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**Datasheet for the decision
of 16 October 2015**

Case Number: T 1620/11 - 3.2.02

Application Number: 02748634.9

Publication Number: 1427467

IPC: A61M25/00

Language of the proceedings: EN

Title of invention:

A CATHETER ASSEMBLY

Patent Proprietor:

Coloplast A/S

Opponents:

Astra Tech AB
HOLLISTER INCORPORATED

Headword:

Relevant legal provisions:

EPC Art. 54, 56
RPBA Art. 13

Keyword:

Novelty - (yes)
Inventive step - (yes)
Late-filed argument -
justification for late filing (no), admitted (no)

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
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Case Number: T 1620/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 16 October 2015

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
6 May 2011 concerning the maintenance of
European Patent No. 1427467 in amended form.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

- I. Opponent 2 (hereinafter "the appellant") has appealed the Opposition Division's interlocutory decision, dispatched on 6 May 2011, concerning the maintenance of European patent No. 1 427 467 in amended form according to the then pending auxiliary request 2.
- II. The notice of appeal was received on 15 July 2011. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 14 September 2011.

In the statement of grounds, the appellant argued that the subject-matter of claim 1 as found allowable by the Opposition Division lacked novelty over each of the following documents:

D2: EP-A-1 023 882;
D10: US-A-2,856,932;
D12: US-A-5,041,085;
D15: WO-A-03/008029;
D16: EP-B-1 406 690;
D17: US-A-5,454,798.

It also argued that the subject-matter of claim 1 lacked an inventive step over the combination of the closest prior-art document:

D6: WO-A-98/06642

with D2 or D12.

- III. Opponent 1 too appealed the decision, by notice of appeal received on 15 July 2011. The appeal was,

however, withdrawn by letter dated 6 September 2011.

- IV. The patent proprietor (hereinafter "the respondent") replied to the statement of grounds by letter received on 27 January 2012.
- V. The Board summoned the parties to oral proceedings to be held on 16 October 2015 and set out its provisional opinion in a communication dated 24 July 2015. In the communication the Board drew the parties' attention in particular to the provisions of Article 114(2) EPC and Articles 12 and 13 RPBA, setting a time limit of one month before the date of the oral proceedings for the filing of any further written submissions.
- VI. Both the appellant and the respondent filed further submissions in preparation for the oral proceedings, by letters received on 24 September 2015 and 11 September 2015 respectively. Opponent 1 announced that it would not be represented at the oral proceedings, by letter received on 24 September 2015.
- VII. Oral proceedings were held on 16 October 2015, in the absence of opponent 1. In those proceedings the appellant intended to present a further line of argument for showing a lack of inventive step of the subject-matter of claim 1 as found allowable by the Opposition Division, starting from D2 as the closest prior art.
- VIII. The appellant requested that the decision under appeal be set aside and that the patent be revoked.
- IX. The respondent requested that the appeal be dismissed, i.e. that the patent be maintained as found allowable by the Opposition Division, or, in the alternative,

that the decision under appeal be set aside and that the patent be maintained on the basis of one of the auxiliary requests I and J, filed on 11 September 2015, auxiliary request G filed on 27 January 2012 and auxiliary requests H and K filed on 11 September 2015, considered in that order.

X. Opponent 1 submitted neither requests nor arguments.

XI. Claim 1 of the request found allowable by the Opposition Division reads as follows:

"A catheter assembly allowing for non-contaminated insertion of a catheter into a urinary canal, said assembly comprising:

- a catheter (1) defining a conduit (2) between a proximal end (5) adapted for insertion into a body opening of an individual and an opposite distal end,
- a package (3;38) having a hose (9;79) with a cavity (10) for accommodation of the catheter (1) and, in a proximal end of the package (3;38), an opening for dispensing the proximal end of the catheter (1) from the package (3;38), characterised by
- sealing means (4;37;46;91) adapted to provide a substantially liquid tight seal between the catheter package (3;38) and the urinary catheter (1), while the catheter is being dispensed from the package, so as to prevent urine from draining out of the proximal end of the package (3;38)
- wherein the sealing means is arranged between an outer surface of the urinary catheter and an inner surface of the hose and the sealing means is

provided in the form of a sliding seal adapted to move in relation to the inner surface of the hose."

Claims 2 to 16 are dependent claims.

XII. The appellant's arguments may be summarised as follows:

a) Novelty

The priority claim of the patent was not valid for the subject-matter of claim 1 as found allowable by the Opposition Division. It followed that D15 and D16 belonged to the state of the art according to Article 54(3) EPC.

D2 was novelty-destroying for the subject-matter of claim 1 as found allowable by the Opposition Division. In particular, it disclosed a catheter assembly with a urinary catheter (1 in figure 4) and a catheter package having a hose (4 in figure 4), and sealing means in the form of a radially outwardly extending protrusion of a connector member (3 in figure 4) of the urinary catheter. Claim 1 simply required that the seal between the catheter package and the urinary catheter be "substantially liquid tight". For example, there was no requirement whatsoever that a receptacle be defined between the catheter and the hose as mentioned in paragraph [0011] of the description in relation to a preferred embodiment. The protrusion of the connector member of D2 constituted a substantially liquid-tight seal within the meaning of the claim. The Opposition Division too found in the impugned decision that the catheter assembly of figure 4 of D2 comprised a substantially liquid-tight seal. A mere

comparison of the drawings of the patent (particularly figures 8 and 9) and of D2 (figure 4) showed a striking similarity. The jurisprudence of the boards of appeal, in particular decisions T 204/83 and T 169/83, clearly held that drawings could disclose further features in addition to what was disclosed in the description. According to paragraph [0031] of D2, the outer diameter of the connector member was smaller than the inner diameter of the hose. However, this was consistent with the provision of a seal between the radially outwardly extending protrusion and the inner diameter of the hose, since the diameter of the protrusion was clearly larger than that of the rest of the connector member. Furthermore, paragraph [0027] disclosed that liquid was "confined in the relatively narrow cavity of the hose member 4 surrounding the catheter shaft". This required a seal as claimed. Closure elements 7 and 11 in figure 4 constituted additional seals. As was clear from figure 3C, the patent did not rule out such additional seals either. Overall, the disclosure of D2 was clearly concerned with the prevention of spillage of urine, as explicitly mentioned in paragraphs [0015] and [0023]. This too implied a seal as claimed.

D10 was also novelty-destroying for the subject-matter of claim 1. In particular, it disclosed a catheter assembly with a urinary catheter (catheter 2 with body 14 in the figures) and a catheter package having a hose (neck 12 in the figures). As indicated in column 3, lines 35 to 37, the diameter of the neck 12 was substantially the same as the external diameter of

the body 14, resulting in a relatively tight fit between these two elements. Both the neck 12 and the catheter 2 were made of polyethylene, the catheter being explicitly disclosed as having a smooth exterior (column 3, lines 16 to 29). The tight fit between two smooth polyethylene surfaces inevitably resulted in a substantially liquid-tight fit as claimed.

D12 was also novelty-destroying for the subject-matter of claim 1. In particular in column 2, lines 6 to 9 it disclosed a catheter assembly allowing for non-contaminated insertion of a catheter into a passageway of a patient, corresponding to a urinary canal as claimed.

D17 was also novelty-destroying for the subject-matter of claim 1. In particular, it disclosed a catheter assembly with a hose (10 in the figures) and sealing means (glued seal 36 in the figures). As seen from figures 3 and 4, the glued seal 36 was arranged between the outer surface of a urinary catheter (12 in the figures) of the catheter assembly and the inner surface of the hose. The latter comprised a catheter advancement mechanism (14 in the figures). Since the glued seal was adapted to move in relation to the catheter advancement mechanism, it formed a sliding seal adapted to move in relation to the inner surface of the hose as claimed.

D15 was also novelty-destroying for the subject-matter of claim 1. In particular, it disclosed a catheter assembly with a hose (25 and 11 in the figures) and sealing means (collar 50 in the figures). Since the collar 50

was deformable and stretchable, it formed a sliding seal adapted to move in relation to the inner surface of the hose.

D16 was also novelty-destroying for the subject-matter of claim 1. In particular, it disclosed a catheter assembly with a hose (16, 20 and 21 in the figures) and sealing means (wall portion 26 with central aperture 27 in the figures). Since the central aperture 27 had a smaller diameter than the outside diameter of the catheter of the catheter assembly (column 6, lines 40 to 42), the end wall portion 26 was adapted to move when the catheter was sliding through the central aperture, thereby forming a sliding seal as claimed.

b) Inventive step

D6 might be considered to constitute the closest prior art, since it disclosed a catheter assembly within the same technical field and with many technical features in common with the subject-matter of claim 1 as found allowable by the Opposition Division.

In particular in its figures 1 and 3A, D6 disclosed a catheter assembly (10) comprising a urinary catheter (12) and a package having a hose (11) according to the preamble of claim 1. As also explained on page 18, lines 2 to 4, D6 also disclosed a sealing means in the form of a package seal 35, a guide member 15, the lubricant in sub-chamber 40 and a reduced diameter passage 68. The sealing means was in the form of a sliding seal, since it sealed while the catheter could

slide through openings 68 and 76 (figure 5). It also prevented urine from draining out of the proximal end of the catheter when the catheter was dispensed from the package and slid through the sealing means (page 3, lines 11 to 15).

D6 failed to disclose a liquid-tight seal, as the sealing was at least partly provided by the lubricant in the sub-chamber 40. Moreover, the sliding seal was not adapted to move in relation to the inner surface of the hose.

However, these differences provided no technical effect compared with the catheter assembly disclosed in D6, since they provided the same functionality as the sealing means of this document.

The objective technical problem was therefore the provision of an alternative configuration of the sealing means in order to avoid any leakage.

In view of this problem, the skilled person would consult D2. From just "a quick look" at figure 4, it was apparent that an alternative solution was provided by a liquid-tight sliding seal arranged between the catheter package and the unitary catheter. The skilled person only required an obvious modification to the design of the catheter assembly of D6 to arrive at the subject-matter of claim 1 without exercising any inventive skill.

The skilled person could also find inspiration in D12, which related to a percutaneous urinary catheter. Such catheters belonged to a technical field close to that of intermittent catheters as

the one disclosed in D6. D12 also taught the necessity of avoiding backflow of urine (column 2, lines 57 to 64) and disclosed a liquid-tight seal in the form of a collar arranged between the outer surface of the urinary catheter and the inner surface of a sleeve surrounding the catheter. D12 provided, amongst others, a solution to the objective technical problem as formulated above. In view of the latter, the skilled person would take the sealing arrangement disclosed in D12 and implement it in the catheter assembly of D6, thereby arriving at the subject-matter of claim 1 in an obvious way.

- c) The subject-matter of claim 1 as found allowable by the Opposition Division was not inventive in view of D2 as the closest prior art either.

This line of argument was presented for the first time during the oral proceedings, because the appellant reviewed the case while preparing for the oral proceedings. Until then, the case had been pending for five years without any substantial action. Moreover, D2 was a document with which the parties were well acquainted. It followed that the new line of argument should be admitted into the proceedings.

XIII. The respondent's arguments may be summarised as follows:

- a) Novelty

D2 and D10 did not disclose a substantially liquid-tight seal as claimed in claim 1 found allowable by the Opposition Division. D12

disclosed neither a catheter assembly for insertion of a catheter into a urinary canal nor a catheter package as claimed. D17 disclosed neither a substantially liquid-tight seal nor a sliding seal adapted to move in relation to the inner surface of a hose for accommodation of a catheter. D15 and D16 disclosed neither a hose with a cavity for accommodation of a catheter nor a sliding seal adapted to move in relation to the inner surface of a such a hose. It followed that the subject-matter of claim 1 was novel.

b) Inventive step

D6, regarded by the appellant as the closest prior art, failed to disclose a liquid-tight seal and a sliding seal adapted to move in relation to the inner surface of a hose as claimed in claim 1 as found allowable by the Opposition Division.

The effect of these differences was explained in paragraph [0012] of the patent, i.e. the hose could be divided into an upper and a lower receptacle, whereby the upper receptacle could be used for storing a friction-reducing substance.

It followed that the movable liquid-tight seal allowed for a compact construction in which the same volume could initially be used for storage of the friction-reducing substance and subsequently as a drainage extension preventing back-flow of urine. Providing such a compact construction was also the objective technical problem solved by the invention.

D6 did not address this problem. D2 did not

disclose a liquid-tight seal as claimed, so it did not provide any solution to that problem either. D12 would not be considered by the skilled person, since it belonged to a completely different technical field and had a very complicated structure. It followed that the subject-matter of claim 1 as found allowable by the Opposition Division was inventive too.

- c) The new line of argument for showing a lack of inventive step based on D2 as the closest prior art constituted an amendment to the appellant's case which was sought to be made at a very late stage. It could and should have been presented earlier so as to give sufficient time for the respondent to prepare a reply. For this reason it should not be admitted into the proceedings.

Further details of the respondent's arguments, on which the present decision is based, are addressed in the reasons that follow.

Reasons for the Decision

1. The appeal is admissible.
2. Although having been duly summoned, opponent 1, party as of right, was not present at the oral proceedings, as it had previously announced. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without this party.

3. *The invention*

The invention relates to a catheter assembly allowing for non-contaminated insertion of a catheter into a urinary canal.

Such catheters are typically used to drain the bladder of patients who cannot urinate voluntarily. They can be of the intermittent type, to be inserted and kept in place only for the time needed to urinate, or of the indwelling/permanent type, kept in place for a longer period.

The claimed assembly comprises a catheter package having a hose with a cavity for accommodation of the catheter. The catheter can be dispensed from the package, e.g. by pulling its proximal end out of a proximal end of the hose, in order to permit insertion.

The invention focuses on the provision of sealing means in the form of a sliding seal between the outer surface of the catheter and the inner surface of the hose, so as to prevent urine flowing through the catheter from draining out the proximal end of the package, i.e. the end of the hose from which the proximal end of the catheter extends. In use, a proximal part of the catheter is extracted from the hose while the distal end is kept within the hose, in sealed engagement with it. Upon catheterisation, the urine flows through the catheter into the hose and is then kept there or exits a further opening at the distal end of the hose. In such a way the package itself, together with the catheter, can function as a fluid conduit with a length much larger than the individual length of each of the catheter and the package (column 3, lines 13 to 17 of the patent), with no leaks.

Claim 1 of the request found allowable by the Opposition Division is based on claim 1 and page 3, lines 4 to 8 and 19 to 23 of the application as filed. With respect to claim 1 as granted the definition of the sliding seal and its position have been added, thereby limiting its scope.

4. *Novelty of the subject-matter of claim 1 of the request found allowable by the Opposition Division*

4.1 As the appellant submitted, D2 discloses a urinary catheter assembly comprising a package in the form of a hose member. The most relevant embodiment is shown in figure 4. While the catheter is dispensed from a proximal end of the package (the side with closure part 7), a connector member (3) of the catheter slides within the hose 4.

The appellant argued that such sliding relationship between the connector member and the hose provided a "substantially liquid tight" sliding seal as required by claim 1. However, D2 expressly discloses that the outer diameter of connector member 3 is smaller than the internal diameter of hose 4 (paragraph [0031]), remaining silent about any possible sealing interaction, let alone a substantially liquid-tight one. Neither in that paragraph nor elsewhere in D2 is there any mention that the reference to the "outer diameter" of the connector element might refer to something other than its common meaning, i.e. the largest outer element of the connector element, which is the one at its distal "radially outwardly extending protrusion", in the words of the appellant. Moreover, as the respondent pointed out, the presence of corrugations 14 along the hose 4 appears to exclude any

intention to obtain a sliding seal between the hose and the connector member, especially in their region. The disclosure in paragraph [0027] of D2, relating to the possibility of confining a liquid swelling medium "in the relatively narrow cavity of the hose member [...] surrounding the catheter shaft", does not assist the appellant either, since such possibility may well derive exclusively from the presence of closures 7 and 11. The disclosure in D2 (paragraphs [0015] and [0023]) that with its catheter assembly "spillage of urine" may be prevented is in relation to the catheter package, i.e. the hose, being in its extended position. In this context, the Opposition Division in the impugned decision (point 11.7 of the reasons) identified a substantially liquid-tight seal, as the appellant argued. However, such a seal would be between the hose and a stop member (17), which does not constitute a sliding seal between an outer surface of the catheter and an inner surface of the hose as claimed. Hence, this argument of the appellant is not convincing either. According to the jurisprudence of the boards of appeal cited by the appellant, under some particular circumstances figures of a document may be regarded as disclosing features in addition to what is expressly mentioned in the description. In the present instance, however, the Board simply cannot infer any direct and unambiguous disclosure of a "substantially liquid tight" sliding seal as claimed from the schematic nature of figure 4 alone, especially as this even appears to go against the teaching of other parts of D2 as identified above.

The Board therefore concludes that D2 does not disclose a sealing means in the form of a sliding seal adapted to move in relation to the inner surface of the hose and adapted to provide a substantially liquid-tight

seal between the catheter package and the catheter so as to prevent urine from draining out of the proximal end of the package while the catheter is being dispensed from the package, as required by claim 1.

Hence, the subject-matter of claim 1 is novel over D2.

- 4.2 D10 relates to a urinary catheter with a package in the form of a flexible bag, for maintaining the catheter sterile until use and for collecting urine. As shown in particular in figure 2, the flexible bag 10 has an appendage (neck 12) in the form of a hose, from which the catheter extends in use. The hose has a diameter being "substantially the same as the external diameter" of the catheter, "so that there is a relatively tight fit" (column 3, lines 35 to 37). However, irrespective of the material of which the catheter and the hose are made, there is no direct and unambiguous disclosure that this "relatively tight fit" should constitute a sealing means as claimed in claim 1. Hence, like D2, D10 fails to disclose a sealing means in the form of a sliding seal adapted to move in relation to the inner surface of the hose and adapted to provide a substantially liquid-tight seal between the catheter package and the catheter so as to prevent urine from draining out of the proximal end of the package while the catheter is being dispensed from the package, as required by claim 1.

It follows that the subject-matter of claim 1 is novel over D10 too.

- 4.3 D12 relates to suprapubic catheterisation of the bladder, more particularly to a catheter for percutaneous insertion into a patient. As the respondent argued, the percutaneous catheter has a

mechanical structure, in particular its distal end 105 being "preformed into a predetermined configuration such as a well-known pigtail" (column 3, lines 61 to 63), that does not render it suitable for insertion into a urinary canal. The "cavity or passageway of a patient" mentioned in column 2, lines 6 to 9 cannot reasonably be interpreted as meaning a urinary canal. Hence, D12 fails to disclose a catheter assembly allowing for non-contaminated insertion of a catheter into a urinary canal.

It follows that the subject-matter of claim 1 is novel over D12 too.

- 4.4 D17 discloses a disposable urine bag comprising a urinary catheter and a "catheter advancement mechanism" (14, best seen in figures 2 and 3). There are two sealing means disclosed: a "welded or glued seal" 36 (column 3, lines 9 to 13) between a catheter 12 and a disposable urine bag 24 or advancement mechanism 14 (though tubular member 54), and a "U-cup seal" 56 (column 4, lines 39 to 43) between the catheter 12 and the advancement mechanism 14. Apart from the fact that the urine bag and the advancement mechanism can hardly be considered as a hose within the meaning of claim 1, even considering the sealing means as being arranged between an outer surface of the catheter and an inner surface of such a hose, that sealing means is not a sliding seal adapted to move in relation to that inner surface while the catheter is being dispensed from the package, as required by claim 1. Both seals remain stationary with respect to the surface of contact with the elements that could be considered as a hose.

Hence, the subject-matter of claim 1 is novel over D17

too.

- 4.5 D15 discloses a urinary catheter assembly (figure 1), comprising a package (11) in the form of a flat, elongated pouch or bag (page 6, lines 4 to 8). Within the package 11 a tubular lubricating device (24) is present. The catheter can slide within the lubricating device, through a seal in the form of a collar (50, figure 6 and page 10, lines 25 to 29). The appellant considered the tubular lubricating device as the hose of the catheter package within the meaning of claim 1. Even if this interpretation were to be accepted, D15 still fails to disclose a sliding seal adapted to move in relation to the inner surface of the hose while the catheter is being dispensed from the package as required by claim 1. Seal 50 is fixed with respect to the rest of the lubricating device. The fact that it may be deformable and stretchable to some extent, as the appellant argued, does not render it a sliding seal as claimed. While the catheter is being dispensed from the package the seal is possibly stretched and deformed and is in sealing movement with respect to the catheter itself. No appreciable movement with respect to the inner surface of the lubricating device takes place. Even if under some conditions some movement of some parts of the seal with respect to the lubricating device may be possible (due to the deformation of the seal), that movement is not related to a sliding sealing action with respect to the inner surface of the hose. Hence, it is not the movement of a sliding seal that the skilled person would understand as being required by the claim.

It follows that the subject-matter of claim 1 is novel over D15 too.

4.6 The disclosure of D16 is similar to that of D15. More particularly, D16 also discloses a urinary catheter assembly (figure 1), comprising a package (11) in the form of a flat, elongated pouch or bag (paragraph [0014]). Within the package 11 a tubular lubricating device (16) is present. The catheter can slide within the lubricating device, through an aperture (27) having a smaller diameter than the catheter (paragraph [0022]). However, considering again the tubular lubricating device as the hose within the meaning of claim 1, D16 too fails to disclose a sliding seal adapted to move in relation to the inner surface of the hose while the catheter is being dispensed from the package as required by claim 1. A wall 26 provided with an aperture 27 is fixed with respect to the rest of the lubricating device. While the catheter is being dispensed, the package wall 26, which makes up a seal, is possibly stretched and deformed and is in sealing movement with respect to the catheter itself. No appreciable movement with respect to the inner surface of the lubricating device takes place. Even if under some conditions some movement of some parts of the seal with respect to the lubricating device may be possible (due to the deformation of the seal), that movement is not related to a sliding sealing action with respect to the inner surface of the hose. Hence, it is not the movement of a sliding seal that the skilled person would understand as being required by the claim.

It follows that the subject-matter of claim 1 is novel over D16 too.

4.7 It is therefore concluded that, irrespective of the validity of the priority claims of the patent, claim 1 complies with Article 52(1) EPC in conjunction with

Article 54 EPC.

5. *Inventive step of the subject-matter of claim 1 of the request found allowable by the Opposition Division*

5.1 It is noted that both D15 and D16 were published later than the filing date of the application of the patent in suit. Irrespective of the validity of the priority claims of the patent in suit and of D15 and D16 themselves, these two documents do not belong to the state of the art relevant for assessing inventive step.

It follows that there is no need for the Board to decide on the validity of the priority claims.

5.2 The appellant argued that D6 should represent the closest prior art. The respondent did not question this.

5.3 D6 relates to a urinary catheter and a package assembly defining an elongate sealed catheter chamber. In use, the catheter is exposed through one end of the chamber, whereas the other end of the chamber is for discharging urine. Hence, like the claimed invention, the chamber can function as an extension of the catheter, also to reduce the danger of contamination (page 2, lines 21 to 24). In the chamber (in particular sub-chambers 40 and 41, figure 1) there is present a lubricant which provides some seal between the distal end of the catheter and the proximal end of the chamber (page 3, lines 11 to 15) when the proximal end of the catheter is exposed. As pointed out by the appellant, on page 18, lines 2 to 4, D6 further discloses a sealing means in the form of a package seal 35, a guide member 15, the lubricant in sub-chamber 40 and a reduced diameter passage 68. The sealing means is in

- the form of a sliding seal, since it seals while the catheter can slide through openings 68 and 76 (figure 5). It also prevents urine from draining out of the proximal end of the catheter when the catheter is dispensed from the package and slides through the sealing means (page 3, lines 11 to 15).
- 5.4 The parties do not dispute that document D6 fails to disclose at least a sealing means in the form of a sliding seal adapted to move in relation to the inner surface of the hose.
- 5.5 The Board agrees with the respondent that, by virtue of this difference, the hose of the claimed catheter assembly, in its storage condition, could be divided into two receptacles, whereby the proximal receptacle could be used for storing a friction-reducing substance, as explained in paragraph [0012] of the patent. The associated technical effect is a compact construction of the catheter assembly, in which the same volume could initially be used for storage of the friction-reducing substance and, subsequently, as a drainage extension preventing back-flow of urine. In D6, instead, the sub-chamber (40) for the lubricant cannot be used as part of the drainage extension.
- 5.6 The objective technical problem is therefore how to provide a more compact catheter assembly allowing for a relatively comfortable insertion of a catheter into a urinary canal.
- 5.7 Amongst the cited prior art, the only document showing a sealing means as defined in claim 1 is D12 (sliding seal 106, figure 3 and column 5, lines 8 to 10). However, as already mentioned above, D12 is not concerned with a urinary catheter for insertion into

the urinary canal of a patient, let alone with the problem formulated above. The skilled person would disregard it for this reason alone. Moreover, as the respondent convincingly argued, applying such a seal to the catheter assembly of D6 would require a complete re-design of the device.

As regards a possible combination with D2, as envisaged by the appellant, it suffices to note that D2 simply does not show a sealing means as defined in claim 1 (point 4.1 above).

Hence, the subject-matter of claim 1 of the main request is inventive when starting from D6 as the closest prior art.

5.8 The appellant's new line of argument for showing a lack of inventive step based on D2 as the closest prior art constitutes an amendment to the appellant's case within the meaning of Article 13 RPBA. The parties were informed by the Board's communication dated 24 July 2015 that any further submissions should be filed as soon as possible after that communication and no later than one month before the date of the oral proceedings. The appellant filed such submissions on 16 September 2015. However, the respondent and the Board were presented with the above-mentioned amendment to the case for the first time at the oral proceedings, after the discussion of novelty had already taken place. Such a late amendment, submitted by the appellant for no compelling reason, would have required time for the respondent and the Board to deal with. Although document D2 had already been considered for novelty, an analysis of inventive step needs other considerations and might have even required an adjournment of the oral proceedings.

For these reasons the Board exercises its discretion under Article 13(1) and (3) RPBA and decides not to admit the amendment to the appellant's case.

6. In conclusion, the subject-matter of claim 1 and its dependent claims of the request found allowable by the Opposition Division is considered to fulfil the requirements of Article 52(1) in conjunction with Articles 54 and 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated