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Datasheet for the decision of 9 December 2024

Case Number: T 2561/22 - 3.2.02

Application Number: 16719677.3

Publication Number: 3307370

IPC: A61M25/00

Language of the proceedings: EN

Title of invention:
URINARY CATHETERS HAVING LIMITED REUSABILITY

Patent Proprietor:
Hollister Incorporated

Opponent:
Coloplast A/S

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
RPBA 2020 Art. 13(2)

Keyword:

Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - added subject-matter (no)
Late-filed argument - admitted (yes)
Late-filed objection - admitted (no)

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Case Number: T 2561/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 9 December 2024

Appellant: (Opponent)	Coloplast A/S Holtedam 1 3050 Humlebaek (DK)
Representative:	Inspicos P/S Agern Allé 24 2970 Hørsholm (DK)
Respondent: (Patent Proprietor)	Hollister Incorporated 2000 Hollister Drive Libertyville, IL 60048 (US)
Representative:	FRKelly Waterways House Grand Canal Quay Dublin D02 PD39 (IE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 October 2022 rejecting the opposition filed against European patent No. 3307370 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. The opponent filed an appeal against the decision of the opposition division to reject its opposition to the contested patent.

II. In its decision, the opposition division found that the invention claimed in the patent as granted was sufficiently disclosed, that claim 7 as granted did not contain added subject-matter, and that the subject-matter of claim 1 as granted was novel over D1, D2, D3 and D5 and involved an inventive step starting from D2 or D5.

D1, D2, D3 and D5 are the following documents:

D1 WO 86/06284 A1
D2 US 2003/0004496 A1
D3 US 4,811,847
D5 US 2014/0127270 A1

III. The **appellant (opponent)** requested that the decision under appeal be set aside and that the patent be revoked.

The **respondent (patent proprietor)** requested that the appeal be dismissed, i.e. that the patent be maintained as granted (main request), or alternatively that the patent be maintained as amended on the basis of one of auxiliary requests 1 or 2 on which the decision under appeal was based and which were refiled with the reply to the statement of grounds of appeal, or on the basis of one of auxiliary requests 3 to 9 filed with the submission of 8 August 2024.

IV. Oral proceedings were held before the Board on 9 December 2024, at the end of which this decision was announced.

V. This decision also refers to the following documents:

D4 WO 96/00099 A1

D7 "Self-Cath® *Plus*", Mentor

D8 "LoFric® The Leading Low Friction, Low Risk Catheter", Astra Tech

VI. **Claim 1 as granted (main request)** reads as follows (with the feature numbering used in the decision under appeal):

1a "*A reusable urinary catheter assembly (10, 100), comprising:*

1b *a catheter shaft (12, 102); and*

1c *a plurality of removable members (22b, 22c, 22d, 112a, 112b, 112c) associated with the catheter shaft (12, 102),*

1d *wherein a different one of said removable members (22b, 22c, 22d, 112a, 112b, 112c) is configured to be removed from the catheter shaft (12, 102) between each consecutive use of the reusable urinary catheter assembly (10, 100), and*

1e *the number of times that the reusable urinary catheter assembly (10, 100) may be reused is limited by the number of removable members (22b, 22c, 22d, 112a, 112b, 112c).*"

VII. The **appellant's arguments** relevant to the present decision can be summarised as follows.

Sufficiency of disclosure

The invention as claimed in the patent as granted was insufficiently disclosed.

The patent did not sufficiently disclose feature 1e. Even if the person skilled in the art were to follow the teachings of the patent to construct a catheter assembly according to claim 1, for example one as disclosed in Figure 1, they would not be able to reliably make a catheter, the number of reuses of which was limited by the number of removable members. Indeed, it was up to the user whether and how many removable segments were removed after each use of the catheter, and there was nothing to prevent it from being reused several times between segment removals or even after all segments had been removed. Thus there was no upper limit to the number of times the catheter could be reused.

Furthermore, the person skilled in the art was completely left in the dark as to how to make a urinary catheter according to claim 13 as granted in which the removable members were concentric cover layers arranged on the catheter shaft. The patent provided no guidance as to how such thin layers could be designed to be individually peelable while remaining aligned with each other without the outer diameter being significantly increased or the flexibility of the catheter shaft being compromised.

In addition, the patent did not disclose what features of the claimed catheters made them "reusable" as compared with single-use catheters. These features could not be the material used and the structure of the catheters, since the single-use catheters disclosed in D7 and D8 had essentially the same material and structure as the "reusable" catheters of the patent.

Added subject-matter

Claim 7 as granted contained added subject-matter, in breach of Article 123(2) EPC.

According to the decision under appeal (point 2.1), claim 7 as granted was supported by claim 18 as filed and the description as filed on page 4, line 32 to page 5, line 7 and page 5, line 27 to page 6, line 3.

However, claim 18 as filed did not include feature 1e, which a catheter assembly according to claim 7 as granted included by virtue of the dependency of claim 7 on claims 1 and 2 as granted. If this feature, as alleged in the decision, was supported by these passages of the original description relating to the embodiment of Figure 1, then each and every feature disclosed in relation to that embodiment would also have to be included in the granted claim in order to comply with Article 123(2) EPC. However, this was not the case, as several features were omitted from claim 7 as granted, such as a through-hole or fluid passage extending in each of the segments. It followed that claim 7 as granted was based on an unallowable intermediate generalisation.

Moreover, the feature "at least the distal-most segment is configured to be removed" of claim 18 had been replaced in claim 1 as granted - on which, again, claim 7 as granted depended - by the feature "a different one of said removable members is configured to be removed", which was different. This also provided the person skilled in the art with new information not disclosed in the original application.

Novelty over D5, D3, D2 and D1

The subject-matter of claim 1 as granted was not novel over each of D5, D3, D2 and D1.

D5

The urinary catheter of D5 was reusable, as required by feature 1a. A user of the catheter could well reuse it several times by removing one of the concentric cover layers after each successive use, the layers thus forming a counter indicating the number of times the catheter had been used. There was no particular feature in the contested patent that determined whether a catheter was reusable or not: it was simply a matter of choice for the user.

The respondent's argument concerning the balloon at the distal end of the catheter of D5 was raised for the first time at the oral proceedings before the Board and should not be admitted. Its admission at such a late stage of the proceedings would unfairly prejudice the appellant, who would not be able to respond to it in an appropriate manner, for example by carrying out an additional search.

In any case, this argument was not convincing. Indeed, not all balloons used in such indwelling catheters were irreversibly deformed upon inflation. On the contrary, there were catheter balloons that could be reversibly inflated and deflated and would not have caused a bulky protrusion at the distal end of the catheter, and thus would not have prevented its reinsertion into the patient's urethra.

D3

D3 disclosed (Figure 2) a urinary catheter assembly in which a plurality of caps were associated with a catheter shaft. These caps were configured to be removed sequentially from the catheter shaft for the purpose of cleaning the urethral ostia multiple times (column 4, lines 54-68). However, the use or reuse of the catheter, which was not defined in the contested patent, did not necessarily relate to catheterisation but could also relate to a cleaning step such as in D3. D3 therefore disclosed features 1a and 1d.

D2

D2 disclosed (Figure 2 and paragraph [0058]) a kit forming a reusable urinary catheter assembly comprising a reusable handle section with which were associated a number of insertion sections, each of which could be mounted on the reusable handle section and then removed therefrom after use. The number of insertion sections provided in the kit determined the number of times that the reusable catheter assembly could be reused. These insertion sections thus formed a plurality of removable members, which anticipated features 1c and 1d.

D1

D1 disclosed a reusable urinary catheter assembly (page 1, last paragraph) comprising a catheter shaft and a plurality of removable members in the form of tablets (see tablets 5 in Figure 1 and tube 31 containing such tablets in Figure 4). The tablets were intended to be dissolved, one at a time, in water in the catheter package to provide a sterilisation bath for sterilising the catheter after each use (page 5,

lines 8-12 and 23-24). Providing a limited number of tablets in the package limited the number of uses of the catheter (page 1, last paragraph). The plurality of tablets were associated with the catheter shaft because they were provided in the same package. Moreover, they were configured to be removed from the assembly, including the catheter shaft, between each consecutive use (page 5, lines 8-12 and 23-24). Thus D1 disclosed features 1c and 1d.

Inventive step starting from D2 or D5

If features 1c and 1d, on the one hand, and feature 1a, on the other hand, were to be regarded as novel over D2 and D5 respectively, these features would in any event not render the subject-matter of claim 1 as granted inventive over these documents.

Starting from D2

According to paragraph [0003] of the contested patent, the effect of features 1c and 1d was to provide a reusable catheter assembly with affirmative means to limit the number of times that a catheter could be reused. However, this effect was already achieved in D2 by providing a limited number of insertion sections in the package (see Figure 2 and paragraph [0058]). Therefore, starting from D2, the objective technical problem was simply to provide an alternative package for the removable members to that disclosed in Figure 2 of D2.

A straightforward solution to this problem would have been, instead of storing the plurality of insertion sections loosely in the package, to attach them end-to-end in extension of each other to the handle section in

such a way that they could be broken off sequentially after each consecutive use. For example, D3 (see Figures 2-3 and sentence bridging columns 3 and 4) or D4 (see Figure 1) would obviously have led the person skilled in the art faced with this technical problem to this solution. In this way, the person skilled in the art would have arrived at the subject-matter of claim 1 without any inventive activity.

Starting from D5

This objection was raised in the statement of grounds of appeal. The appellant did not comment further on it at the oral proceedings before the Board.

The effect of the reusability of the catheter assembly (feature 1a) was to avoid the disposal of single-use catheters as mentioned in paragraph [0003] of the contested patent. Starting from D5, the objective technical problem to be solved could therefore be seen as providing a catheter assembly that reduced waste.

The contested patent itself acknowledged in paragraph [0003] that reusable catheters were well known in the art and that reusing catheters avoided disposal of single-use catheters, thereby reducing waste.

The person skilled in the art would have recognised that by removing a cover layer from the catheter of D5 microbes formed on its outer surface could be removed, thereby making the catheter suitable for a new catheterisation. Thus the person skilled in the art, relying on common general knowledge or, alternatively, prompted by the disclosure in D1, page 1, lines 24-25 that it was desirable to enable repeated use of a catheter, would obviously have considered reusing the

catheter of D5 in order to solve the technical problem of reducing waste. No structural modification of the catheter was required for this purpose, as it was only a question of how to use the catheter.

It followed that the person skilled in the art starting from D5 would have arrived at the subject-matter of claim 1 as granted without any inventive activity.

VIII. The **respondent's arguments** relevant to the present decision can be summarised as follows.

Sufficiency of disclosure

The invention as claimed in the patent as granted was sufficiently disclosed.

Feature 1e did not mean that the catheter was necessarily physically limited to a certain number of uses, or that continued use was impossible beyond a certain point. Features 1c and 1d only provided a way to signal to a user that a limit of use had been reached.

Using information provided in the contested patent and common general knowledge, the person skilled in the art would have had no difficulty in selecting appropriate materials and thicknesses to make a working catheter assembly in which the removable members were concentric cover layers.

It was common general knowledge that not all urinary catheters were reusable. For example, indwelling or Foley catheters were single-use catheters. The limitations implied by the reusability of a urinary

catheter were well known to the person skilled in the art.

Added subject-matter

Claim 7 as granted did not contain added subject-matter. This claim was supported by claim 18 as filed, the general "Summary" section on page 2, lines 19-20 of the description as filed, and the other passages of the description as filed relating to the embodiment of Figure 1, in particular on page 4, line 32 to page 5, line 7 and page 5, line 27 to page 6, line 3, as required by Article 123(2) EPC.

Novelty over D5, D3, D2 and D1

The subject-matter of claim 1 as granted was novel over each of D5, D3, D2 and D1.

D5

The catheter disclosed in D5 was an indwelling or Foley catheter intended for long-term catheterisation and was not suitable for reuse. Thus D5 did not disclose at least feature 1a.

As argued by the respondent at the oral proceedings before the Board, the balloon provided at the distal end of the catheter of D5, once deflated for removing the catheter from the patient, did not necessarily return to its initial compact and smooth pre-use configuration shown in Figure 1, but instead would generally form a bulky protrusion at the distal end of the catheter. While this bulky protrusion did not prevent the removal of the catheter, it did prevent its reinsertion into the patient's urethra due to the

"snaking" of the catheter, and therefore its reuse. In any event, even if there were balloons which could reversibly inflate and deflate and thus return to their pre-use configuration, as claimed by the appellant, D5 did not contain any details as to the type of balloon used in the catheter and there was no indication in D5 that the balloon was such a balloon.

This argument merely built on the consistent argument which the respondent had previously made that an indwelling catheter such as the catheter of D5 was not suitable for reuse. It should therefore be taken into account by the Board.

D3

Use or reuse of the claimed catheter necessarily included catheterisation. Therefore the cleaning steps disclosed in D3 in connection with the removal of the caps 9, 10 and 11 did not anticipate any use or reuse of the catheter. Furthermore, the catheter of D3 was, like that of D5, an indwelling catheter with an inflatable balloon, and D3 explicitly disclosed that some parts of the catheter were destroyed upon use. It followed that the catheter of D3 was not reusable. D3 therefore did not disclose features 1a and 1d.

D2

The insertion sections provided loosely in the package of Figure 2 of D2 did not anticipate a plurality of removable members as defined in features 1c and 1d.

D1

The tablets of D1 were not "associated" with the catheter shaft and "configured to be removed" therefrom. Therefore D1 did not disclose features 1c and 1d.

Inventive step starting from D2 or D5

The subject-matter of claim 1 as granted involved an inventive step starting from D2 or D5.

Starting from D2

The subject-matter of claim 1 as granted differed from D2 by features 1c and 1d, which solved the objective technical problem of reliably and safely monitoring and limiting the number of uses of the catheter.

Starting from D2, the person skilled in the art would have had no motivation to associate with the catheter shaft the various insertion sections provided in the package of Figure 2 by stacking them in extension of each other. To do so would be contrary to the teaching of D2, which in fact aimed at reducing the overall length of existing catheters by breaking them into several parts, as shown in Figure 1 and described in paragraphs [0006] and [0008].

In any event, the caps disclosed in D3 had a completely different purpose, namely to allow thorough cleaning of the urethral ostia. The combination of D2 with D3 would therefore not have led the person skilled in the art to features 1c and 1d in an obvious manner.

The inventive-step objection based on the combination of D2 with D4 had never been raised until the oral proceedings before the Board. This objection was *prima*

facie unconvincing, since D4 related to the field of vascular catheters, which was very far removed from that of urinary catheters, so the person skilled in the art starting from D2 would not have consulted D4. This new objection should therefore not be admitted at this stage of the appeal proceedings.

Starting from D5

The subject-matter of claim 1 as granted differed from D5 at least by feature 1a.

D5 explicitly described the catheter as an indwelling catheter, and the purpose sought in D5 was to enable the biofilm on the outer surface of the catheter to be removed without having to remove the catheter from the patient, contrary to what was usually the case with previous catheters (paragraph [0032]). The person skilled in the art would therefore have been deterred from modifying the catheter of D5 to make it reusable.

Reasons for the Decision

1. Subject-matter of the contested patent

The contested patent relates to a reusable urinary catheter assembly as defined in claim 1 as granted, which comprises specific features for limiting the number of times that the catheter may be reused (paragraphs [0001], [0003]).

For this purpose, the claimed catheter assembly comprises a plurality of removable members (22b-22d, 112a-112c) associated with the catheter shaft (12, 102) (feature 1c). Claim 1 stipulates that a different one

of the removable members is configured to be removed from the catheter shaft between each consecutive use of the reusable urinary catheter assembly (feature 1d).

In a first embodiment (see Figure 1 reproduced below), the removable members are formed by the different segments (22b-22d) of a frangible drainage member (18). After each use, one or more segments can be removed from the remainder of the drainage member (paragraph [0014]). This can be done by applying a force to break the segment(s) apart from the adjacent more proximal segment (paragraph [0015]) or by pressing the drainage member into a cavity formed in the lid of a storage container, the cavity being adapted to break off and retain the distal-most segment of the frangible drainage member (Figure 2 and paragraph [0023]).

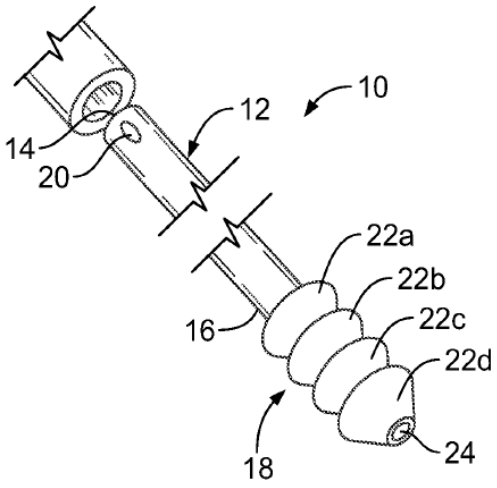

FIG. 1

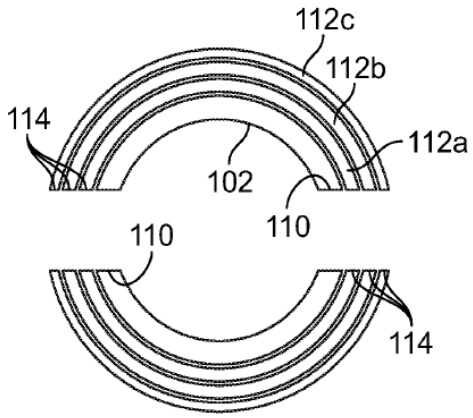

FIG. 9

In a second embodiment (see Figure 9 reproduced above), the removable members are formed by a plurality of concentric cover layers (112a-112c) associated with the catheter shaft (paragraph [0028]). After each use, the catheter assembly can be reconditioned for reuse by removing the outermost cover layer, with the adjacent

inner cover layer becoming the new, sterile, outermost cover layer of the catheter (paragraph [0039]).

Claim 1 as granted further specifies that "the number of times that the reusable urinary catheter assembly may be reused is limited by the number of removable members" (feature 1e) (paragraphs [0019], [0024], [0042]).

2. Sufficiency of disclosure

2.1 Contrary to the appellant's view, the contested patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

2.2 Feature 1e

The appellant objected that the patent did not sufficiently disclose feature 1e. This is not convincing.

It is true that the construction of the catheter assembly as disclosed in the patent specification does not physically prevent a user from reusing the catheter. Indeed, a user is free to remove one or more removable segments after each use of the catheter, or even to remove no segment at all. Moreover, the user is not prevented from reusing the catheter several times between segment removals, or even after all segments have been removed.

However, as argued by the respondent, the person skilled in the art would not read this limitation in the claim. Instead, they would give a broader interpretation of feature 1e and understand, from the

patent specification as a whole (see in particular paragraphs [0019], [0024] and [0042]) as well, that feature 1e does not mean that the catheter is necessarily physically limited to a certain number of uses, i.e. that further use is impossible beyond a certain point. Rather, they would understand that the intended limitation results from the "signal" provided to the user that a limit to the number of uses of the catheter has been reached when all of the removable members defined in feature 1c have been removed in accordance with feature 1d, thereby "signal[ling] the need" to replace the urinary catheter assembly (paragraph [0042]).

In this respect, while the patent explains that "the number of times that a reusable urinary catheter assembly may be reused may be varied by providing it with differing numbers of removable members" (paragraphs [0024] and [0042]), the person skilled in the art would also understand that this number of times is not necessarily equal to the number of removable members associated with the catheter shaft, but ultimately depends on whether the user has effectively removed one or more removable members between each consecutive use of the catheter and the number of removable members that have been removed on those occasions.

The appellant did not contest, and the Board agrees, that the first embodiment in which the removable members are segments of a frangible member associated with the catheter shaft is sufficiently disclosed in the contested patent to enable the person skilled in the art to reproduce features 1a to 1d thereof without undue burden. As set out above, feature 1e results implicitly from features 1c and 1d.

2.3 Concentric cover layers

On the other hand, the appellant objected that the patent did not provide sufficient information as to the second embodiment in which the removable members are concentric cover layers arranged from an innermost cover layer associated with the outer surface of the catheter shaft to an outermost cover layer.

This is not convincing either. Contrary to the appellant's argument, the person skilled in the art would have no difficulty, using common general knowledge, in selecting appropriate materials and thicknesses to make the cover layers so that they are individually peelable while remaining aligned with each other, without the outer diameter being significantly increased or the flexibility of the catheter shaft being compromised.

2.4 Feature 1a

The appellant also objected that the patent as granted did not disclose what features of the claimed urinary catheter made it "reusable" (feature 1a) and different from a single-use catheter.

This is unconvincing as well. As argued by the respondent and acknowledged in the "Background" section of the contested patent (paragraph [0003]), the person skilled in the art would know that not all urinary catheters are suitable for reuse, and would be well aware of the limitations implied by the reusability of a urinary catheter. Therefore the fact that the patent does not describe in detail any structural features of

the claimed catheter to make it "reusable" does not negatively affect the sufficiency of the disclosure.

The Board sees no contradiction in the fact that, as the appellant argued, the claimed catheter may essentially be made of the same materials and have the same tubular shape as single-use catheters known in the art, such as those of D7 or D8, which are also made of medical-grade PVC with a hydrophilic coating. The definition in feature 1a that the catheter assembly is "reusable" implicitly defines limiting structural and functional features of the claimed catheter that the catheters known from D7 or D8, which are themselves described as single-use catheters in these documents, do not necessarily have.

3. Added subject-matter

3.1 The Board agrees with the respondent that the subject-matter of claim 7 as granted is disclosed in claim 18 as filed, the general "Summary" section on page 2, line 19 of the description as filed and the other passages of the description as filed relating to the embodiment of Figure 1, in particular on page 4, line 32 to page 5, line 7 and page 5, line 27 to page 6, line 3, as required by Article 123(2) EPC. The appellant's arguments to the contrary are not convincing.

3.2 The appellant acknowledged that most of the features defined in claim 7 as granted, in particular those relating to the plurality of segments of the frangible drainage member, are disclosed in the original claim 18 (see table on page 3 of the statement of grounds of appeal), but objected that claim 7 as granted contained

added subject-matter in relation to the following features.

3.3 Feature 1e

As argued by the appellant, claim 7 as granted does not recite feature 1e, but a catheter assembly according to claim 7 comprises this feature by virtue of the dependency of claim 7 on claim 2 as granted, which in turn depends on claim 1 as granted, where feature 1e is defined.

It is true that claim 18 as filed does not explicitly define feature 1e. However, the application as filed as a whole is directed to urinary catheters having limited reusability determined by the number of removable members associated with the catheter shaft, i.e. as defined by feature 1e. As argued by the respondent, the person skilled in the art would understand that this is also the case for the catheter assembly defined in claim 18 as filed. Indeed, this catheter assembly comprises a frangible drainage member associated with the distal end of the catheter shaft and including a plurality of segments arranged from a proximal-most segment to a distal-most segment, with at least the distal-most segment comprising a removable member. The person skilled in the art would thus understand that the number of uses of this catheter assembly is limited by the number of those segments of the frangible member which comprise a removable member. In other words, feature 1e is implicit in claim 18 as filed. It follows that a catheter assembly according to claim 7 as granted does not extend beyond the content of the application as filed.

Moreover, as further argued by the respondent, feature 1e is in fact explicitly disclosed for the embodiment of Figure 1 to which the catheter assembly of claim 7 as granted undisputedly corresponds (see for example page 4, line 15 to page 5, line 4). The appellant has not convincingly argued that feature 1e is inextricably linked to any other feature of this embodiment which might have been omitted in claim 7 as granted or the claims on which the latter depends. In particular, the Board sees no such inextricable link with the through-hole or fluid passage extending in each of the segments. It follows that, contrary to the appellant's argument, claim 7 as granted does not constitute an unallowable intermediate generalisation of the original disclosure.

3.4 *Feature "a different one of said removable members is configured to be removed from the catheter shaft between each consecutive use"*

The catheter assembly of claim 7 as granted also includes the feature "a different one of said removable members is configured to be removed from the catheter shaft between each consecutive use" defined in claim 1 as granted.

Contrary to the appellant's argument, this feature does not present the person skilled in the art with any new information not disclosed in the original disclosure. In particular, it is irrelevant that claim 18 as filed does not include this feature, but instead refers to "at least the distal-most segment". This is because, due to the dependency of claim 7 as granted on claim 2, a catheter assembly according to claim 7 as granted not only includes the above disputed feature, but also the feature that the removable members are arranged from a

proximal-most removable member to a distal-most removable member, i.e. end-to-end in extension of each other as shown in Figure 1. This arrangement excludes the possibility, which the appellant considered to be improperly covered by claim 7 as granted, that one of the segments could be removed without also removing the distal-most segment.

In any event, as argued by the respondent, the above disputed feature is disclosed in the general "Summary" section on page 2, line 19 of the description as filed, which would also be understood by the person skilled in the art to apply to the specific embodiment of Figure 1.

4. Novelty

4.1 Contrary to the appellant's view, D5, D3, D2 and D1 do not disclose all the features of claim 1 as granted, and the subject-matter of this claim is novel over each of these documents.

4.2 Novelty over D5

4.2.1 It is common ground that D5 discloses an indwelling or Foley catheter. In its communication under Rule 15(1) RPBA, the Board had expressed the preliminary view that a user could well reuse the catheter of D5 for catheterisation several times, removing a cover layer after each consecutive use.

4.2.2 At the oral proceedings before the Board, the respondent contradicted this view, and referred to the balloon D provided at the distal end of the catheter as shown in Figure 1 which, when inflated, was used to secure the position of the catheter in the patient's

bladder (paragraph [0067]). The respondent argued that while this balloon initially had a smooth and compact pre-use configuration as shown in Figure 1, making it suitable for insertion into the patient's urethra, the balloon, once deflated for removal of the catheter from the patient, did not necessarily return to its pre-use configuration but instead would generally form a bulky protrusion at the distal end of the catheter. Such a bulky protrusion would prevent the catheter from being reinserted into the patient's urethra and thus from being reused. Moreover, even if there were balloons which could reversibly inflate and deflate and thus return to their smooth and compact pre-use configuration, as claimed by the appellant, D5 did not contain any details as to the type of balloon used in the catheter, and there was no indication in D5 that the balloon was such a balloon. It followed that D5 did not directly and unambiguously disclose feature 1a.

The Board found this argument *prima facie* convincing.

4.2.3 It is common ground that no argument concerning the balloon of the catheter of D5 had been raised earlier in the proceedings and that the respondent's argument therefore constituted an amendment to its appeal case. The appellant requested that it not be admitted at such a late stage of the appeal proceedings.

4.2.4 Pursuant to Article 13(2) RPBA, an amendment to a party's appeal case made at that stage of the appeal proceedings must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

For the reasons set out below, the Board considered that there were exceptional circumstances which justified taking the respondent's argument into account.

As submitted by the respondent, this argument builds on and merely refines the consistent line of argument previously put forward by it throughout the opposition and appeal proceedings - and found convincing by the opposition division in the decision under appeal - according to which an indwelling catheter such as the catheter of D5 is not suitable for reuse. This argument does not raise any surprising issues going beyond the general discussion of that question.

Furthermore, this argument is not complex and is immediately understandable to both the Board and the respondent. As stated above, the Board found it *prima facie* convincing.

Moreover, the admission of this argument would not - and in the end did not - prevent the appellant from responding to it in an appropriate manner in the course of the ongoing oral proceedings. In particular, contrary to what the appellant claimed, the results of an additional search would not have had any bearing on the merits of this argument. Indeed, even if the appellant had produced evidence of a catheter balloon which could reversibly inflate and deflate and thus, when used in the catheter of D5, return to a smooth and compact configuration after deflation, thereby allowing the catheter to be reused - which arguably could be the case - there would still be no direct and unambiguous disclosure in D5 that such a balloon was used in the disclosed catheter. Therefore the same conclusion would

have been reached as if that evidence had not been produced.

The Board therefore decided to take this argument into account.

4.2.5 The respondent's argument is also convincing on closer examination. Indeed, a bulky protrusion formed at the distal end of the catheter by the deflated balloon, while not preventing removal of the catheter from the patient, would prevent its reinsertion into the patient's urethra due to the "snaking" of the catheter. This effect is mentioned in paragraph [0002] of the contested patent.

D5 is silent on any measures to avoid the formation of such a bulky protrusion and to ensure that the balloon, upon deflation, returns to a smooth and compact configuration - similar to its pre-use configuration - which would allow the catheter to be reinserted and thus reused. Indeed, D5 does not contain any information as to the type of balloon used in the disclosed catheter.

Contrary to the appellant's view, it is immaterial that there may well be catheter balloons which are adapted to return to their smooth and compact pre-use configuration after deflation, for example balloons which reversibly inflate and deflate, as suggested by the appellant. Even on this assumption, there is still no direct and unambiguous disclosure in D5 that such a balloon is used in the disclosed catheter.

The Board therefore agrees with the respondent that D5 does not directly and unambiguously disclose that the catheter is reusable as required by feature 1a.

4.3 Novelty over D3

D3 discloses (Figure 2) a urinary catheter assembly in which a plurality of caps 9, 10, 11 are associated end-to-end at the distal end of a catheter shaft C. As submitted by the appellant, these caps are configured to be sequentially removed from the catheter shaft. However, this is for the purpose of cleaning the urethral ostia multiple times (column 4, lines 54-68).

Contrary to the appellant's view, the person skilled in the art would consider the use or reuse of the urinary catheter claimed in the contested patent to necessarily include the step of catheterisation, during which the catheter is inserted into the patient's urethra. In D3, catheterisation can only take place once all caps have been removed from the catheter shaft. Therefore the cleaning steps disclosed in connection with the removal of the caps do not anticipate a use or reuse of the catheter in the interpretation set out above.

Furthermore, the catheter of D3 is an indwelling catheter with an inflatable balloon which, as discussed for D5 above, does not necessarily allow further catheterisation. In fact, D3 explicitly discloses that some parts of the catheter must be destroyed during use, thereby preventing it from being reused.

It follows that D3 does not disclose features 1a and 1d.

4.4 Novelty over D2

D2 discloses (Figure 2 and paragraph [0058]) a kit comprising, in the same package, a reusable handle

section and a number of insertion sections, each of which is adapted to be attached to the reusable handle section in use and then removed therefrom after use.

Contrary to the appellant's view, the person skilled in the art would understand from the wording of claim 1 as granted, in particular from features 1c and 1d, that the expression "associated with the catheter shaft" in the context of the contested patent requires the removable members to be initially physically connected to the catheter shaft, so that they can later be removed therefrom.

While Figure 2 shows an insertion section attached to the handle section so that the two sections together form a rigid catheter (paragraph [0057]), the remaining insertion sections loosely provided in the package are neither "associated" with nor "configured to be removed" from the handle section. It follows that D2 does not disclose features 1c and 1d.

4.5 Novelty over D1

D1 discloses a reusable urinary catheter assembly (page 1, last paragraph) comprising a catheter shaft and a plurality of tablets (see tablets 5 in Figure 1 and tube 31 containing such tablets in Figure 4). The tablets are intended to be dissolved, one at a time, in water in the catheter package to provide a sterilisation bath for sterilising the catheter after each use (page 5, lines 8-12 and 23-24). D1 discloses that providing a limited number of tablets in the package limits the number of uses of the catheter (page 1, last paragraph).

For the same reason as discussed above with respect to D2, the tablets disclosed in D1, which the appellant has identified as removable members, are neither "associated" with nor "configured to be removed" from the catheter shaft. Therefore D1 does not disclose features 1c and 1d either.

5. Inventive step

5.1 Contrary to the appellant's view, the subject-matter of claim 1 as granted involves an inventive step starting from D2 or D5.

5.2 Starting from D2

5.2.1 As set out in point 4.4 above, the subject-matter of claim 1 as granted differs from the catheter assembly of D2 by features 1c and 1d. It is common ground that the effect of these features is to provide a reusable catheter assembly with affirmative means to limit the number of times that a catheter can be reused ("limit" being interpreted as set out in point 2.2 above).

5.2.2 Even accepting the objective technical problem formulated by the appellant in respect of D2 - to provide an alternative package for the removable members to that disclosed in Figure 2 of D2, in which the additional insertion sections are stored loosely and separately from the handle section - the Board agrees with the respondent that the person skilled in the art would not have arrived at the subject-matter of claim 1 as granted without an inventive step.

5.2.3 Indeed, to associate the plurality of insertion sections with the handle section by stacking them end-to-end in extension of each other, as suggested by the

appellant, would have been contrary to the teaching of D2, which instead aims at reducing the overall length of existing catheters by breaking them into several parts, as shown in Figure 1 and described in paragraphs [0006] and [0008]. It is irrelevant in this respect that D2 discloses other embodiments of a catheter having a bendable insertion section, such as those shown in Figures 5 and 6, to which the appellant has referred. These other embodiments are merely alternative embodiments to the embodiment shown in Figure 2, and also aim at reducing the overall length of the catheter, particularly in its pre-use packaged configuration. Without hindsight, the person skilled in the art starting from D2 would therefore not have considered the modification proposed by the appellant.

5.2.4 Contrary to the appellant's view, D3 would not have motivated the person skilled in the art to make this modification in D2 either. As discussed in point 4.3 above, the caps disclosed in D3 have a completely different purpose, namely to allow thorough cleaning of the urethral ostia. Without the benefit of hindsight, the person skilled in the art faced with the above technical problem would not have looked for a solution in D3.

5.2.5 The other inventive-step objection based on the combination of D2 with D4 raised by the appellant at the oral proceedings before the Board had not been raised until then. Its admittance was therefore also subject to Article 13(2) RPBA.

The appellant did not raise any exceptional circumstances that would justify admitting this objection at this stage of the appeal proceedings, and

the Board saw none. The Board therefore decided to disregard this new objection.

In any event, as argued by the respondent, this objection is not *prima facie* convincing. D4 relates to the field of vascular catheters, which is very far removed from that of urinary catheters. It is therefore doubtful whether the person skilled in the art would have consulted D4 when starting from D2.

5.3 Starting from D5

As set out in point 4.2 above, the subject-matter of claim 1 as granted differs from the catheter assembly of D5 by feature 1a.

In its statement of grounds of appeal, the appellant argued that the person skilled in the art would obviously have considered reusing the catheter of D5 in order to solve the technical problem of reducing waste. The appellant submitted that this did not require any structural change to the catheter, since it was only a question of how to use it.

The Board disagrees. As discussed in point 4.2 above, the indwelling catheter disclosed in D5 cannot be reused unless, *inter alia*, the balloon at its distal end is adapted to return to a smooth and compact configuration upon deflation, thereby making the catheter suitable for reuse, a measure on which D5 is entirely silent. The appellant did not elaborate on this point at the oral proceedings before the Board, but referred to its written submissions.

As argued by the respondent, the person skilled in the art would not have been motivated to modify the

catheter of D5 in order to make it reusable. Indeed, D5 emphasises the advantages of the disclosed urinary catheter with removable concentric cover layers, namely that it makes it possible to remove the biofilm that would have formed on the outer surface of the implanted catheter without having to remove the catheter from the patient, which latter D5 describes as "undesirable" (paragraph [0032]). In view of this explicit teaching, the person skilled in the art would have been deterred from modifying the catheter of D5 to make it reusable and suitable for multiple insertion into and removal from the patient. Thus, without the benefit of hindsight, the person skilled in the art would not have arrived at the subject-matter of claim 1 in an obvious manner.

6. Conclusion

It follows from the foregoing that none of the appellant's objections taken into account prejudice maintenance of the contested patent as granted. The appeal is therefore to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated