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Datasheet for the decision of 28 May 2015

Case Number: T 0386/10 - 3.2.02

Application Number: 96116149.4

Publication Number: 0768097

IPC: A61M25/10, A61M29/02, A61M25/00

Language of the proceedings: EN

Title of invention:
Catheter balloon and balloon catheter

Patent Proprietor:
Terumo Kabushiki Kaisha

Opponent:
Boston Scientific Corporation

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 100(a), 100(b), 100(c), 114(2)
EPC R. 101
RPBA Art. 12, 13

Keyword:
Admissibility of appeal - (yes)
Main and first auxiliary requests disregarded (no)
Late-filed document - admitted (no)
Grounds for opposition - added subject-matter (no) - insufficiency of disclosure (no) - lack of patentability (no)

Decisions cited:
T 0220/83, T 0145/88, T 0493/95, J 0022/86

Catchword:

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Case Number: T 0386/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 28 May 2015

Appellant: (Patent Proprietor)	Terumo Kabushiki Kaisha 44-1, Hatagaya 2-chome, Shibuya-ku Tokyo (JP)
Representative:	Casalonga, Axel Casalonga & Partners Bayerstrasse 73 80335 München (DE)
Respondent: (Opponent)	Boston Scientific Corporation One Boston Scientific Place Natick, Massachusetts 01760-1537 (US)
Representative:	Peterreins, Frank Peterreins Schley Patent- und Rechtsanwälte Söltlstraße 2a 81545 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 December 2009 revoking European patent No. 0768097 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	C. Körber

Summary of Facts and Submissions

I. The appeal of the patent proprietor is against the decision of the Opposition Division, posted on 23 December 2009 to revoke the patent.

The notice of appeal was filed on 23 February 2010 and the appeal fee paid on the same day. The statement of the grounds of appeal was filed on 23 April 2010.

II. Oral proceedings were held on 28 May 2015.

The appellant requested that the decision of the opposition division be set aside and that the patent be maintained on the basis of the main request or, in the alternative, of one of the auxiliary requests 1 to 10, all filed with letter dated 3 August 2012.

The appellant further requested the admission into the proceedings of D32 describing the properties of Nylon 12.

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

The respondent further requested the admission into the proceedings of D33 describing the properties of Pebax®.

III. The following documents are mentioned in the decision:

D1: EP-A-0768097 (application as published)
D3: WO-A-97/32624
D4: WO-A-95/23619
D5: Material Testing Analysis & Characterization
D5': Affidavit of Dr John Chen dated 20 August 2009 regarding measurements for Traytuf® 7357

D6: Nylon Plastics Handbook, Melvin I.Kohan 1995, pages 298 to 302
D7: WO-A-95/09667
D13: EP-A-0636382
D15: WO-A-92/19316
D18a: DuPont Product Information HTY-401 (R2), "Hytrel® polyester elastomer", Nov. 1993
D18b: DuPont Engineering Polymers, "From concept to commercialisation", Sept. 1996
D18c: DuPont Injection Molding Guide, "Hytrel® polyester elastomer", Oct. 1996
D18d: DuPont Product and Properties Guide, "Hytrel® polyester elastomer", Nov. 1999
D18e: Data sheets of Hytrel® grades
D18f: Table "Hytrel® grades available before October 1996"
D19: EP-A-0485903
D20: DuPont Selar® PT 4368 — data sheet
D23: EP-A-0592885
D32: MatWeb Technical data sheet for Nylon 12 from www.matweb.com 14.04.2014
D33: Technical data sheet for Pebax® 7033SA01, April 2008

IV. The independent claims of the main request read as follows:

Claim 1

"A catheter balloon comprising a cylindrical portion and attaching portions for a catheter, said catheter balloon having a base layer formed of a high-strength polymer and one or more covering layers formed over at least one surface of said base layer of a flexible polymer having a elongation at break close to that of said high-strength polymer and being more flexible that

said high-strength polymer and said covering layer or covering layers together bearing 10% or more part of the bursting stress of the balloon and said cylindrical portion having a wall thickness of 25 µm or thinner."

Claim 5

"A catheter balloon comprising a cylindrical portion and attaching portions for a catheter, said catheter balloon having a base layer formed of a high-strength polymer, a first covering layer formed over the outside surface of said base of an flexible polymer having a elongation at break close to that of the high-strength polymer and being more flexible that the high-strength polymer, and the second covering layer is formed over the outside surface of said first covering layer of another flexible polymer more flexible than said flexible polymer for said first covering layer."

Claim 15

"A balloon catheter comprises of a tubular body and a balloon attached to a distal end portion of said tubular catheter body, characterised by that said balloon is the catheter balloon of any one of claims 1 to 14."

Claims 2 to 4, 6 to 14 and 16 are dependent claims.

V. The arguments of the appellant relevant for the decision can be summarised as follows:

Admissibility of the appeal

The appeal should be considered admissible since in the statement setting out the grounds of appeal all the

objections raised in the decision were addressed in detail. While it was true that inventive step of claim 1 of the main request had not been addressed directly, this was also not the case in the decision under appeal. The same standard should be applied for deciding on the admissibility of the appeal.

Admissibility of the main request

For the same reasons as above, there was no reason not to admit the main requests into the appeal proceedings. Furthermore, this request already had been filed with the statement setting out the grounds of appeal, so it was not late-filed.

Admissibility of D32

This document was filed in response to the decision of the Opposition Division (considering that the elongation at break of Nylon 12 was 270%) to prove the different possible values of the elongation at break of Nylon 12, so that it had to be admitted into the proceedings.

Sufficiency of disclosure

It was the elongation at break of the material itself which had to be considered as indicated in the claim wording, and the test to be used was indicated throughout the patent as being ASTM D648. Paragraph [0048] of the patent gave a clear definition of how the 10% feature had to be determined, and any bursting test was suitable to test the balloon since a ratio was required. In addition, the person skilled in the art would not consider embodiments which made no sense for the intended use.

Therefore a balloon having the features of claim 1 could be made by the person skilled in the art.

Main request – added subject-matter

In the description of the embodiment according to Figure 1, both features - elongation at break and bursting stress - were already presented in combination and this was confirmed by the examples.

Therefore there was no problem with added subject-matter.

Main request - novelty

It was accepted that the priority of the patent in suit was not valid for the subject-matter of claim 1.

It was self-evident that for a comparison of the elongations at break to be made, these had to be determined according to the same testing protocol.

Novelty over D3 – claim 1

D3 itself did not indicate any values for the elongations at break of Traytuf® 7357 and Arnitel® EM740. A fortiori, no testing protocol was indicated. The values of the elongation at break for Traytuf® 7357 found in D5 were not reliable since 3 of the 5 tests made there were out of gauge. In D4 no testing protocol was indicated for the determination of the elongation at break of Arnitel® EM740. D18e showed that the testing protocol had a significant influence on the value obtained. Hence no conclusion could be drawn as to the closeness of the elongations at break of the two

mentioned materials, so that the subject-matter of claim 1 was novel over D3.

Novelty over D7 – claim 1

D7 did not disclose any value of the elongations at break for the PET and Hytrel® used for the balloon layers. By using the value of the elongation at break of the specific PET described in the patent in suit the respondent made a selection not even implicitly disclosed in D7. Therefore no conclusion could be drawn for the closeness of the elongations at break.

Novelty over D13 – claims 1 and 5

Whatever combination of materials proposed by the respondent was considered, D13 did not disclose any value of the elongations at break of the materials. Moreover in D13, column 3, it was suggested to use materials with significantly different elongations at break, so that the person skilled in the art was not taught to take close ones. In addition, the respondent had selected a PET in D19 which was different from that disclosed in the patent in suit, so the elongation at break was not necessarily identical. Moreover, D23 and D4 did not disclose any testing protocol for the elongations at break mentioned therein.
D33 was not to be admitted into the proceedings because it was post-published and the material mentioned therein was not the same Pebax® and had not the same elongation at break as those mentioned in D4.

Therefore no conclusion could be drawn from D13 in relation to the closeness of the elongations at break.

Novelty over D15 – claim 1

The respondent had not only chosen the PET according to the patent; also, the testing protocol indicated in the patent was ASTM D648, whereas the testing protocol indicated in D20 was ASTM D882, so that no conclusions could be drawn in relation to the closeness of the elongations at break.

Inventive step – claim 5

The issue in D13 was the collapsibility, not the bursting strength. In addition, D13 taught the use of different elongations at break for the materials used for the base and the cover layer, and therefore D13 taught away from the invention.

D7 and D15 could not be the closest prior art because they disclosed only two layer balloons.

Inventive step – claim 1

The arguments were similar for inventive step of the subject-matter of claim 5.

VI. The arguments of the respondent relevant for the decision can be summarised as follows:

Admissibility of the appeal

The statement setting out the grounds of appeal had to be complete. Since inventive step was only addressed starting with the fifth auxiliary request, the appeal was not admissible.

Admissibility of the main request

For the same reasons as above, at least the main request was not to be admitted into the appeal proceedings.

Admissibility of D32

This document was not only late filed but had also a publication date after the priority date. Moreover, it covered blends of materials similar to Nylon 12. Therefore this document was not to be admitted into the proceedings.

Sufficiency of disclosure

It was an undue burden for the person skilled in the art to select polymers fulfilling the features that the cover layer had to bear at least 10% of the bursting pressure, and that the elongations at break had to be close, because no testing methods were disclosed, and the properties were dependent on a lot of factors such as temperature, time, etc... The wording of the claim even covered such a combination as the base layer bearing 1% and the cover layer bearing 99% of the bursting pressure.

Hence, several features of claim 1 were not disclosed sufficiently clearly and completely for the person skilled in the art to carry them out.

Main request – added subject-matter

In the application as filed, the feature of the elongations at break of the two materials being close and the feature of the cover layer bearing 10% of the bursting pressure were presented as two separate solutions to a single problem, whereas in claim 1 they

were now associated. Therefore the ground of opposition pursuant to Article 100(c) EPC prejudiced the maintenance of the patent.

Main request – novelty

The priority of claim 1 of the patent in suit was not valid, so that D3 was a document according to Article 54(3) EPC for that claim.

The testing protocol for measuring the different elongations at break not being mentioned in claim 1, any combination of values obtained in any manner had to be considered to fall under the wording of that feature of the claim.

Novelty over D3 – claim 1

In example 1 of D3, Traytuf® 7357 and Arnitel® EM740 were mentioned as materials for the base layer and the cover layer. According to D5, the elongation at break of the first was 300% and according to D4 that of the second was 340%, so the feature of the closeness of the elongations at break of the two materials according to claim 1 was anticipated. No change in the commercially available mixture of polymers for Traytuf® 7357 was known between the filing date of D3 and the date of the tests made according to D5.

Novelty over D7 – claim 1

The balloon described in this document was made of PET for the base layer and of Hytrel® for the cover layer. The elongation at break of PET was known from the patent in suit and the elongation at break of Hytrel® was known from the collection of documents D18. The

elongation at break of PET was 500%, and when a flexural modulus above 21 000 psi was taken into consideration (as recommended in D7), the elongation at break of Hytrel® was between 340% and 500% (D18f), so that the feature of the closeness of the elongations at break was anticipated.

Novelty over D13 – claims 1 and 5

The balloon disclosed in D13 could have two or three layers. When it had two layers, the base layer and the cover layer could respectively be made either of PET and PU, or of Nylon 12 and Pebax®. In the first case, D19 disclosed UNIPET®580 (which was the same as in the patent in suit with an elongation at break of 500%) and D23 disclosed a PU with 250% elongation at break, so the closeness condition of claim 1 was satisfied. In the second case, according to the patent in suit the elongation at break of Nylon 12 was 270%, and according to D4 the elongation at break of Pebax® was 300% or 400%, so that also in this case the closeness condition of claim 1 was satisfied. The relationship between the two elongations at break mentioned in paragraph 3 of column 3 of D13 was only an optional feature.

In relation to the second case, D33 had been filed during the oral proceedings as an additional disclosure of the properties of Pebax® and had to be admitted into the proceedings.

The second polymer cover layer of claim 5 was anticipated by the Hydrogel layer 24 of D13.

Novelty over D15 – claim 1

When, for the balloon according to D15, a combination of PET and Selar®PT4368 was chosen for the base and the cover layers, the elongations at break were close. The properties of PET were known from the patent and those of Selar®PT4368 were known from D20.

Inventive step – claim 5

Starting from the balloon according to D13 made of PET and PU, it was obvious to take two materials having close elongations at break in order to improve the bursting pressure resistance. In this way the two layers broke at the same time.

The subject-matter of claim 5 was also not inventive when starting from D7 or D15 and adding a softer layer as was done in D13.

Inventive step – claim 1

In the written submissions, it was considered that the subject-matter of claim 1 lacked an inventive step over D7 alone, D13 alone, and the combinations of D13 and D15, and D13 and D4.

Reasons for the Decision

1. Admissibility of the appeal (Rule 101 EPC)

In the impugned decision, the subject-matter of claims 1 according to the main, first to third and fifth auxiliary requests was considered to lack novelty under Article 54(3) EPC over D3 and the subject-matter of claims 1 according to the sixth to ninth auxiliary

requests was considered to lack inventive step over D13 combined with D7 and D4 (the fourth auxiliary request was not admitted into the proceedings).

With its statement setting out the grounds of appeal the appellant filed the first to seventh auxiliary requests, the main request being based on claim 1 of the patent as granted. The appellant explained why, in its opinion, the subject-matter of claim 1 according to the main, first to fourth auxiliary requests was novel over D3 and why the subject-matter of claim 1 according to the fifth (identical to the sixth in the opposition proceedings) to seventh auxiliary requests was inventive over D13 in combination with D4. All the versions of claim 1 were based on claim 1 of the patent as granted, to which features had been added or disclaimed (seventh auxiliary request).

However, the appellant did not explain why the subject-matter of the different claims 1 according to the main and first to fourth auxiliary requests involved an inventive step, although the reasoning used in the decision against claim 1 of the sixth auxiliary request (combination of claims 1 and 12 as granted) must have been valid at least against the more general claim 1 of main request as well.

According to established jurisprudence expressed in many decisions (e.g. T 220/83, OJ EPO 1986, 249, T 493/95, T 145/88, J 22/86), the statement of the grounds of appeal should specify the legal or factual reasons on which the case for setting aside the decision is based. The arguments must be clearly and concisely presented to enable the board and the other party or parties to understand immediately why the decision is alleged to be incorrect, and on what facts

the appellant bases his arguments, without first having to make investigations of their own.

It might be considered questionable whether these requirements are met in the present case, when the statement setting out the grounds of appeal does not explain why the subject-matter of claim 1 according to the main request was inventive.

In the present case the Board considers, however, that the requirements for admissibility are met. The objection raised in the decision against claim 1 according to the main request has been dealt with in the statement setting out the grounds of appeal. In addition, a reasoning as to why the appellant contests the lack of inventive step objection raised in the decision against lower ranking requests is also present. This reasoning is at least partially valid for claim 1 of the main request. Since, in the decision under appeal, the inventive step of the subject-matter of claim 1 according to the main request was only addressed indirectly, it seems reasonable to the Board to accept that it is also addressed indirectly in the statement setting out the grounds of appeal. In other words, the reasons as to why the decision should be set aside are present.

Therefore the appeal is admissible.

2. Admission into the appeal proceedings of the main request (Article 12 RPBA)

The respondent submitted that the main request should not be admitted into the appeal proceedings because no reasoning had been filed with the statement setting out the grounds of appeal as to why an inventive step was

present in the subject-matter of claim 1 according to this request. Hence, full reasons as to why a patent could be maintained on the basis of this request had not been given.

The Board does not share this opinion. First of all, the said request was filed with the statement setting out the grounds of appeal, so it was not late-filed. Secondly, while strictly speaking no specific reasons were filed as to why the subject-matter of claim 1 according to the main request was to be considered inventive, such reasoning was filed for the lower-ranking fifth auxiliary request. As claim 1 according to this lower-ranking request includes the additional feature of the nature of the two polymers according to claim 12 of the granted patent, the reasoning in favour of the presence of an inventive step for the subject-matter of claim 1 according to the fifth auxiliary request is at least partially applicable to the subject-matter of claim 1, as already mentioned above. This is indirectly confirmed by the respondent, since it used the same combination of documents for its lack of inventive step reasoning against claim 1 according to the main request as that used in the impugned decision.

Therefore the Board sees no reason to disregard the main request in the appeal proceedings.

3. Admission into the proceedings of D32 (Article 114(2) EPC, Article 12 RPBA)

The appellant considered that document D32 should be admitted into the proceedings; it proved that the elongation at break of Nylon 12 was between 350% and

500% and not necessarily 270% as accepted by the Opposition Division.

The Board notes that the document has a date in 2010, i.e. clearly after the filing date of the patent in suit, so that it is at least questionable whether the materials having the listed properties were available before the priority date of the patent in suit. Furthermore, the paragraph "*Material notes*" indicates that "*This property data is a summary of similar materials in the MatWeb database for the category "Nylon12".*", which suggests that the listed properties are not for Nylon 12 alone but for equivalent or similar materials as well. Consequently nothing about the properties of Nylon 12 mentioned in the present prior-art documents can be deduced from this document.

Therefore the Board decides not to admit this document into the appeal proceedings.

4. The invention concerns a catheter balloon and the balloon catheter including the catheter balloon. It aims at obtaining a balloon with a good balance between all desired properties (compliance, flexibility, resistance to internal pressure, tracking capability, resistance to pin holes) by forming the balloon from a combination of different layers of different polymers.

5. Main request – sufficiency (Article 100(b) EPC)

The respondent submitted that it was an undue burden for the person skilled in the art to carry out the invention according to claim 1, because the parameters present in the claim were too vague. In particular, it was impossible to know when the elongations at break of the layers were close, and it was not defined how the

feature that "*said covering layer or covering layers together bearing 10% or more part of the bursting stress of the balloon*" was to be carried out on the basis of the information available in the patent. When the bursting stress was measured for the layers together, it was difficult to know which layer bore how much of the stress. In addition, the general testing conditions were not defined, although the results depended on time, temperature and so on. The definition of paragraph [0048] was of no help in this respect.

The Board does not share this opinion. The claim wording requires that the cover layer be made of a flexible polymer having an elongation at break close to that of the high-strength polymer of the base layer. Hence for the comparison of the elongations at break, the elongations at break of the starting materials are meant and not the elongations at break of the finished balloon layers. The elongation at break of a polymer is measured according to any one of the known test protocols and is one of its technical characteristics, so that the person skilled in the art has no difficulty finding two polymers fulfilling this requirement of claim 1. Furthermore, for a comparison to be meaningful the same test protocol has to be used for both materials, otherwise the comparison would make no technical sense.

Concerning the closeness of the elongations at break, not only the description of the patent mentions a variation of +/-30% as being close (paragraph [0060]), but even the claim wording that the covering layer or covering layers together should bear 10% or more of the bursting stress of the balloon is an indication for the person skilled in the art. As a matter of fact, if one layer bears 10% of the bursting stress, this means that

shortly before bursting both layers must still contribute to bear the pressure, otherwise one layer would bear 100% of the bursting stress. This also gives the person skilled in the art information as to the closeness of the elongations at break.

Concerning the "10% feature" the patent gives a clear definition of what is meant, in paragraph [0048]: "*That the covering layer bears 10% or more part of the bursting stress means that when the bursting strength of a balloon having the base layer and covering layer is X kg/cm^2 and the bursting strength of a balloon having the base layer only is Y kg/cm^2, Y/X is equal to or smaller than 0.9.*" In other words, the bursting strength has to be established for the base layer alone and for both layers together, so that a ratio can be calculated. The Board therefore does not see why the person skilled in the art would not be able to carry out this feature.

As far as the general testing conditions are concerned, not only the description gives some indications, such as the testing in water at 37°C with pressure increments of 1kg/cm^2 (paragraph [0119]) but the person skilled in the art will also obviously adapt the tests to the desired type of device and eliminate testing conditions which are not realistically linked to the intended use of the device. In the present case, the catheter balloon is meant for use in the human body for certain types of applications so that the person skilled in the art will, for instance, know the temperature of use of the balloon, and that it will not remain for hours inflated at its maximum pressure in the human body, etc. The same is true for the proportion of the bursting stress to be supported by the two different layers. The person skilled in the art

will not consider proportions which make no technical sense, like 1% - 99% as suggested by the respondent.

Therefore, in the opinion of the Board the requirements of sufficiency of disclosure are fulfilled.

Hence, the ground for opposition pursuant to Article 100(b) EPC does not prejudice the maintenance of the patent on the basis of the main request.

6. Main request – added subject-matter (Article 100(c) EPC)

The respondent submitted that the feature that the more "*flexible polymer having a elongation at break close to that of said high-strength polymer*" and the feature that "*said covering layer or covering layers together bearing 10% or more part of the bursting stress*" were presented in the original application as two different solutions to the same problem, as could be seen for instance from the fact that two independent claims 1 and 2 were present in the application as filed, each only including one of the two features.

The Board does not share this opinion. Already the detailed description (page 3, penultimate paragraph to page 4, first paragraph) of Figure 1 associates the two features for the embodiment shown in that figure. This association of the two features objected to is confirmed in relation to the experiments presented later in the description, in particular examples 1 to 5 and experiment 1. From the table disclosed on page 23 it is clear that in examples 1 to 5 the elongations at break of the materials for the base layer and for the first cover layer are close to each other, and that the bursting stress borne by the covering layer is higher

than 10% (according to the definition given in paragraph [0048]). The same can be concluded from the other tables.

Therefore the combination of the two above-mentioned features in claim 1 does not add any subject-matter beyond the content of the application as filed.

Hence, the ground for opposition pursuant to Article 100(c) EPC does not prejudice the maintenance of the patent on the basis of the main request.

7. Main request - novelty (Articles 100(a) and 54 EPC)

In the following the Board will concentrate on the feature of the closeness of the elongations at break of the materials used for the layers, namely the high-strength polymer used for the base layer and the more flexible polymer used for the covering layer(s). This however does not mean that the Board considers all the other features of claim 1 to be disclosed by each of the respective documents.

Concerning the said feature, the respondent considered that it had to be interpreted as non-limitative, as no testing protocol and no definition of closeness were present in the claim.

The Board does not share this opinion. As already mentioned above, for a comparison to be technically meaningful the elongation at break of the two materials has to be measured under the same testing conditions. As exemplified, for instance, in the D18 documents, the elongation at break may vary greatly depending on the testing protocol used. Concerning the requirement of closeness, the Board considers that since the patent in

suit in its description mentions a variation of +/-30% as being close (paragraph [0060]), and this is also claimed in claim 2 of the patent as granted, the closeness required by claim 1 can be somewhat less but still of the same order of magnitude.

7.1 Novelty over D3 – claim 1

In the impugned decision, novelty was considered lacking on the basis of D3, because the priority of the invention claimed in claim 1 of the patent as granted was considered not to be validly claimed.

The application leading to the patent in suit was filed on 9 October 1996 with a Japanese priority of 11 October 1995. It is not disputed by the parties that the feature of the wall thickness of 25 µm or thinner present in claim 1 was not disclosed in the priority document.

For this reason, D3 filed on 6 March 1997 with a valid US priority of 6 March 1996 is a document under Article 54(3) EPC, the relevant formal conditions being fulfilled. This was not disputed by the parties either.

The respondent considered that example 1 on page 10 of D3 anticipated the subject-matter of claim 1, the properties of the two polymers cited being known from D4 and D5, D5'.

The Board does not share this opinion. D3 discloses in example 1 a catheter balloon comprising two layers, these being made of a PET (Traytuf® 7357) belonging to the high-strength polymers (page 5, line 19 onwards) as base layer with another polymer (Arnitel® EM 740) belonging to the more flexible polymers (page 6, line 5

onwards). The elongations at break of the two polymers are not mentioned in D3. However, the elongation at break for the polymer Arnitel® would be found in D4 (example 10 page 11) and that of the polymer Traytuf® would be found in D5, D5'.

An ultimate elongation of 340% for the polymer Arnitel® EM 740 is indeed mentioned in D4 in relation to example 10. However, in the patent in suit the testing protocol ASTM D638 is always mentioned in relation to the elongation at break, whereas no testing protocol at all is mentioned in D4. The appellant mentioned at least ISO 527 and Nominal ISO 527 as other possible testing protocols.

For the elongation at break of the polymer Traytuf® 7357, documents D5 and D5' (affidavit from Dr Chen) were cited. The Board notes that the trademark Traytuf® is not present on the test sheets D5, only PET is mentioned. A strain at break of around 300% is mentioned in the tables. In his affidavit Dr Chen explains that the protocol of ASTM D638 was used to test the samples. However, more importantly, the tests were made well after the filing date of D3 as well as of the patent in suit (9 October 1996), namely in October 2007, and there is no information in the affidavit from Dr Chen on whether the composition of the polymer with the trademark Traytuf® 7357 was, at the time of testing, identical to the composition of the same polymer at the filing date of the patent or of D3 in which the use of a polymer of this name is mentioned.

It follows that for the elongation at break of the polymer Arnitel® EM 740 no testing protocol is mentioned in D4 and for the elongation at break of the

polymer Traytuf® 7357 no reliable information is present in the file.

At least for the above reasons, D3 does not directly and unambiguously disclose that the two materials should be selected so that their elongations at break are close, so the subject-matter of claim 1 of the main request is novel over D3.

7.2 Novelty over D7 – claim 1

According to the respondent, the embodiment described from page 9, line 34 to page 10, line 4 anticipates the feature of close elongations at break of claim 1. A two-layer balloon is described, whereby the interior layer is made of the material PET and the outer layer is made of a material named Hytrel®. Additionally it is explained that a "flexural modulus" for the outer layer of about 21 000 to 440 000 psi is preferred, which is said to be the case for the polymer Hytrel® (page 6 second paragraph). The other technical characteristics of the materials are taken by the respondent either from the patent in suit (paragraph [0102]: elongation at break for PET) or from the set of D18 documents, in particular D18f (for the elongation at break of the polymer Hytrel®).

Documents D18a to D18f are all about the material with the trademark Hytrel®, D18f being a summary of some properties. From D18f it appears that the elongation at break varies from 200% to 700% depending on the type of polymer Hytrel® chosen. For the polymers Hytrel® having a flexural modulus higher than 21 000 psi, the elongation at break varies from 340% to 500%. On D18b page 28, where the properties are taken from, the same

testing method ASTM D638 is mentioned as in the patent in suit.

In the patent in suit (paragraph [0102]) the elongation at break of the PET cited is said to be 500% (ASTM D638). This is, however, for the PET named "UNIPET® RT580CA" from Japan Unipet Co. According to the respondent, since the elongations at break of the two materials Hytrel® and UNIPET® seem to fulfil the condition mentioned in the description of the patent (paragraph [0039]), the feature of claim 1 of the elongations being close is anticipated.

The Board does not share this opinion. Document D7 does not mention the PET "UNIPET® RT580CA" but only PET in general, so in the opinion of the Board it cannot be considered that the PETs mentioned in D7, i.e. all the PETs available on the market at the filing date of D7 and adapted for catheter balloons, necessarily all have the properties of the PET "UNIPET® RT580CA" mentioned in the patent in suit.

For the above reasons, even though it is accepted that the person skilled in the art would seriously contemplate carrying out the invention of D7 with a polymer Hytrel® having a flexural modulus greater than 21 000 psi, the choice of two polymers having close elongations at break for the two layers of the catheter balloon is not directly and unambiguously derivable from D7.

7.3 Novelty over D13 – claim 1

D13 describes a catheter balloon having a two- (or three-) layer wall, whereby the outer layer (or middle layer) is more flexible than the base layer.

In a first embodiment described starting column 4, line 45, the inner wall is PET and the outer wall is polyurethane (column 5, lines 10 to 35).

The respondent submitted that D19 (column 11, lines 19 to 25) discloses a PET (UNIPET® 580) which is the same as that disclosed in the patent in suit in paragraph [102], and there this polymer was indicated to have an elongation at break of 500%. Concerning polyurethane (PU), D23 (page 7, lines 15 to 18) disclosed a PU (PELLETHANE® 2363-75D) having an elongation at break of 250%, so the closeness of the elongations at break of the materials of the two layers was anticipated.

The Board does not share this opinion. Apart from the fact that there seems to be no specific reason apparent in D13 as to why the skilled person reading this document would specifically choose a combination of the materials UNIPET®580 and PELLETHANE® 2363-75D, the elongations at break considered by the respondent cannot be compared. D19 does not indicate any value for the elongation at break of the Polymer UNIPET®580 and the patent in suit does not mention this polymer but UNIPET®580CA. For this reason it cannot be considered that the polymer disclosed in D19 has the same elongation at break as the polymer mentioned in the patent in suit. Concerning the elongation at break of the PU indicated in D23, no testing method is mentioned. It follows that no comparison can be made anyway. In addition, even if a comparison could be made, in the opinion of the Board one elongation at break of 500% and another of 250% cannot be considered to be close, even with a broad interpretation of that feature of the claim.

Thus it is not directly and unambiguously derivable from this embodiment disclosed in D13 to take a PET and a PU with close elongations at break for the manufacturing of the catheter balloon described there.

The respondent further considered that in another embodiment Nylon 12 was mentioned as an alternative to PET for the inner layer (claims 4, 15, column 2, lines 13 to 18) and other elastomeric materials than PU were mentioned as alternatives for the outer layer (column 2, lines 46 to 49, claims 5, 16). The specific combination of Nylon 12 and polyetheresteramide terpolymer was mentioned in column 4, lines 24 to 29. The respondent submitted that Nylon 12 and the polymer Pebax® (a polyetheresteramide terpolymer) fulfilled the condition of the elongations at break being close. The properties of the polymer Pebax® were clear from D3 or D4. Concerning the elongation at break of Nylon 12, it was not disputed that it was 270%. The respondent further submitted that the elongation at break of the polymer Pebax® was confirmed in the patent in suit itself, in paragraph [0123].

The Board notes that the name Pebax® is not mentioned in D13 and the polymer Pebax® is only one of the possible polyetheresteramide terpolymers mentioned in line 49 of column 2. In addition, in D4, Pebax® 6333 and Pebax® 7033 are cited, respectively with an elongation at break of 300% and 400% (examples 6 and 1). However, here again, no testing method is mentioned. Furthermore, on page 6, lines 25 to 28 of D4, it is mentioned that other PEBA polymers could be used. The patent in suit is of no help in this respect, as it mentions Pebax® 6333SA01 and not Pebax® 6333, so that the identity of the polymers cannot be assumed.

The respondent filed document D33 during the oral proceedings in order to confirm the properties of the polymer Pebax®. However, the Board agrees with the appellant that this document should not be admitted into the appeal proceedings pursuant to Article 114(2) EPC and Article 13 RPBA, because it concerns the polymer Pebax® 7033SA01 which was mentioned in none of the cited documents or patent in suit, because document D33 was published in 2008 and hence after the filing date of the patent in suit, and because in the document the elongation at break is said to be over 350% which corresponds neither to that of the polymer Pebax® 6333 (300%) nor to that of the polymer Pebax® 7033 (400%) indicated in D4.

For all these reasons, it is not directly and unambiguously derivable from this embodiment disclosed in D13 that, if Nylon 12 and a polyetheresteramide terpolymer are used for the layers of the balloon, the elongations at break of both materials would inevitably be close.

7.4 Novelty over D15

According to the respondent, when, according to D15, a combination of PET and the polymer Selar®PT4368 was used for the base and cover layers, the elongations at break were close. The properties of PET were known from the patent in suit and the properties of polymer Selar® PT4368 were known from D20.

The Board does not share this opinion. Apart from the fact that no specific PET is mentioned in D15, so that there seems to be no reason for choosing the specific PET UNIPET® RT580CA, the testing method used in the patent in suit is ASTM D680 whereas the testing method

mentioned in D20 is ASTM D882. In the absence of any evidence as to the nature of the results obtained by both methods, the Board cannot conclude that identical or even similar results would be obtained.

Therefore, also in relation to D15 there is no directly and unambiguously derivable embodiment anticipating the feature of the elongations at break of the two materials chosen being close.

7.5 Novelty over D13 - claim 5

The respondent challenged the novelty of the subject-matter of claim 5 over D13.

Claim 5 requires 3 layers: a base high-strength polymer layer, a first covering layer of a more flexible polymer than the high-strength polymer and having an elongation at break close to that of the high-strength polymer, and a second covering layer of an even more flexible polymer than the polymer of the first covering layer.

This was disclosed in D13 with layers of PET, PU and hydrogel (column 5, lines 52 to 57).

As already explained above, it is not directly and unambiguously derivable from D13 that the elongations at break of the PET and PU chosen for the layers should be close. So for this reason alone the subject-matter of claim 5 is novel as well.

7.6 Therefore the ground for opposition of lack of novelty (Article 54 EPC) pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent on the basis of the main request.

8. Main request - inventive step (Articles 100(a) and 56 EPC)

8.1 Inventive step – claim 5

8.1.1 The Board will first analyse inventive step of the subject-matter of claim 5, starting with D13 and thus concentrating on the differentiating feature that the elongations at break of the materials of the base layer and of the (first) cover layer are close.

The respondent argued that starting from the first embodiment of D13 and, hence, the combination PET and PU as materials for the base layer and the first cover layer, it would be obvious for the person skilled in the art to choose two materials having close elongations at break, in order to improve the balloon's resistance to pin holes and to bursting. In this way the two layers would burst together.

The Board does not share this opinion. While for mechanical reasons taken in isolation it might be of interest to have the elongations at break of the materials used being close, this does not mean that the person skilled in the art would automatically attach primary importance to this feature when designing a balloon, because other properties are equally important for such a balloon introduced into the human body, some of them possibly even being antinomical. For the person skilled in the art it is clear that the mechanical strength can be given by one of the layers only. In D13 the primary interest lies with the resistance to pin holes and good collapsibility of the balloon (column 1, lines 38 to 44). In order to improve the collapsibility of the balloon, D13 suggests using a cover or outer

layer (called elastomeric sleeve) which is more elastic than the inner layer (called balloon). The outer layer then serves as an aid for the deflation of the balloon. Column 2, lines 22 to 28: "*The natural, resilient character of the elastomeric sleeve causes compression of the non-resilient balloon back to a deflated, minimum-diameter condition, being driven by the natural contraction of the stretched elastomeric sleeve back toward its original configuration*". This difference in the properties of the two layers may go so far as choosing a material having an elongation at break of at least 100% for the elastomeric sleeve and a relatively inelastic material having an elongation at break of no more than 30% for the balloon (column 3, lines 9 to 17). As a consequence, the person skilled in the art, even if he wished to improve the mechanical resistance of the balloon described in D13, would not wish to lose the good collapsibility so achieved, and would not have any reason to choose materials having close elongations at break for the base layer and the cover layer.

Hence, starting from D13, the subject-matter of claim 5 is not obvious because it goes against the teaching of this document. This is obviously true irrespective of whether D13 is considered alone or in combination with any other document cited by the respondent, because the teaching of D13 remains the same.

8.1.2 In the written proceedings the respondent further argued that the subject-matter of claim 5 was not inventive over D7 and D13, and D15 and D13, because it was obvious to add a lubricious hydrophilic coating such as hydrogel to the starting balloons described in D7 or D15. The respondent did not wish to further comment on these combinations during the oral proceedings.

As explained above, the lack of a lubricious hydrophilic coating is not the only difference between the balloons according to D7 or D15 and the claimed balloon, the closeness of the elongations at break being at least one other difference. However, the respondent failed to present a lack of inventive step reasoning encompassing this additional difference and the Board does not see any.

8.1.3 Hence, the subject-matter of claim 5 is not rendered obvious by the cited documents.

8.2 Inventive step – claim 1

In its written submissions, the respondent contended the subject-matter of claim 1 lacked inventive step over D7 alone, D13 alone, D13 and D15, and D13 and D4. It did not wish to further comment on these attacks during the oral proceedings.

The feature of the elongations at break of the materials for the base layer and for the cover being close is common to the balloon claimed in claim 5 and that claimed in claim 1. Consequently, the reasoning above, according to which the balloon according to claim 5 is not obvious when starting from D13, is also valid for the balloon according to claim 1.

The respondent further considered that the above differentiating feature was obvious for the person skilled in the art starting from D7 and wishing to achieve a higher burst strength, since he would select the polymer UNIPET®580 (D19) as a PET for the base layer and a polymer Hytrel® (D18) with a flexural

modulus above 21 000 psi for the cover layer, without the need for any inventive step.

As already explained above, there is no information on file indicating that, even if the person skilled in the art chose the two specific polymers cited above, the elongations at break would be close. So there is no evidence on file that the litigious feature would be achieved. For this reason alone the subject-matter of claim 1 must be considered non-obvious when starting from D7. In addition, the aim of the invention in D7 is to manufacture a balloon combining the advantages of "compliant" and "non-compliant" balloons (page 1, line 29 to page 2, line 24). In one embodiment a layer of PET is combined with a layer of the polymer Hytrel® (page 9, line 34 to page 10, line 4). However, there is no indication in D7 as to why the specific polymer UNIPET®580 should be used, let alone any indication that the closeness of the elongations at break of the two materials chosen would provide any further advantage. In the opinion of the Board, the reasoning of the respondent is a typical ex-post-facto analysis, made with hindsight.

For the above reasons, the subject-matter of claim 1 is not rendered obvious by the cited documents.

8.3 Therefore the ground for opposition of lack of inventive step (Article 56 EPC) pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent on the basis of the main request.

9. The respondent had no objections to the description, drawings and sub-claims intended for maintenance. Nor does the Board.

10. Since the patent can be maintained on the basis of the main request, there is no need for the Board to deal with the auxiliary requests.

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:

- claims 1 to 16 of the main request filed with letter dated 3 August 2012; and
- the description and figures of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated