polymer chains in the PAE layer which increases the burst pressure of the balloon, hence its resistance to rupture.

2. Main request - inventive step starting from D10

2.1 It is common ground that, as held in points 1.6.2 to 1.6.5 of the decision under appeal, the subject-matter of claim 1 as granted differs from the balloon disclosed in D10 (see paragraph [0047]) only in that the refraction indices n_{r1} and n_{r2} meet the criterion $n_{r1} - n_{r2} \geq 0.01$. The Board also shares this view.

2.2 The parties disagree on whether this distinguishing feature has the technical effect of improving the burst resistance of the balloon, as alleged by the appellant.

2.2.1 According to the appellant, the requirement that $n_{r1} - n_{r2} \geq 0.01$ implies that the polymer chains in the inner PAE layer are on average less oriented in the circumferential direction than the polymer chains in the outer PA layer with the higher refraction index. Accordingly, the polymer chains in the inner PAE layer have more freedom to rotate and align in response to stress resulting from balloon inflation, which increases the ability of the inner layer to withstand high internal pressure, and thus the burst resistance of the balloon.

The Board disagrees.

2.2.2 The Board acknowledges that, as explained for example in ANNEX 20a and illustrated in ANNEX 16, polymers may exhibit birefringence as the result of their microscopic structure and that refraction indices may directly relate to the orientation of the polymer chains. In particular, in a polymeric material where the polymer chains are oriented, for example due to uni-axial stretching, the refraction index in the direction of alignment of the chains will be higher than the refraction index in a perpendicular direction. This was also acknowledged by the respondent.

However, the Board concurs with the respondent that this conclusion concerning a *given* material analysed in two different directions cannot be transferred to the situation of claim 1 where a single refraction index measured in one direction is compared for two *different* materials. In other words, given that the inner and outer layers of the claimed balloon are made of *different* materials PA and PAE (see paragraphs [0052] to [0081] of the contested patent), it is not possible to draw any conclusion on the polymer chain orientation

in these layers from the mere comparison of the refraction indices n_{r1} and n_{r2} measured, in the same circumferential direction, in these layers.

This is because the refraction index measured in a given direction does not only depend on the polymer chain orientation but also on polarisability, which may be significantly different for the materials of the inner and outer layers (see, in this regard, section 3.2 of D20a). This is also reflected, notably, in the way polarisability α_m is involved in the Lorentz-Lorenz equation, which leads to the refraction index increasing not only with N but also with α_m, as pointed out by the appellant itself (see page 6 of the statement of grounds of appeal). Moreover, as argued by the respondent, the refraction indices n_{r1} and n_{r2} for the PA and PAE layers will also depend *inter alia* on the presence of various crystalline/amorphous phases (see D4, page 387, last five lines) or any additives in the materials (see D5, page 7, lines 6-13).

Therefore, contrary to the appellant's assertion, the refraction indices n_{r1} and n_{r2} defined in claim 1 cannot on their own indicate the degree of orientation of the polymer chains in the different PA and PAE layers. The appellant's argument in support of inventive step, based on that assumption, fails for this reason alone.

2.2.3 The Board also concurs with the respondent that the examples given in the patent (see ANNEXES 21 and 22 in this respect) do not convincingly support the alleged correlation between $n_{r1} - n_{r2}$ and the balloon's burst pressure either.

First, as argued by the respondent, all examples refer to balloons having three layers, and not two as claimed. While it is true that cracks may in principle start from the inside of the balloon, which supports the key role of the innermost layer, the appellant's assertion that the outermost layer does not affect the burst pressure, this pressure being allegedly only controlled by the difference $n_{r1} - n_{r2}$ for the two innermost layers, is not convincing and appears rather speculative. In any event, it is not demonstrated by the examples given in the patent.

Furthermore, only four PAE/PA material combinations are considered in the examples, what is more with differing layer thicknesses. These few, very specific examples cannot support the alleged general correlation.

Besides, in examples 2 and 5, for which the inner PAE layer has the same thickness but is made of different materials, the same difference $n_{r1} - n_{r2}$ of 0.013 is measured, but significantly different burst pressures of 36.8 and 28.1 atm are reported; these burst pressures even correspond approximately to the highest and lowest burst pressures reported for the whole set of examples 1 to 9. This demonstrates that other parameters distinct from the difference $n_{r1} - n_{r2}$ also have a significant influence on the burst pressure, which the examples given in the patent do not allow to distinguish from the alleged influence of the difference $n_{r1} - n_{r2}$. It further results that the lower burst pressures obtained in the comparative examples 1 and 2 cannot be simply attributed to a difference $n_{r1} - n_{r2}$ lower than 0.01 as asserted by the appellant, but could well be due to the particular choice of material used for the inner PAE layer.

2.2.4 In conclusion, the Board shares the respondent's view, also taken by the Opposition Division, that it is not credible that the claimed criterion $n_{r1} - n_{r2} \geq 0.01$ leads to an increased burst pressure of the balloon.

2.3 Accordingly, in the absence of a credible technical effect achieved, the technical problem to be solved starting from D10 is limited to the mere provision of an alternative balloon to the balloon known from D10. As explained by the Opposition Division in points 1.7.20 to 1.7.22 of the decision under appeal, it would have been obvious to the person skilled in the art starting from D10 to solve this technical problem.

It follows that the subject-matter of claim 1 as granted does not involve an inventive step starting from D10, contrary to the appellant's argument.

3. Admittance of the auxiliary requests

3.1 The respondent contested the admittance of the appellant's first to fourth auxiliary requests into the appeal proceedings.

These claim requests were filed by the appellant for the first time on appeal, with its statement of grounds of appeal. They differ from the auxiliary requests 1 to 7 on which the decision under appeal is based.

3.2 Pursuant to Article 12(6) RPBA 2020, the Board shall not admit requests which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

3.3 The appellant has not explained why the first to fourth auxiliary requests were not filed in the first-instance opposition proceedings and did not put forward any particular circumstances that would justify their admittance on appeal. The Board does not see any such circumstances.

These requests, according to which claim 1 includes additional features that limit its scope compared to claim 1 as granted, aim at overcoming the Opposition Division's inventive-step objection to the main request substantiated in the decision under appeal and discussed above.

However, in its preliminary opinion (point 1.4.10 of the communication annexed to the summons to attend oral proceedings), the Opposition Division had already drawn the parties' attention to the issue - initially raised by the respondent in its notice of opposition (see first two lines of page 12) - that the refraction index n_r might not be sufficient to serve as a measure for the orientation of the polymer chains in the balloon materials, and thus to support the presence of an inventive step. As indicated on page 5, fourth paragraph of the minutes and for the reasons given in points 1.7.8 to 1.7.20 of the decision under appeal, the Opposition Division finally adopted this view at the oral proceedings.

The appellant was given the opportunity to react and actually did so by filing several new auxiliary requests. After the Opposition Division announced that none of the appellant's requests on file at that time were allowable, the appellant confirmed that it did not have any further request (penultimate paragraph of page 7 of the minutes).

The Board therefore concurs with the respondent that the first to fourth auxiliary requests filed on appeal could, and should, have been filed during the first-instance opposition proceedings.

3.4 In any event, the amendments made in these requests *prima facie* do not lend an inventive step to claim 1 without raising any new issue. In particular, as argued by the respondent, producing the laminated balloon from a parison being biaxially stretched is known in the art according to paragraph [0005] of the contested patent itself. Specifying a biaxial stretch for the balloon therefore cannot *prima facie* make the subject-matter of claim 1 inventive.

3.5 For these reasons, the Board decides not to admit the appellant's first to fourth auxiliary requests into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated