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**Datasheet for the decision  
of 23 February 2017**

**Case Number:** T 1477/15 - 3.2.02

**Application Number:** 01114582.8

**Publication Number:** 1145729

**IPC:** A61M25/00, A61M25/01

**Language of the proceedings:** EN

**Title of invention:**

A ready-to-use urinary catheter assembly

**Patent Proprietor:**

Coloplast A/S

**Opponents:**

Hollister Limited  
Dansac A/S  
Kain-Märk Gesellschaft m.b.H.  
Medical4You B.V.

**Headword:**

**Relevant legal provisions:**

EPC Art. 56, 69, 84, 100(a), 100(b), 111(1), 112(1), 113(2),  
123(2)

EPC R. 80, 99, 101(1)

RPBA Art. 12, 13(3)

EPC Prot. Interpretation Article 69

**Keyword:**

Admissibility of the appeals (yes)

Insufficiency of disclosure - admitted (no)

Referral to the Enlarged Board of Appeal - (no)

Novelty - main request (no)

Admissibility - auxiliary requests 3 and 9 (yes)

Remittal to the department of first instance - (no)

Admissibility of a new line of argument during oral  
proceedings (no)

Added subject-matter - auxiliary request 3 (no)

Clarity - auxiliary request 3 (yes)

Inventive step - auxiliary request 3 (yes)

Amendments to description occasioned by ground for opposition  
(no)

Right to withdraw requests (yes)

**Decisions cited:**

R 0013/13, T 0155/85, T 0570/91, T 0439/92, T 1040/93,

T 0817/94, T 1149/97, T 0190/99, T 1192/02, T 1574/05,

T 0468/09, T 2125/10, T 0012/11, T 0801/13, T 1155/13

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 1477/15 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 23 February 2017**

**Appellant:** Coloplast A/S  
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**Representative:** Inspicos P/S  
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**Appellant:** Hollister Limited  
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**Appellant:** Dansac A/S  
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**Representative:** Høiberg P/S  
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**Appellant:** Medical4You B.V.  
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**Representative:** Holme Patent A/S  
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2500 Valby (DK)

**Party as of right:** Kain-Märk Gesellschaft m.b.H.  
(Opponent 4) Sonnenweg 7  
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**Representative:** Holme Patent A/S  
Valbygårdsvej 33  
2500 Valby (DK)

**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
8 July 2015 concerning maintenance of the  
European Patent No. 1145729 in amended form.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** P. L. P. Weber  
D. Ceccarelli

## **Summary of Facts and Submissions**

- I. In its interlocutory decision taken in the oral proceedings held on 11 and 12 May 2015 and posted on 8 July 2015, the Opposition Division held that the patent and the invention to which it related, as amended according to auxiliary request 2, met the requirements of the EPC.
- II. The patent in suit is based on divisional application 01114582.8 (EP-A-1145729) of 97918923.0 (EP-A-0923398). For the patent in suit the present Board took a first decision (T 0468/09 of 28 September 2011) finding that the invention as defined in an amended main request was sufficiently disclosed, and a second decision (T 0801/13 of 27 February 2014) finding that the subject-matter of the patent according to the main request did not extend beyond the content of the application or the parent application as filed.
- For the parent application and patent, in two decisions (T 1574/05 of 18 December 2008 and T 2125/10 of 23 March 2012) the present Board concluded that a patent could be maintained in amended form on the basis of the main request.
- Moreover, in a further decision (T 1155/13 of 7 May 2014) concerning a patent (EP-B-1642611) based on a divisional application of the application on which the patent in suit is based, the present Board decided that the patent could be maintained in amended form on the basis of an auxiliary request.
- III. Interventions during the opposition proceedings following the remittal ordered in T 0801/13

The notice of intervention of opponent 4, filed on 23 January 2015, was based on the grounds of lack of novelty and inventive step pursuant to Article 100(a) EPC.

The notice of intervention of opponent 5, filed on 26 March 2015, was based on the grounds of lack of novelty and inventive step pursuant to Article 100(a) EPC, insufficiency of disclosure pursuant to Article 100(b) EPC and added subject-matter pursuant to Article 100(c) EPC.

- IV. In the impugned decision the Opposition Division also held that decision T 0468/09 had been res judicata when the interventions were filed; it could therefore no longer examine the ground for opposition pursuant to Article 100(b) EPC.
- V. Opponent 2 filed notice of appeal on 27 May 2015 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 18 November 2015.
- VI. Opponent 5 filed notice of appeal on 11 June 2015 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 16 November 2015.
- VII. Opponent 1 filed notice of appeal on 12 June 2015 and paid the appeal fee on 15 June 2015. The statement setting out the grounds of appeal was filed on 18 November 2015.
- VIII. The patent proprietor filed notice of appeal on 16 September 2015, paying the appeal fee and filing the

statement setting out the grounds of appeal on the same day.

Under point 4.5 of the statement setting out the grounds of appeal the patent proprietor explained *inter alia* that its understanding of the feature that the catheter package should be made of impermeable material was that *"Any technically ascertainable evaporation of the liquid swelling medium which goes beyond production and measuring tolerances is excluded by claim 1 according to the definitions in paragraph [0010] and the analysis underlying decision T 801/13."*

- IX. Opponent 4 did not file any appeal.
  
- X. Under point 2 of a letter dated 7 October 2016 the patent proprietor commented again on the interpretation of the above feature, concluding in the last sentence of point 2.7 that *"Thus, following the above analysis of T 468/09 and T 801/13, and in a bona fide attempt to expedite the proceedings, notice is hereby given that we renounce our previously expressed contention that any technically ascertainable evaporation of the liquid swelling medium, which goes beyond production and measuring tolerances, is excluded by claim 1."*
  
- XI. Oral proceedings were held on 16 and 17 November 2016 and continued on 23 February 2017.

The final requests of the parties were as follows:

The appellant/patent proprietor (hereinafter patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed with letter dated 16 September 2015 or, in the alternative, of one of the

new auxiliary request 3, filed on 17 November 2016 and the auxiliary request 9, filed with letter dated 16 September 2015.

The appellant/opponent 1 (hereinafter opponent 1) requested that the decision under appeal be set aside and the patent be revoked.

The appellant/opponent 2 (hereinafter opponent 2) requested that the decision under appeal be set aside and the patent be revoked.

The appellant/opponent 5 (hereinafter opponent 5) requested that the decision under appeal be set aside and the patent be revoked.

The party as or right/opponent 4 (hereinafter opponent 4) requested that the appeal of the patent proprietor be dismissed.

XII. The different versions of the claims relevant for the decision are the following:

Claims 1, 8, 9 and 10 of the main request as filed with letter dated 16 September 2015 reads as follows:

"1. A urinary catheter assembly comprising at least one urinary catheter (1) having on at least a part of its surface a hydrophilic surface layer (6) intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package (7, 16, 29, 34, 42, 46, 51, 51') made of a gas impermeable material and having a cavity (11,18, 39, 48, 53) for accommodation of the catheter (1, 58, 69), characterized in that the cavity accommodates said



liquid swelling medium for provision of a ready-to-use catheter assembly."

"8. A urinary catheter assembly as claimed in any of the preceding claims, characterized in that the catheter (1) is provided with means preventing said swelling medium from getting into contact with internal or external surface parts of the catheter not provided with said hydrophilic coating (6) for an activation period during which said medium is applied to the surface part provided with said hydrophilic coating (6)."

"9. A urinary catheter assembly as claimed in claim 8, characterized in that said means comprises a film layer (55) of a material soluble by said swelling medium applied to said parts not provided with said hydrophilic coating."

"10. A urinary catheter assembly as claimed in any of the preceding claims, characterised in that said package includes a bag (52) communicating with the catheter (1) for collection of urine."

Claim 1 of (withdrawn) auxiliary requests 1 and 2 as filed with letter dated 16 September 2015 reads as follows (amendments to claim 1 according to the main request underlined by the Board):

"A urinary catheter assembly comprising at least one urinary catheter (1) having on at least a part of its surface a hydrophilic surface layer (6) intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package (7, 16, 29, 34, 42, 46, 51, 51') made of a gas impermeable

material formed by a multiple layer thermoplastic film material comprising aluminium, the package having a cavity (11,18, 39, 48, 53) for accommodation of the catheter (1, 58, 69), characterized in that the cavity accommodates said liquid swelling medium for provision of a ready-to-use catheter assembly."

Claim 1 of (withdrawn) auxiliary request 3 as filed with letter dated 16 September 2015 reads as follows (amendments to claim 1 according to the main request underlined by the Board):

"A urinary catheter assembly comprising at least one urinary catheter (1), the catheter having a catheter tube coated on its external surface on a substantial part of its length from its distal end with a hydrophilic surface layer in the form of a hydrophilic coating intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package (7, 16, 29, 34, 42, 46, 51, 51') made of a gas impermeable material and having a cavity (11, 18, 39, 48, 53) for accommodation of the catheter (1, 58, 69), wherein the cavity accommodates said liquid swelling medium for provision of a ready-to-use catheter assembly."

Claim 1 of new auxiliary request 3 as filed on 17 November 2016 reads as follows (amendments to claim 1 according to the main request underlined by the Board):

"A urinary catheter assembly comprising at least one urinary catheter (1), the catheter having a catheter tube coated on its external surface on a substantial part of its length from its distal end with a

hydrophilic surface layer in the form of a hydrophilic coating intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package (7, 16, 29, 34, 42, 46, 51, 51') made of a gas impermeable material formed by a multiple layer thermoplastic film material comprising aluminium, the package having a cavity (11, 18, 39, 48, 53) for accommodation of the catheter (1, 58, 69), wherein the cavity accommodates said liquid swelling medium for provision of a ready-to-use catheter assembly."

Claim 1 of auxiliary request 9 as filed with letter dated 16 September 2015 reads as follows (amendments to claim 1 according to the main request underlined by the Board):

"A urinary catheter assembly comprising at least one urinary catheter (1), the catheter having a catheter tube coated on its external surface on a substantial part of its length from its distal end with a hydrophilic surface layer in the form of a hydrophilic coating intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter, said assembly further comprising a catheter package (7, 16, 29, 34, 42, 46, 51, 51') made from a gas impermeable material and having a cavity (11, 18, 39, 48, 53) for accommodation of the catheter (1, 58, 69), the package being formed from two sheets of gas impermeable multiple layer thermoplastic film material comprising aluminium connected with each other by a gas impermeable joint defining the cavity for accommodating the catheter (1) and the liquid swelling medium, wherein the cavity accommodates said liquid swelling

medium for provision of a ready-to-use catheter assembly."

XIII. The documents cited in this decision are the following:

D1: CN-A-1106744;  
D1A: EN translation of D1 provided by opponent 1;  
D2: JP-A-55 12265;  
D2A: EN translation of D2 provided by opponent 1;  
D3: US-A-2947415;  
D4: WO-A-96/30277;  
D7: Expert report of M. Svanum (15 September 2005);  
D26: EP-A-0586324;  
D27: EP-A-0217771;  
D28: WO-A-94/16747;  
D29: Solemn declaration of M. Svanum (21 April 2009);  
D34: US-A-4026296;  
D36: Solemn declaration of K. Almdal (8 October 2012);  
D38: "Introduction to Humidity - Basic principles on Physics of Water Vapor", SENSIRION The sensor company, version 2.0 - August 2009;  
D42: "Medical Device packaging Handbook" by J.D. O'Brien, published 1990 by Marcel Dekker, Inc., pages 86 to 90, 118 to 122 and 139 to 140;  
D44: Expert opinion of S. B. Jørgensen, (25 February 2015);  
D62: "Fundamentals of packaging technology" by W. Soroka (published 1995 by Institute of Packaging Professionals), "Contents" and pages 315 to 349  
D63: "Handbook of Package Engineering" by J. Hanton (2nd edition, 1992, by Technomic Publishing Company, Inc.), pages 3-50 to 3-59.

XIV. The arguments of the opponents relevant for the decision may be summarised as follows:

*Admissibility of the appeals*

After the interpretation given by the patent proprietor in its letter dated 7 October 2016, its appeal had to be considered inadmissible because the main argument about "gas-impermeability" presented in its statement of grounds had been withdrawn.

*Main request - sufficiency of disclosure  
(Article 100(b) EPC) - referral to the Enlarged Board  
(Article 112 EPC)*

The wording of claim 1 covered two types of embodiments: a first type in which the liquid swelling medium was confined in a storage body during storage of the catheter assembly, and a second type in which the catheter was stored with its hydrophilic coating in an activated state.

The first type of embodiments could not be carried out because the patent failed to indicate an appropriate storage material for "confining" the liquid swelling medium, and the second type could not be carried out because there was no way of sterilising a "wet catheter" without its coating deteriorating.

Moreover, the skilled person faced an undue burden when trying to carry out catheter assemblies according to claims 8 and 9, because the patent did not give any examples of suitable materials.

If the Board were of the opinion that it could not deal with these objections because of its former decision T 468/09, it should refer a question to the Enlarged Board of Appeal.

*Main request - novelty in view of D2*

Subject-matter of claim 1 of the main request was anticipated by D2 (the arguments submitted were mainly those set out in the "Reasons for the Decision" below).

*New auxiliary request 3 and auxiliary request 9 - admissibility*

New auxiliary request 3 should not be admitted into the proceedings, because it was a departure from all the requests on file, did not further address the material of the packaging, and raised new issues, in particular one of clarity. Therefore, like auxiliary request 9, it was not *prima facie* allowable.

*New auxiliary request 3 - remittal*

Since the main arguments for allowing this request had not been presented yet, the case should be remitted to the first-instance department so that the opponents could have these issues considered by two instances.

*New auxiliary request 3 - admissibility of an insufficiency objection*

Since the feature of the coating had not been considered relevant for sufficiency in T 0468/09 but had now become an essential feature of the invention, sufficiency had to be examined again.

*New auxiliary request 3 - added subject-matter*

Specifying that the catheter tube should be coated on a substantial part of its length with the hydrophilic layer covered embodiments in which the hydrophilic

layer might only partly coat the tube, and such embodiments had not been originally disclosed. Moreover, the presence of aluminium in a multilayer film material was disclosed only together with two sheets of material welded together. This could not be generalised.

Claim 10 contained added subject-matter, since no urine collection bag made of a multilayer film material comprising aluminium had been disclosed in the application as filed.

*New auxiliary request 3 - clarity*

Stating that the catheter tube was coated "on a substantial part of its length" was not clear, as it covered any length above 0% and below 100%. The same was true as regards specifying that the coating should run from the distal end of the catheter tube, because it was not clear where exactly the distal end started and ended.

Additionally, the feature that the gas-impermeable material should contain aluminium was not clear because it did not define the form in which the aluminium was present.

*New auxiliary request 3 - inventive step*

The following prior art showed that the subject-matter of claim 1 lacked inventive step:

D1 combined with general knowledge and/or D26, D27, D28, D2, D4, and

D34 combined with D3 or D42, D62, D63.

Not only documents disclosing intermittent catheters could be chosen as closest prior art, but also documents disclosing indwelling catheters having a hydrophilic coating, because they could also be used as intermittent catheters under the same conditions. Therefore both D1 and D34 could be used as starting points. The position taken by the Board in T 2125/10 in this respect was not relevant, because there the only choice had been between an intermittent catheter and a gel catheter.

The catheter of D34 was suitable for intermittent use. The fact that it could stay longer in the urethra did not disqualify it as an intermittent catheter. This catheter had a hydrophilic coating and in at least one example was said to be for single use, which was typical for an intermittent catheter.

The only two differences between the catheter assembly of D1 and that of claim 1 were that the latter included a catheter tube coated with a hydrophilic material instead of the whole catheter wall being of the same material, and that the package was made of a multiple-layer film material comprising aluminium (objection originally raised against withdrawn auxiliary request 1 which had already included this feature).

There was no combinatory or synergistic effect between these two features, so they solved two separate problems.

It was obvious for the skilled person to use a multiple-layer film material comprising aluminium as necessary, because from his common general knowledge he



was aware that it was a well-known material for packing wet medical devices.

Concerning the use of a hydrophilic coating on a catheter tube instead of using a catheter wall made as a whole of a single hydrophilic material, this was a mere alternative, and - as stated in T 0155/85 - there could be no invention in worsening the prior art.

Therefore, the subject-matter of claim 1 was not inventive.

*Inventive step starting from other documents as closest prior art*

If one line of argument against inventive step was not successful, the opponents had a right to present others starting from different closest prior art (here D34, D2 or D4), since all potential starting points and lines of attack had to be considered.

*New auxiliary request 3 - adaptation of the description*

Several mistakes in the description (references to a first series of embodiments, to Figure 13 which no longer existed, to Figure 12, etc.) had to be corrected.

*Withdrawal of auxiliary requests 1 and 2*

These requests formed the basis of the appeal filed by the opponents, who had a right to a decision on them, particularly on auxiliary request 2 maintained by the Opposition Division. The Board should not accept their withdrawal by the patent proprietor.

XV. The arguments of the patent proprietor relevant for the decision may be summarised as follows:

*Admissibility of the appeals*

Opponents 4 and 5 had not filed a joint intervention, so they could not file a joint appeal. Moreover, their requests were not clear. In particular, as opponent 4 had not filed any notice of appeal, it could not request revocation of the patent, and opponent 5's appeal was therefore not admissible.

In its letter of 7 October 2016, the patent proprietor had only been trying to expedite the proceedings by abandoning one line of argument. This could not lead to its appeal being declared inadmissible.

*Main request - sufficiency of disclosure  
(Article 100(b) EPC) - referral to the Enlarged Board  
(Article 112 EPC)*

Decision T 0468/09 was *res judicata* and covered both types of embodiments, so the Board had no power to decide a second time on the question of insufficiency of disclosure pursuant to Article 100(b) EPC.

Moreover the word "confine" had to be read in context, and a partial activation of the hydrophilic coating was not problematic for carrying out the first embodiments. Concerning the second embodiments, at least manufacturing the whole assembly in a sterile environment would provide a sterile catheter assembly, and anyway the best mode of manufacture was not required.

On the basis of paragraphs [0036] and [0037] and his common general knowledge, the skilled person would know how to carry out the subject-matter of claims 8 and 9.

*Main request - novelty in view of D2*

This document did not disclose a hydrophilic layer intended to produce a low-friction surface, or a gas-impermeable material for the package, or a cavity in the package for accommodating the entire catheter with the liquid swelling medium. The inner glass tube could not be considered to be the package because it did not accommodate the catheter in its entirety and the polyethylene packaging was not gas-impermeable. Moreover, the rubber stoppers closing the glass tube were not gas-impermeable either, because according to the dimensions disclosed in D2 there was a clearance between the catheter body and the inside hole of the rubber stopper. In addition, according to the analysis in D36, the drug would only impregnate the layer, not swell it, and would not lead to a low-friction surface.

*New auxiliary request 3 and auxiliary request 9 - admissibility*

These requests should be admitted into the proceedings (the arguments submitted were mainly those set out in the "Reasons for the Decision" below).

*New auxiliary request 3 - remittal*

The arguments submitted for not remitting the case were mainly those set out in the "Reasons for the Decision" below.

*New auxiliary request 3 - admissibility of an insufficiency objection*

Sufficiency should not be re-examined again. No new evidence had been filed since the discussion of the main request, and auxiliary request 9, including the claim 1 feature objected to, had been on file right from the start of the appeal proceedings.

*New auxiliary request 3 - added subject-matter*

Only opponent 5 should be allowed to present its case because it was the only one who had raised an objection.

A skilled person reading the application would not think of a "dual embodiment" with only a partial coating. In any case, the very same wording was in the application as filed.

The presence of aluminium was for gas-impermeability and had no link with welding two sheets together. Therefore, taking only the aluminium into the claim did not add matter.

Claim 10 was based on claims 28 and 5 and the description of the application as filed.

*New auxiliary request 3 - clarity*

A skilled person would read the claim with a view to making technical sense of it. He would understand from Figures 1 and 2 and from paragraphs [0019] and [0020] where the distal end was and that the substantial length had to be the insertable length. He would also

understand that aluminium was present to avoid evaporation.

*New auxiliary request 3 - inventive step*

Only documents disclosing intermittent catheters could be chosen as closest prior art, because the whole invention was concerned with that kind of catheter.

D1 did not disclose an intermittent catheter coated with a hydrophilic surface layer. Moreover, in the examples given, the catheters stayed for several days in the urethras of several patients, which was typical for an indwelling catheter. The fact that the document referred to self-treatment at home was not enough to suggest that it disclosed intermittent catheters. The aim in D1 was to develop catheters for indwelling use.

In any case this document did not disclose or suggest a package made of a multiple-layer film material comprising aluminium and having a cavity for the catheter, the material used for the catheter was not hydrophilic but hydrophobic, as stated in D36 (argument raised against the corresponding feature of claim 1 according to withdrawn auxiliary request 1), it did not exhibit any swelling when wetted, and the fluid in the package was only for sterility, not to provide a low-friction surface.

*Inventive step starting from other documents as closest prior art*

If the line of argument against inventive step starting from the closest prior art was not successful, according to the problem-solution approach the

opponents had no right to present other lines of argument starting from different and less promising prior art.

*New auxiliary request 3 - adaptation of the description*

After grant, only limited corrections were allowed, namely those necessary as a result of opposition and appeal proceedings, in particular in view of amended claims.

*Withdrawal of auxiliary requests 1 and 2*

The patent proprietor was free to choose the requests he wanted the Board to decide on.

## **Reasons for the Decision**

### *1. Admissibility of the appeals*

1.1 The patent proprietor objected that opponent 5's appeal was inadmissible, because the grounds of appeal dated 16 November 2015 stated the following:

*"Further to the Notice of Appeal dated June 11, 2015 we herewith submit the Grounds for Appeal for the appellant, Medical4You B.V.*

*The present submission is also considered to be a response to the Proprietor's submissions dated September 16, 2015, both for the appellant Medical4You B.V. and for Kain-Märk Gesellschaft m.b.H; party as of right, Art 107 EPC, second sentence.*

*In the following the parties: Medical4You B.V and Kain-Märk Gesellschaft m.b.H will, for the sake of simplicity, be referred to as the Opponent."*

*This was followed by requests like "The Opponent requests that the Board of Appeal set aside the Decision of the Opposition Division of July 8, 2015, and revokes the patent EP 1 145 729 B1 in its entirety."*

*The patent proprietor argued that opponents 4 and 5 could not appeal jointly, because they had intervened separately. Nor was it clear which requests were for the one, the other or both of these opponents; that too was a requirement for the appeal to be admissible.*

*The notice of appeal of opponent 5 states the following:*

*"On behalf of the Opponent (Intervener)*

*Medical4You B.V.  
Wilhelminalaan 41  
(6641 JA) Beuningen  
The Netherlands*

*we hereby lodge an Appeal against the Opposition Division decision to maintain the above mentioned patent in amended form. Said decision was pronounced during the Oral Proceedings held on May 11 and 12, 2015.*

*It is requested that the decision is set aside and that the patent is revoked in its entirety (...)"*.

The above notice of appeal was thus filed on behalf of opponent 5, which was identified by its name and address. It does not give the name and address of opponent 4. Furthermore, the contentious first sentence of the above statement of grounds of appeal confirmed that it was being filed further only to opponent 5's notice of appeal.

The second sentence of the above statement of grounds of appeal draws a clear distinction between the appellant Medical4You B.V. (opponent 5) and the party as of right Kain-Märk Gesellschaft m.b.H. (opponent 4). It is therefore clear to the Board that the writer did not intend to file a joint statement of grounds of appeal on behalf of both opponents 4 and 5. The letter dated 16 November 2015 was intended as the statement of grounds of opponent 5, and also as the replies of both opponent 5 and (as a party as of right) opponent 4 to the patent proprietor's appeal. It is possible of course that opponent 4, as a party as of right, might not be entitled to make all the requests submitted. However, that does not change the fact that opponent 5's appeal fulfils all the requirements for admissibility.

Therefore, the appeal of opponent 5 is admissible.

- 1.2 The opponents argued that the appeal of the patent proprietor was not admissible because by letter dated 7 October 2016, point 2 (point X above) it had withdrawn its position on the interpretation of "gas impermeable material", which was an essential part of its argumentation in its statement setting out the grounds of appeal. This voided that statement, and was tantamount to withdrawing the appeal.



The Board notes that the opponents must have considered the patent proprietor's appeal admissible before the letter mentioned above. As the Board understands it, in that letter the patent proprietor, after reconsidering the present Board's earlier decisions T 0468/09 and T 0801/13 and in an attempt to expedite the proceedings, decided not to pursue some of the reasoning set out in its statement of grounds of appeal and concerning the claim feature relating to the gas-impermeable material. The Board fails to see how this could render its appeal inadmissible. In the Board's opinion the patent proprietor has done nothing more than drop a particular line of argument, because, for instance, given the arguments on file, it no longer believed it had any prospect of success. The patent proprietor has not stated anything more, in particular that it was withdrawing the appeal.

Hence, the patent proprietor's appeal remains admissible after the letter of 7 October 2016.

1.3 The admissibility of the other appeals was not challenged.

2. *Technical field of the invention and general content of the description as originally filed*

As already established in T 0801/13, urinary catheters are essentially of two types: indwelling catheters which remain in the urethra for some time and are in general fitted in hospital, and intermittent catheters which are intended to be inserted into the urethra - in particular by the patient - for a single emptying of the bladder and then taken out again.

Intermittent catheters can be further subdivided into those that are lubricated with a gel or other lubricant and those that have a hydrophilic surface which needs to be activated (by water or saline solution) to demonstrate its low-friction properties.

With prior-art catheter assemblies of this latter type the patient has to pour water into the package cavity accommodating the catheter and wait for the hydrophilic coating to swell before the catheter is ready to use. Depending on the quality of the water used as liquid swelling medium, risks of infection exist.

The invention as presented in the introductory part of the description (paragraph [0008] of the application as filed, published A1 version) aims at allowing patients to prepare the catheter for use wherever they are, without having to find water or carry it with them in another receptacle and then pour it into the package cavity containing the catheter, a process which can involve a risk of infection.

The general concept of the invention is to propose an assembly comprising a catheter package for accommodating the catheter and the liquid swelling medium (in a gas-impermeable package) so that the liquid necessary to activate the catheter's low-friction surface is always available together with the catheter in that package. The gas-impermeability must of course be adapted to the intended shelf-life for such products (paragraph [0010]).

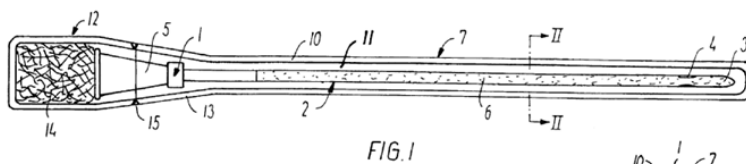
The original description presents two sets (called series) of embodiments. In the general part of the description the two series are described starting from paragraphs [0011] and [0022] respectively. Specific

embodiments are then described in more detail, starting for the first series from paragraph [0026] and Figure 1, and for the second series from paragraph [0046] and Figure 7.

The essential difference between the two series of embodiments is summarised e.g. in paragraph [0045], which reads as follows:

*"Whereas, in the embodiments described so far the compartment for the liquid swelling medium is in direct liquid flow communication with the cavity narrowly surrounding the catheter tube, which requires the package as a whole to be made of a gas-impermeable material, the compartment for the swelling liquid may alternatively be separated from the catheter cavity in such a way that the liquid flow communication therebetween is not established, until preparation of the catheter is performed prior to the intended use. Thereby, only the swelling medium compartment itself needs to have walls of a gas-impermeable material preventing leakage of the swelling medium by diffusion, whereas the wall parts of the package surrounding the catheter may be made of a relatively cheaper liquid tight material."*

The patent in suit concentrates on the first series of embodiments, and more particularly on those in which the cavity and the compartment form a single space.



3. As the wording of claim 1 according to the main request is the same as that of claim 1 according to the main request in the impugned decision and also the same as

that of claim 1 of the main request in the earlier appeal proceedings (T 0468/09), the interpretation of claim 1 given in points 4.3 and 4.4 of that decision is also relevant here. The Board took the view that the wording of the claim covered both the embodiment of Figures 1 and 2 (point 4.3) in which the catheter is in a cavity and the end portion of the cavity (or compartment) contains a spongy material retaining the liquid swelling medium until it is expressed from that material and flows into the cavity to prepare the low-friction surface (paragraphs [0023] and [0024] of the patent as granted), and the unillustrated embodiment in which the liquid swelling medium is placed directly into the cavity during the manufacturing process (point 4.4), without any spongy material being present (paragraph [0029] of the patent as granted).

The last part of claim 1, which requires *that the cavity accommodates said liquid swelling medium for provision of a ready-to-use catheter assembly*, does not specify whether the liquid swelling medium is in a storage element (such as the spongy material 14) in the cavity and/or whether or not the low-friction surface layer is in an activated state.

However, in the Board's opinion the wording of claim 1 clearly does not cover embodiments in which the liquid swelling medium is in a completely closed and separate compartment, as in the second series of embodiments in which only the compartment - and not necessarily the rest of the package - is made of gas-impermeable material. This is expressed in claim 1 by the wording that the *catheter package* (should be) *made of a gas impermeable material* and that *the cavity accommodates said liquid swelling medium*. In the context of the patent this can only mean that the liquid swelling

medium has no barrier in the cavity, as is the case in the embodiments according to Figures 1 and 2 and when the swelling medium is injected into the cavity during the manufacturing process, before the sheets forming the package are welded together (paragraph [0029] of the patent as granted).

4. *Main request - sufficiency of disclosure  
(Article 100(b) EPC) - referral to the Enlarged Board  
of Appeal (Article 112 EPC)*

Although in view of T 0468/09 the present patent should not give rise to any problems with sufficiency of disclosure, that decision was taken before opponents 4 and 5 intervened in the opposition proceedings. In its intervention opponent 5 again raised an insufficiency objection, partly on the basis of additional documents filed with the intervention. It also requested a referral to the Enlarged Board if the Board decided not to consider its objection.

However, for a question to be referred to the Enlarged Board there must be need for it in the sense that the answer to the question posed may change the outcome in the case at issue. For this reason, the present Board decided to first assess the effect of the objections raised on the outcome of the present case.

Claim 1 of the main request, as expressed in T 0468/09 and T 0801/13, is meant to cover two types of embodiments: a first type in which the liquid swelling medium for activating the hydrophilic coating is confined in a storage body and a second type in which the hydrophilic coating is in an activated state in the package.

### First type of embodiments

According to opponent 5, for the first type of embodiment the patent in suit did not disclose any material able to strictly confine the liquid swelling medium; the patent referred only to spongy or gel-like materials. Opponent 5 considered that because the word "confine", when used in connection with embodiments including a separate compartment, meant that no liquid swelling medium could leave the gas-impermeable compartment, it had to have the same meaning when used with embodiments in which the liquid swelling medium was contained in a storage body, such as a spongy material, in the cavity of the package without any barrier between the storage body and the catheter's hydrophilic surface coating. Since the patent in suit did not disclose any such material for storing the liquid without any evaporation, the requirements of sufficiency of disclosure were not fulfilled.

In the Board's view, opponent 5's interpretation of the word "confine" is too restrictive, and not based on an objective technical assessment. In view of the laws of physics, as explained for instance in document D38 representing common general knowledge, if a spongy material is full of water or similar liquid swelling medium and it is in a closed space - such as the catheter cavity of the patent in suit - some of the liquid it contains will evaporate into the air captured in the same closed cavity, until an equilibrium is reached. This means that the hydrophilic surface coating may to some degree be activated by the vapour present in the air in that confined space. The patent proprietor has not denied that this phenomenon may occur. Opponent 5 has not shown that such partial activation of the surface coating would make the

catheter unusable, or that known spongy materials would not be suitable for use in such a context.

Under these circumstances, the Board does not see any undue burden for the skilled person in carrying out the invention for this first type of embodiments.

Second type of embodiments

For this (wet storage) type of embodiments, opponent 5's main argument was that no sterilisation method was suitable for sterilising an already wetted low-friction surface coating: gas sterilisation was obviously not possible since the package was gas-impermeable, and - as explained in D7 and D29 - radiation sterilisation would lead to cross-linking of the coating, which would render the catheter unusable.

The Board does not share opponent 5's opinion. While some alteration of the product may occur if the wetted catheter is sterilised using electron beam sterilisation, D29 mentioned only that the product would not be commercially usable due to discolouration. It is established jurisprudence that the "best mode" is not necessary for sufficiency of disclosure requirements to be fulfilled. In addition, in the present case, as mentioned by the patent proprietor, it would be possible to produce the assembly, including the wetted catheter, in a completely sterilised environment so as to arrive at a sterile product. This has not been denied by opponent 5.

Hence, also for the second type of assemblies falling under the wording of claim 1, the skilled person would have no undue burden in carrying out an embodiment according to the invention.

Claims 8 and 9

These claims require that means are provided for preventing the liquid swelling medium from coming into contact, during an activation period, with the surfaces of the catheter not provided with the hydrophilic coating, the means possibly being a film layer of a material soluble by the liquid swelling medium.

Opponent 5 considered that the patent contained no teaching allowing the features of dependent claims 8 and 9 to be carried out. More precisely, the patent did not disclose any material suitable for this function, nor give any definition of the activation period, in particular for the "wet storage embodiment".

It appears from paragraphs [0036] and [0037] of the patent as granted that the idea is to minimise the amount of liquid swelling medium necessary by preventing it from reaching places on the catheter where it is not needed, so that all the liquid available is used to activate the coating. The activation period in the claims therefore appears to mean the period needed to activate the hydrophilic coating. Many materials exist which are soluble in water or saline (needed to activate the coating) and could be used for temporarily closing the access ports to the interior of the catheter. The Board is convinced that the skilled person is able, by conducting routine tests, to select an appropriate material for the purpose specified. The opponents have not demonstrated that such a selection would place an undue burden on him. Concerning the "wet storage embodiment", it seems self-evident that once the coating is activated and



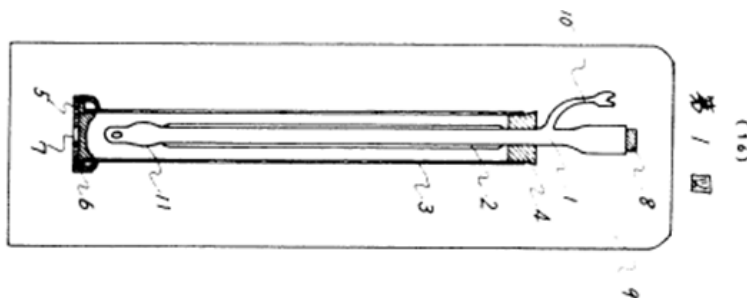
packed in the gas-impermeable package, there is no longer any need to keep the access ports closed.

Thus, the ground for opposition under Article 100(b) EPC would not, in substance, prejudice the maintenance of the patent on the basis of the main request. Therefore, whether this ground is admitted into the present appeal proceedings and/or how the general principle of *res judicata* is applied is not decisive for the outcome of the present case, so no referral to the Enlarged Board under Article 112 EPC is necessary.

5. *Main request - novelty in view of D2*

The Opposition Division considered that the subject-matter of claim 1 lacked novelty over D2, so the Board decided to analyse that objection first.

Example 1 of D2 discloses a urinary catheter 1 enclosed in a polyethylene sterile plastic bag 9. The catheter has a hydrophilic resin coating 2. The part of the catheter with the coating is enclosed by a glass tube 3 with rubber stoppers 4, 5 closing the tube. A small quantity of drug is present in the glass tube and this drug is meant to impregnate the coating to provide a low-friction surface and subsequent release of the drug in the urethra of the patient.



In the Board's opinion, this embodiment of D2 anticipates the "wet storage embodiment" falling under claim 1 of the patent in suit.

The patent proprietor argued that the cavity of this embodiment of D2 did not accommodate the catheter in its entirety. In the Board's opinion, in this embodiment of D2 the whole catheter is in the cavity necessarily defined by the polyethylene plastic bag 9 to accommodate it, and the glass tube 3 does no more than render the package 9 gas-impermeable where there is a risk of evaporation of the liquid swelling medium, i.e. the drug in this case. This is in line with the Board's conclusion under point 6 of T 0801/13: *"... when claim 1 recites that the package (should be) made of gas impermeable material, for the person skilled in the art it means that everywhere where there is a risk of evaporation of the liquid swelling medium the package should be made of such material."*

The patent proprietor further contended that the glass tube together with the stoppers was not gas-impermeable because, according to the dimensions indicated in D2, the catheter was thinner than the hole in the rubber stopper 4.

While it is true that such a difference of diameter exists as long as the rubber stopper and catheter are not yet mounted in the glass tube, there is no indication in D2 that this would still be the case in the mounted configuration. In the Board's opinion this would also not make much technical sense, because if such a clearance existed, not only would the catheter not be properly maintained in position in relation to the glass tube, but also the liquid drug introduced into the glass tube to impregnate the hydrophilic layer

could escape through said clearance into the polyethylene package, which clearly is undesirable. This is indirectly confirmed on page 6, third paragraph, fourth sentence of the translation D2A, which reads as follows: "*The catheter having the hydrophilic resin covering layer 2 is fixed in a glass tube 3 (casing) with a rubber stopper 4*" (emphasis added) - which clearly implies that the rubber stopper has a fixing and maintaining function, and thus there cannot be any clearance between the stopper and the catheter.

The patent proprietor further argued that, as Mr Almdal had explained in D36, D2 did not disclose a hydrophilic layer intended to produce a low-friction surface character by treatment with a liquid swelling medium.

The Board does not share this opinion. The fact that the resin constituting the surface layer 2 is hydrophilic is mentioned at several points in D2A, *inter alia* in the above-mentioned sentence on page 6, but also in relation to example 1 on page 8, penultimate sentence of the first paragraph, or in claim 1. While the Board agrees that there is no explicit statement that the impregnated resin has a low-friction quality, several passages in D2 suggest that it does. The second paragraph on page 2 for example states that "*Catheters which have a thick covering layer made of a hydrophilic resin on the surface of the part inserted into the human body have the advantage that because of this hydrophilicity the compatibility with the human body is good, and discomfort and pain due to insertion are decreased.*" This paragraph makes an explicit link between hydrophilicity and reducing the pain caused by insertion. In the Board's view it follows that this

reduction in pain is at least partly due to the improved low-friction quality of the hydrophilic resin layer. Hence, the water-based drug impregnating the hydrophilic resin layer contributes to that quality. Indeed, the first paragraph on page 6 indicates that the layer's water absorbency is preferably 10% or more, and when such a humid catheter is introduced into the urethra, which is also humid by nature, it seems inevitable that a thin liquid layer will form or be present between the catheter's outside surface and the urethra's inside surface, which will facilitate painless insertion and extraction of the catheter. It also seems inevitable that some swelling will take place when as much water as just mentioned is absorbed by the hydrophilic layer. This is indeed confirmed by Mr Almdal in D36 (page 4, end of the first paragraph and penultimate paragraph). While he explains that D2 does not explicitly mention swelling, he nevertheless concedes that limited swelling takes place in water or water solution, which is enough to anticipate the corresponding feature of the claim. Mr Jørgensen also confirms the presence of a hydrophilic surface coating to produce a low-friction character by treatment with a drug dissolved in water (point 10 of D44).

For the reasons above, the subject-matter of claim 1 according to the main request is not new in view of D2.

6. *New auxiliary request 3 - admissibility*

New auxiliary request 3 was filed during the oral proceedings held on 16 and 17 November 2016. The opponents considered that new auxiliary request 3 should not be admitted because it departed from all requests on file, did not further specify the material of the packaging and so was in breach of Rule 80 EPC,

and potentially raised clarity issues. It was therefore not an attempt to overcome all the objections and had to be rejected as inadmissible.

Claim 1 according to new auxiliary request 3 is basically a combination of the features of claim 1 according to withdrawn auxiliary request 1 or 2 with those of claim 1 according to withdrawn auxiliary request 3. Withdrawn auxiliary requests 1, 2 and 3 have been on file since the beginning of the appeal proceedings, so the Board fails to see why the opponents could not deal with this new request when they must have prepared to address the other three.

Furthermore, given the number of documents and objections on file, the Board considers it fair to give the patent proprietor an opportunity to combine two requests already on file, in particular with a view to procedural efficiency. The other option - requiring the patent proprietor to file all possible combinations dealing with all possible objections right at the start of the proceedings - would have made the proceedings unnecessarily complex.

The Board would also point out that Rule 80 EPC gives the patent proprietor the possibility to file an amended version of the patent to overcome potential objections under any ground for opposition. Adding a feature in claim 1, as in the present case, will normally improve the patent proprietor's position regarding any novelty or inventive-step objections. Possible clarity issues can be dealt with once the request is in the proceedings.

Hence, for the reasons given above, new auxiliary request 3 is admitted into the proceedings pursuant to Article 13(3) RPBA.

7. *Auxiliary request 9 - admissibility*

Auxiliary request 9 has been on file right from the start of the appeal proceedings, and claim 1 according to that request includes at least one more feature than claim 1 of new auxiliary request 3, so the requests are converging. Otherwise the same reasons as those set out above apply to the present request. It is further noted that the patent proprietor has significantly reduced the number of remaining auxiliary requests, which is in the interests of procedural efficiency.

Therefore, the Board admits auxiliary request 9 into the proceedings pursuant to Article 12 RPBA.

8. *New auxiliary request 3 - remittal*

The opponents requested remittal of the case to the department of first instance, so that all issues could be considered by two instances. They further contended that no arguments as to why the subject-matter of present claim 1 was allowable had ever been presented.

Given that the present patent is now before the Board for the third time, that the original filing date is 18 September 1997, that several sets of infringement proceedings are pending, and that the point at issue has been on file right from the start of the appeal proceedings, the Board considers that remittal pursuant to Article 111(1) EPC is not appropriate.

9. *New auxiliary request 3 - admissibility of the insufficiency objections*

Concerning the feature of claim 1 that the catheter should have a catheter tube coated, on its external surface on a substantial part of its length from its distal end, with a hydrophilic surface layer in the form of a hydrophilic coating, the opponents argued that since this feature had been seen as irrelevant for sufficiency in T 0468/09 but had now been introduced into claim 1 and had therefore now become an essential feature of the invention, a discussion on insufficiency was justified and even necessary in view of the opponents' right to be heard.

As already mentioned in relation to the admissibility of new auxiliary request 3, the Board notes that the feature objected to was present in claim 1 of withdrawn auxiliary request 3, and also in claim 1 of auxiliary request 9 filed with the statement setting out the grounds of appeal. In its statement setting out the grounds of appeal, opponent 5 addressed the question of insufficiency of all requests (pages 10 to 14, in particular first paragraph of point 5 specifying that "*The opposed patent (all requests) does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*") and set out its objections regarding the hydrophilic coatings. These points were discussed and examined by the Board in the first part of the oral proceedings held on 16 and 17 November 2016 (point 4 above). In the interval until the oral proceedings were resumed on 23 February 2017, no new arguments were filed, and only during these second oral proceedings did the opponent wish to raise further arguments, which

was clearly late. Also, they might require further new investigations by the patent proprietor and the Board.

Hence, the Board decides that these new lines of argument about sufficiency of the disclosure of a feature on file since the start of the appeal proceedings are not admitted into the proceedings pursuant to Article 13 RPBA.

The Board would like to add that nothing stated in T 0468/09 has any bearing on this issue, because as is apparent from the above the reasons for disregarding the new lines of argument are unconnected with that decision.

10. *New auxiliary request 3 - added subject-matter*

The patent proprietor argued that only opponent 5 should be allowed to raise an objection of added subject-matter, because it was the only party to have raised such an objection earlier.

This demonstrates that the objection was already part of the appeal proceedings, and the Board does not see any reason why the other opponents should not be able to express their views on an objection originally put forward by only one of them.

Compared to claim 1 of the patent as granted, two features have been amended.

i) The feature that the urinary catheter assembly should comprise "*at least one urinary catheter (1) having on at least a part of its surface a hydrophilic surface layer (6) intended to produce a low-friction surface character*" has been amended to "*at least one*



*urinary catheter (1), the catheter having a catheter tube coated on its external surface on a substantial part of its length from its distal end with a hydrophilic surface layer in the form of a hydrophilic coating intended to produce a low-friction surface character"* (emphasis added by the Board).

ii) Whereas claim 1 of the patent as granted required that the urinary catheter assembly comprised "a catheter package", in claim 1 of new auxiliary request 3 this feature now reads "a catheter package made of gas impermeable material formed by a multiple layer thermoplastic film material comprising aluminium" (emphasis added by the Board).

As to feature i), the opponents took the view that the wording that the catheter tube should be coated with the hydrophilic layer "... *on a substantial part of its length*" added subject-matter, because this wording covered embodiments with only a partly coated tube, e.g. one or more coated parts and one or more non-coated parts, and such embodiments were not disclosed in the application as filed.

The first paragraph of the application [0001] (A1 publication) already mentions that the invention relates to a "...*urinary catheter assembly comprising a urinary catheter having on at least a part of its surface a hydrophilic surface layer intended to produce a low-friction surface character ...*" (emphasis added). This is repeated several times in the application as filed, including its claim 1. Moreover, that the catheter tube may be coated with a hydrophilic coating on a substantial part of its length from its distal end is disclosed in paragraph [0028] (A1 publication). It follows that even if the wording of the feature

objected to were intended to cover partially coated and non-coated catheter tubes, as submitted by the opponents, this wording would be supported by the application as filed.

Hence, the feature objected to does not add any subject-matter extending beyond the application as filed.

As to feature ii), the opponents argued that claim 1 according to new auxiliary request 3 did not fulfil the requirements of Article 123(2) EPC because the feature that aluminium was present in a multilayer film material was disclosed, in paragraph [0029] of the application as filed, only in the particular context of two sheets of that material being welded together along a welding seam. The generalisation according to claim 1 was therefore not allowable.

In the opinion of the Board, it is clear, in particular from paragraphs [0010] and [0029] of the application, that the gas-impermeability of the package is essential for the provision of a ready-to-use urinary catheter. In this context paragraph [0029] describes an embodiment in which two sheets of the claimed material are welded together to form the package. It is however clear for the skilled person that the choice of the material for manufacturing the package as mentioned in that paragraph is not linked to the specific form in which the material is used (here: two sheets welded together), the important thing being that the package is gas-impermeable. There is no functional link between these two facts. The gas-impermeable material comprising aluminium referred to could be used in another form than sheets, e.g. tubular elements, the essential feature being its gas-impermeability.

Therefore, claim 1 according to new auxiliary request 3 fulfils the requirements of Article 123(2) EPC.

The opponents further objected that the subject-matter of claim 10 of new auxiliary request 3 included added subject-matter because a package including a bag for the collection of urine had never been disclosed as comprising aluminium in its package material.

The Board does not share this opinion. Claim 28 of the application as filed was "according to any preceding claims", i.e. including claim 5 specifying that the cavity itself constituted the compartment and contained the liquid swelling medium for immediate activation. It is therefore self-evident for the skilled person that the whole package, including the urine collection bag, has to be gas-impermeable. And as explained above, according to paragraph [0029] of the application this gas-impermeability is disclosed as improved when a multiple-layer film material comprising aluminium is used.

Therefore, also claim 10 according to new auxiliary request 3 fulfils the requirements of Article 123(2) EPC.

11. *New auxiliary request 3 - clarity*

i) The opponents argued that the feature in claim 1 of "... the catheter having a catheter tube coated on its external surface on a substantial part of its length from its distal end with a hydrophilic surface layer..." was not clear because it was not apparent what was meant by "a substantial part". The word "substantial" did not provide any legal certainty,

since it included everything greater than 0% and smaller than 100%. The same was true for "*distal end*", which likewise did not define anything precise. And the patent proprietor's concept of an "*insertable length*" was not clear either, since it depended on the patient.

ii) The opponents further contended that it was not clear from the added wording in the second amended feature (present for the first time in withdrawn auxiliary request 1) in which form the aluminium was present: was it in the form of a layer of the multilayer plastics material, or was it in some other form, and - if so - which one? Other documents showed that aluminium could also have an effect against UV-rays. Claims had to be clear in themselves.

The Board notes that Article 84 EPC requires that the claims be clear and concise and supported by the description. Clarity and conciseness requirements can conflict to some extent, because where clarity would demand additional explanations, conciseness requires that the claims be as short as possible. The Board considers that it is not desirable to unnecessarily overload a claim in pursuit of an unattainable absolute clarity of wording. It is therefore in line with established jurisprudence, according to which the reference reader for clarity purposes should be the skilled person who has read the patent as a whole with a mind willing to understand rather than desirous to misunderstand (T 0190/99 (point 2.2.5.); T 0012/11 (point 4 of the reasons); T 1192/02 (point 2 of the reasons)).

Concerning the first amendment (paragraph i) above), the Board notes that the patent in suit states several times that the invention concerns an intermittent

catheter which is able to slide easily down the urethra without exposing the urethral walls to any risk of damage, and to that end has been developed to have extremely low friction, at least on that part of its surface which is actually inserted into the urethra (for example paragraph [0004], an introductory passage describing the invention).

This is confirmed in paragraph [0020] of the patent:  
*"On a substantial part of its length from the distal end the catheter tube is, (...) coated on its external surface with a hydrophilic surface coating (...), which (...) provides an extreme low friction character of the catheter surface to enable the catheter to slide very easily through the urethra without exposing the urethral walls to any risk of damage"* (emphasis added).  
Also Figure 1 relating to paragraph [0020] shows what is meant by "substantial" length. In other words, it is clear not only from the intended use, but also from the passages cited above, that the "substantial part of its length" as mentioned in the claim is the part intended to be inserted into the urethra of the patient. This was confirmed by the patent proprietor during the oral proceedings.

Concerning the feature that the coating should be from the distal end, the same reasoning applies. Figure 1 shows that a coating starting from the very end of the distal part is meant; again, the aim of not damaging the walls of the urethra is a strong indication of that interpretation. The skilled person will recognise whether a given urinary catheter is for a man, woman or child and thus know the length of the insertable part.

Concerning the second amendment (paragraph ii) above), the Board notes firstly that saying something contains

aluminium does not express *a priori* any limitation as to the form or function of the aluminium present. The above wording of claim 1 according to new auxiliary request 3 is, however, more precise since it requires that the catheter package is made of gas-impermeable material formed by a multiple-layer thermoplastic film material comprising aluminium. This wording of the claim makes a direct link between the gas-impermeability of the material and the multilayer film comprising aluminium, which is a clear and explicit indication, already in the claim, that the presence of the multilayer film comprising aluminium is linked to the gas-impermeability. But even if doubts persisted about the reasons for the presence of aluminium, as already explained in T 0801/13 the whole patent is about providing an assembly with an intermittent catheter ready for use, e.g. with a package that prevents evaporation of the liquid swelling medium for a predetermined length of time (e.g. paragraph [0010] of the patent). More specifically in paragraph [0029] this direct link between the gas-impermeability and the multiple-layer film material comprising e.g. aluminium is clearly expressed, as mentioned above. The skilled person who has read the patent as a whole is therefore bound to understand that the presence of aluminium is associated with the desired gas-impermeability. It follows that when the claim requires the presence of aluminium it is clear for the skilled person that this aluminium is present for the same reason, namely for improving the gas-impermeability.

Hence, the skilled person who has read the patent in suit will see no lack of clarity in the claim wording, and claim 1 of new auxiliary request 3 therefore fulfils the requirements of Article 84 EPC.

12. *New auxiliary request 3 - inventive step*

During oral proceedings, the opponents presented the following lines of attack in support of lack of inventive step:

D1 combined with common general knowledge and/or D26, D27, D28, D2 and D4, and

D34 combined with D3 or D42, D62 and D63.

12.1 *Closest prior art*

Considering that the patent sought to solve a problem arising with intermittent catheters, the question arose whether the closest prior art had to be a document disclosing an intermittent catheter or whether it could possibly be a different type of catheter instead, namely an indwelling one.

The opponents argued that the position taken by the Board in T 2125/10 - that only a document disclosing an intermittent catheter could be the closest prior art - did not apply in the present case. In the former case, the choice was between gel catheters and intermittent catheters with a hydrophilic coating, but in the present case documents were cited disclosing indwelling catheters with a hydrophilic coating which could also be used as intermittent catheters. Moreover, claim 1 protected a urinary catheter assembly which was not limited as to its use.

In the Board's opinion, it is clear that the invention presented in the patent in suit aims to solve a problem arising with intermittent catheters. This is already expressed throughout the introductory part of the

description, for example when the prior art is presented in paragraph [0004]:

*"An important feature of any urinary catheter used for intermittent catheterisation [sic] of the bladder (...)"*

when the problems arising with the prior art are mentioned, e.g. in paragraph [0006]:

*"When catheters of this kind are used directly by end users outside the medical environment of a hospital or a clinic, (...)"*

and in paragraph [0007], first sentence:

*"In order to reduce the risk of infection inherent with the performance of intermittent catheterisation [sic] (...)",*

and lastly when presenting the objective of the invention in paragraph [0008]:

*"On this background, it is the object of the invention to improve and facilitate the performance of intermittent urinary catheterisation [sic] in any type of environment (...)"*.

It is established case law that the closest prior art should disclose subject-matter conceived for the same purpose or effects as the invention, preferably exhibiting the same kind of technical problems as those solved by the invention (as presented e.g. in Case Law of the Boards of Appeal, 8th edition 2016, I.D.3).

Hence, in the Board's opinion, the closest prior art can only be an assembly comprising an intermittent urinary catheter having a hydrophilic surface layer producing a low-friction surface character when activated.



The opponents considered that D1 and D34 disclosed such intermittent catheters.

Firstly, the Board notes that an intermittent catheter is a catheter that the skilled person would designate as such. This means in particular that in his eyes a catheter which can or could be intermittently used for emptying the bladder of a patient in a situation in which no other choice is available will not necessarily qualify as an intermittent catheter. Secondly, in the Board's opinion, there are some objective elements which normally distinguish intermittent catheters from indwelling catheters. The former do not have balloons or other elements to maintain the catheter in position in relation to the body of the patient, their low-friction surfaces have shorter activation times, and they are not impregnated with drugs for delivery to the patient over days or weeks.

In view of the above, in the Board's opinion D34 does not disclose an intermittent catheter. This document is about tubular surgical devices designed for insertion into cavities of the living body, in particular the urethra, and a process for manufacturing them (summary of the invention).

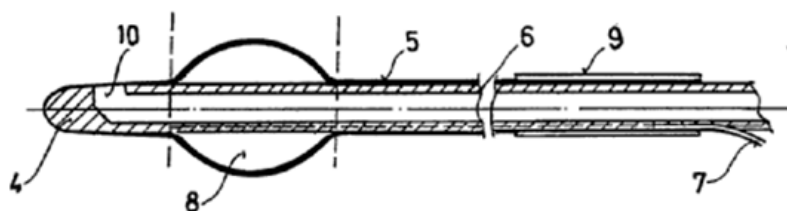


FIG. 2.

The opponents argued that example 2 was an intermittent catheter or at least usable as such. However, this catheter is said to be easy to fix to a patient's body with adhesive tape and to have kept its properties whilst in use for several weeks (column 9, lines 41 to

50). As explained above, these are typical features of an indwelling catheter.

In the Board's opinion, D34 gives no indication that the catheters it discloses are intended to be intermittent ones, but several indications that they are indwelling. In particular, column 2, lines 19 to 21 indicates that the hydrogel can be used for sustained release of appropriate drugs. So does column 7, lines 26 and 27. D34 indicates at several points that inflation takes place, which is a clear indication that a maintaining balloon is present; for instance column 7, lines 6 to 8 ("*The end protruding into the bladder is simultaneously inflated to prevent the catheter from slipping out*"), column 10, lines 23 to 24; column 12, lines 26 and 27. All these elements show the skilled person that the catheters disclosed in D34 are intended for indwelling use. The "one-use-type" catheter mentioned in column 8, lines 59 to 62 in relation to Figure 1 is also not necessarily an intermittent one, since indwelling catheters too can be for single use.

In the Board's opinion (based on the translation D1A), D1 discloses an intermittent catheter with an activated low-friction surface packed in a medical plastic bag (polyethylene) with a sterilising liquid. It says that this catheter is intended in particular for self-treatment at home (page 8, last sentence of the last full paragraph). It contains no pointer that the catheter described is intended for indwelling use, and in particular no indication that the catheter should be fixed to the patient's body for a lengthy period during normal use, and above all no indication that any kind of drug should be absorbed during preparation of the catheter and released in the urethra. The activation time of the low-friction surface plays no role for this

catheter, since it is activated during manufacturing and stored in a package in an activated state.

The patent proprietor considered that the indication in examples 1 and 2 that the catheter was kept in the bodies of some male patients for several days was a sign that it was intended to be indwelling.

The Board is not convinced by this argument. According to D1, the reason for keeping the catheter for longer periods in the bodies of 5 patients out of 30 in example 1, and of 2 patients out of 10 in example 2, was to test more specifically the quality of the claimed low-friction layer in relation to the rejection response of the patients. If the intention had been to test the catheters' use as indwelling ones, the Board fails to see why all 30 (or 10) patients were not tested, and for longer periods than only a few days. The low proportion of patients tested and the relatively short test period (3 to 7 days) suggest that the test was not for that purpose.

Hence, D1 discloses intermittent catheters.

The Board notes that whether or not a coating for the hydrophilic layer is present does not change this finding, since this is a secondary feature which does not change the type of catheter.

Hence, of D1 and D34, D1 is the closer prior art for the assessment of inventive step.

## 12.2 *Differences*

The patent proprietor argued that the surface layer according to D1 was hydrophobic, as explained in

declaration D36 (page 2), that the liquid present in the package was only for sterility, not for activation of the hydrophilic surface, that no swelling of the material took place and that there was no cavity in the package.

The Board notes that it is mentioned at several places in D1 (e.g. page 10, 4th and 5th paragraphs and example 1) that the low-friction surface is obtained by wetting the moulded catheter with water or physiological saline containing 0.1% of hibitane. In the Board's opinion, this implies that the main component of the surface is hydrophilic, and thus able to absorb the water. And, due to the absorption of the water, the component of the surface will also swell, at least to some extent. That the paraffin particles present in the mixture described in D1 improve the low-friction property of the surface does not change the fact that the absorbed water also contributes to achieving the desired combined effect. Claim 1 requires a *"hydrophilic surface layer in the form of a hydrophilic coating intended to produce a low-friction surface character by treatment with a liquid swelling medium"*, or in other words it requires that when a liquid swelling medium has "treated" the surface, the latter exhibits a low-friction character. Nothing else is done in D1. The absorption of the water is part of the process for obtaining the low-friction surface. There is no indication in D1 that the catheter would exhibit a low-friction character without the step of absorbing water (confirmed in D36, page 3, end of the first paragraph and D44, points 22 and 23). On the contrary, as also explained there, the absorption of water is what gives rise to the low-friction character.

Moreover, since the catheter according to D1 is sealed in a plastic package (page 8, end of last complete paragraph), this plastic package necessarily has a cavity to accommodate the catheter. From the above it also follows that the 0.1% aqueous solution of hibitane contained in the package is necessarily absorbable by the hydrophilic material as well. Moreover, since the catheter is sealed in the package with its low-friction surface activated, this also constitutes a ready-to-use catheter assembly.

In the Board's opinion, there thus remain two differences between the urinary catheter assembly according to claim 1 and that disclosed in D1:

i) the former should comprise "*at least one urinary catheter (1), the catheter having a catheter tube coated on its external surface on a substantial part of its length from its distal end with a hydrophilic surface layer in the form of a hydrophilic coating intended to produce a low-friction surface character*", whereas in the latter the hydrophilic surface layer is not in the form of a coating, rather the whole catheter wall is made of a single material exhibiting hydrophilic properties since the catheter is manufactured by pouring a fluid mixture into a mould, thus forming a homogenous wall of the same material (e.g. claim 1 of D1);

ii) the former should also comprise "*a catheter package made of gas impermeable material formed by a multiple layer thermoplastic film material comprising aluminium*", whereas the package of D1 is simply said to be made of polyethylene (page 8, last complete paragraph, last two sentences: "*After sterilisation, the medical catheter (e.g. urinary catheter) can be*

*sealed in polyethylene packing bag containing sterilizing liquid for storage. This sort of package is quite convenient to people (for example, the aged and disabled) for self-treatment at home)". Polyethylene is not necessarily gas-impermeable (as assessed in D36, page 3, second paragraph or D44, paragraph 27).*

12.3 *Technical effects / objective problem / obviousness*

The opponents argued that each of the two differentiating features had a separate individual technical effect; they did not have a combined or synergistic one. The hydrophilic coating of feature (i) was a simple alternative to the hydrophilic wall of D1, without any additional technical effect, and due to the presence of aluminium in the packaging material feature (ii) improved gas-impermeability and/or resistance to UV rays.

More precisely, the skilled person would indistinguishably use a hydrophilic coating or a hydrophilic wall, even though according to D1 catheters with coatings were considered to have some drawbacks. However, such drawbacks would not prevent him from using a coating technology, since according to T 0155/85 (point 13) there could not be any invention in worsening the prior art. This was all the more true in the present case, since in D1 the catheters with coatings were said to be workable.

The opponents further took the view that if the skilled person was faced with a shelf-life problem that necessitated improving the gas-impermeability of the material used for packaging the wet catheter, he would obviously think of a material formed by a multiple-layer thermoplastic film material comprising aluminium,

since such materials were part of his common general knowledge in this field of packaging wet medical products, as was exemplified by D42, page 87, third paragraph.

The patent proprietor considered that the objective problem was to facilitate intermittent catheterisation in any type of environment.

In the Board's opinion, D1 discloses a ready-to-use intermittent catheter made as a whole out of a single hydrophilic material, the catheter being sealed in a polyethylene package together with a quantity of sterilisation fluid, namely the same fluid as that used before sealing to activate the hydrophilic material so as to give the catheter's external surface a low-friction character.

This set of features has a number of technical consequences. The fact that the catheter is manufactured as a whole out of the same material means that this material has to have not only the desired hydrophilicity but also has to provide sufficient column strength to a catheter made of this material and having a small diameter so that it can be inserted easily into the urethra, even by elderly or disabled patients. This clearly limits the choice of suitable materials, and in particular the choice of hydrophilic materials - which can be detrimental to the desired smoothness of the surface to be inserted into the urethra, as smoother material may not have the necessary column strength. The fact that the catheter as a whole is made of the same hydrophilic material also means that a greater quantity of liquid swelling medium is needed to activate the hydrophilic surface than in the case of a catheter with only a coating

layer of that same hydrophilic material. Also, the fact that the polyethylene package is less gas-impermeable than a package made of a multiple-layer thermoplastic film material comprising aluminium in turn means that the package has to contain more liquid swelling medium in order to have the same shelf-life.

From the above it follows that, starting from D1, the technical effects of the differentiating features are at least that a choice can be made between more hydrophilic materials, because the necessary column strength can be provided by the catheter tube and not by the catheter walls made exclusively of hydrophilic material, that less liquid swelling medium is needed to activate the low-friction surface and that less liquid swelling medium has to be present in the package for a given shelf-life. The fact that less liquid swelling medium is necessary also reduces the weight of the catheter assembly, which is particularly important when the patient has to carry around with him the several catheters he needs each day.

The opponents contended that the patent did not address the aims of enhancing column strength or reducing the quantity of liquid swelling medium needed, so the patent proprietor could not base any inventive-step reasoning on these alleged effects.

The Board does not agree. In some instances, technical effects not readily apparent to the skilled person and/or not disclosed or proven to exist may not be taken into account for inventive step, but this is not the case here. Indeed, it is self-evident to the skilled person that a urinary catheter needs to have some column strength so that it can be easily introduced into the urethra; there is no need to specify that in



the patent. The same is true for his constant desire to improve a device's workability, reduce the quantity of materials used and cut costs. Additionally, in the present case the specific wish to reduce the quantity of liquid swelling medium is addressed several times in the patent specification (paragraph [0016], first sentence; paragraph [0025], last sentence; paragraph [0036], first sentence), so there can be nothing unexpected about mentioning this intention and/or effect.

The objective problem can therefore be seen as to provide an improved intermittent catheter assembly at lower cost whilst retaining comparable properties.

The question of obviousness therefore boils down to the following: would it be obvious for the skilled person wishing to produce the intermittent catheter assembly according to D1 at lower cost to replace the polyethylene packaging with a multiple-layer thermoplastic film material comprising aluminium and to replace the one-material catheter wall tubing with a catheter tube with a coating?

In the Board's opinion this is not the case for several reasons, the most important one being that D1 teaches away from such a solution. Indeed the invention presented in D1, namely the single-material wall tubing, is based on an analysis of the drawbacks of prior-art coated catheter tubes. On page 4 (D1A translation), former solutions with coatings are presented and said to be unsatisfactory either because the coating applied to the tubing did not adhere to it firmly enough so that it was easily stripped off if it came into contact with water, or other manufacturing methods used to obtain better adhesion of the coating

had the disadvantage of either needing large amounts of inflammable and poisonous solvents or involving long and complicated steps and hence being too costly. The solution to all the above problems proposed in D1 is basically to manufacture a one-material tubing wall catheter by mixing a desired combination of components to a homogenous mixture and forming the catheters by moulding that mixture to the desired shape. The catheters thus obtained were considered to have good lubricity and to be cheaper.

It follows that the Board sees no reason why it would be obvious for the skilled person starting from D1 and wanting to further improve the catheters disclosed therein to revert to the less advantageous solutions the author of D1 wished to abandon. If the skilled person has deliberately abandoned one type of catheters (the coated-tube type) to arrive at a second type (the one-material wall type), any further development will normally occur within that second type. Going back to the intentionally abandoned first type when further developing the second one can only be the result of *ex post facto* analysis, i.e. an artificial analysis performed with hindsight knowledge of the invention (T 0570/91, point 4.; T 0439/92, point 6.3.4; T 0817/94, point 5.5; T 1040/93, point 5.) This also means that the skilled person starting from D1 would not be able to recognise the advantageous effect achieved by combining a catheter made as a coated tubing with a more gas-impermeable packaging material, because he is "held captive" by the thoughts or considerations set out therein.

The opponents maintained that the case law, especially T 0155/85 (point 13), stated that there could be no invention in merely worsening the prior art. Therefore

the skilled person would not only have no problem in going back to a solution he had decided to abandon, but that solution would also not be inventive.

First of all, the decision cited by the opponents is not based on a situation like the present case, since the prior art to which the inventor reverted was not cited as disadvantageous in the patent in suit there. A patent application is a legal document in which the author sets out the problems in the prior art which he wishes to improve, and what he believes to be the solutions. In D1, to summarise, the teaching is to dispense with coated tubings and opt instead for moulding technology with a one-material tubing wall. The opponents have not presented any convincing argument to explain why the skilled person starting from D1 should and would ignore this teaching and revert to the technology it describes as disadvantageous.

The subject-matter of claim 1 therefore involves an inventive step pursuant to Article 56 EPC.

12.4 *Inventive step starting from other documents as closest prior art.*

In the oral proceedings, the opponents - despite the fact that the Board had asked them at the beginning of the discussion of inventive step to formally present all the lines of argument they wished to pursue and, having heard the parties, had indicated that D1 was closer than D34 - wished to present lines of argument starting from D34, and indeed from other documents.

The Board notes that under the problem-solution approach used to examine inventive step, one important

step is to determine the closest prior art, i.e. the most promising springboard towards the invention. Taking this step avoids examining several other starting points which would be less promising, i.e. less likely to lead to the invention in an obvious way. It follows from this that when obviousness has been examined starting from the closest prior art and the subject-matter of the claim has been found to be inventive, it is no longer necessary to check its inventiveness starting from another document. This way of proceeding has been accepted by the Enlarged Board of Appeal, for instance in R 0013/13 (in particular point 15 of the reasons, including: "*Since the petitioners were given the opportunity to submit their arguments with regard to the issue of determining the closest prior art, their right to be heard has been observed. Once the Board had reached a substantive conclusion by already excluding one or more documents ... as starting points for the assessment of inventive step, it was logically consistent to exclude all other prior art not found to be the closest prior art as starting point for the further discussion of inventive step according to the second and third stages of the problem-solution approach. By following this methodology the Board did not infringe the right to be heard, because - as indicated above - a party is not entitled to be additionally heard on the application of the problem-solution approach starting from other pieces of prior art than the closest prior art*").

For the above reason, the Board decided not to allow a discussion of the objection of lack of inventive step starting from D34.

Concerning a discussion starting from other documents (D2 or D4) not even cited by the opponents when the

Board asked them to present their lines of argument, the Board decided not to allow them into the proceedings pursuant to Article 13(3) RPBA, because otherwise the whole inventive-step discussion would have had to be reopened, even though the opponents had been given the opportunity to present all their lines of argument at the beginning of the discussion, and moreover none of them had filed any submission to that effect during the three months between the first and second oral proceedings, in which the same request was discussed unamended.

13. *New auxiliary request 3 - adaptation of the description*

The opponents considered that the description should be adapted, and even corrected, because several elements were not in line with the claimed embodiments. This was the case, for instance, for the reference to a first series of embodiments in paragraph [0011], for the reference to a Figure 13 which no longer existed, and for Figure 12 which showed an embodiment according to the former second series of embodiments.

Certain principles have to be applied when adapting the description in opposition and opposition appeal proceedings. The grant of a patent marks a cut-off point (T 1149/97, OJ EPO 2000, 259) defining the rights of third parties and the protection enjoyed by the patent proprietor. The extent of protection is determined in particular by applying Article 69 EPC, which stipulates that the description and drawings are to be used to interpret the claims, and the Protocol on the Interpretation of Article 69 EPC. In other words, any amendment of the description and drawings has or may potentially have an effect on how the claims must be interpreted. Rule 80 EPC follows the same line, by

only allowing amendments occasioned by a ground for opposition under Article 100 EPC. The case law has therefore justifiably limited the amendments possible during opposition or opposition appeal proceedings to those rendered necessary as a result of such proceedings, in particular due to amendments made to the claims. This implies in particular that possible "mistakes", inconsistencies or amendments "forgotten" during the grant proceedings and present in the granted patent are not to be corrected unless they result from opposition and/or opposition appeal proceedings.

For the above reasons, the amendments concerning deletion of Figure 12, the reference to a non-existing Figure 13, or suggested corrections to the wording used in the description are not necessary in the sense just explained above and the Board accepts the adapted description (paragraphs [0001] to [0039]) filed on 23 February 2017.

14. *Right to a decision on auxiliary requests 1 and 2*

At the end of the oral proceedings, when the chairman asked for the parties' final requests, the patent proprietor maintained its main request, new auxiliary request 3 and auxiliary request 9, but withdrew auxiliary requests 1 and 2 filed with its statement setting out the grounds of appeal. Since auxiliary request 2 was the request on which the decision under appeal was based, the opponents took the view that they had a right to a substantiated decision on their successful appeal against the impugned decision, so the patent proprietor did not have the right to withdraw this request.

The Board fails to see any basis in the EPC for not allowing the patent proprietor to withdraw its auxiliary requests 1 and 2. On the contrary, Article 113(2) EPC explicitly states that "*The European Patent Office shall examine, and decide upon, the European patent application or the European patent only in the text submitted to it, or agreed, by the applicant or the proprietor of the patent*". It is noteworthy that this provision is specifically worded to require the European Patent Office to decide only on a text submitted (or agreed) by the proprietor of the patent. It therefore obviously applies in opposition proceedings before the opposition divisions. Under Rule 100(1) EPC it also applies before the boards of appeal in opposition appeal proceedings: "*Unless otherwise provided, the provisions relating to proceedings before the department which has taken the decision impugned shall apply to appeal proceedings*". Moreover, it is generally accepted that in appeal proceedings the principle of party disposition applies (see e.g. R 0013/13, point 15), meaning that parties can put forward, withhold or withdraw their requests as they see fit. In other words, if a patent proprietor withdraws or no longer agrees to a text (two auxiliary requests, in this case), this principle prevents the Board of appeal from deciding on these issues.

Therefore the Board has no power to object to the patent proprietor's withdrawal of auxiliary requests 1 and 2.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The appeal of the patent proprietor is dismissed.
3. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:

- Claims 1 to 11 of new auxiliary request 3 as filed on 17 November 2016;
- Description of new auxiliary request 3, paragraphs [0001] to [0039], as filed on 23 February 2017;
- Figures 1 to 5 and 12 of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated





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Case Number: T 1477/15 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 14 September 2017 correcting an error in the decision**  
**of 23 February 2017**

**Appellant:** Coloplast A/S  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
8 July 2015 concerning maintenance of the  
European Patent No. 1145729 in amended form.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** P. L. P. Weber  
D. Ceccarelli

### **Summary of Facts and Submissions**

- I. In case T 1477/15 concerning European patent EP-B-1145729, at the oral proceedings held on 23 February 2017, the Board decided that the patent could be maintained in amended form.
- II. The written decision was posted on 26 July 2017 with the following order:
- “1. The decision under appeal is set aside.  
2. The appeal of the patent proprietor is dismissed.  
3. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:
- Claims 1 to 11 of new auxiliary request 3 as filed on 17 November 2016;
  - Description of new auxiliary request 3, paragraphs [0001] to [0039], as filed on 23 February 2017;
  - Figures 1 to 5 and 12 of the patent as granted.”
- III. The Board noted that a clerical error was made when mentioning the Figures because the last sentence of the order should read: Figures 1 to 6 and 12 of the patent as granted.

### **Reasons for the Decision**

1. Rule 140 EPC allows the Board to correct obvious mistakes.
2. It is clear from the whole of decision T 1477/15 that Figure 6 of the patent as granted was intended to form

part of the version of the patent to be maintained. This is for instance confirmed by the mention of that figure in paragraphs [0017] and [0031] of the description to be maintained. It follows that an obvious mistake was made by the Board when writing the order, since Figure 6 was never meant to be deleted.

3. The requirements of Rule 140 EPC are therefore fulfilled for the correction to be made.

### **Order**

#### **For these reasons it is decided that:**

The order of the decision of 23 February 2017 is corrected as follows:

The last line of the order "Figures 1 to 5 and 12 of the patent as granted" is replaced by the wording

"Figures 1 to 6 and 12 of the patent as granted."

The Registrar:

The Chairman



D. Hampe

E. Dufrasne

Decision electronically authenticated