Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 26 June 2019

Case Number: T 0607/14 - 3.2.02

Application Number: 07700165.9

Publication Number: 1979032

IPC: A61M25/00

Language of the proceedings: EN

Title of invention:
CONTAINER FOR MEDICAL DEVICES

Patent Proprietor:
Coloplast A/S

Opponents:
Dentsply IH AB
Hollister Incorporated

Headword:

Relevant legal provisions:
EPC Art. 54, 56
RPBA Art. 13(1)

Keyword:
Late-filed request - admitted (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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

Case Number: T 0607/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 26 June 2019

Appellant: (Opponent 1)	Dentsply IH AB Aminogatan 1 431 21 Mölndal (SE)
Representative:	AWA Sweden AB P.O. Box 11394 404 28 Göteborg (SE)
Appellant: (Opponent 2)	Hollister Incorporated 2000 Hollister Drive Libertyville, Illinois 60048-3781 (US)
Representative:	FRKelly 27 Clyde Road Dublin D04 F838 (IE)
Respondent: (Patent Proprietor)	Coloplast A/S Holtedam 1 3050 Humlebæk (DK)
Representative:	Coloplast A/S Corporate Patents Holtedam 1 3050 Humlebaek (DK)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 January 2014 rejecting the opposition filed against European patent No. 1979032 pursuant to Article 101(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeals of the opponents are against the decision of the Opposition Division dated 20 January 2014, rejecting the oppositions.

Notice of appeal of opponent 1 was filed on 17 March 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 28 May 2014.

Notice of appeal of opponent 2 was filed on 27 March 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 28 May 2014.

II. The following documents are cited in this decision:

D4: WO-A-2005/014055
D7: WO-A-2004/089454

III. In an annex to the summons (5 April 2019), the Board communicated its preliminary opinion that the subject-matter of claim 1 of the patent as granted was not novel in view of document D7.

IV. Oral proceedings were held on 26 June 2019.

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

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

The respondent/patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of request I, filed with a letter dated 7 May 2019.

V. Claim 1 according to request I reads as follows:

"A package comprising a container (1; 100) defining a compartment (11; 106) containing a liquid (10) and at least partly a catheter (115), said compartment (11; 106) extending in a longitudinal direction from a bottom (6; 102) of the container (1; 100) towards an opening (7; 105) of the container (1; 100),

characterized in that a first section of the compartment (11; 106) has a cross-sectional area which is smaller than a cross-sectional area of a second section of the compartment (11; 106), and

where the first section is arranged between the opening (7; 105) and the second section,

wherein a sub-compartment (13) of the compartment (11), defined by

a plane, tangential to the smallest circumference of the first section of the compartment and parallel to the longitudinal axis of the compartment (11), and

the second section of the compartment (11),

has a volume which is larger than the volume of the liquid contained in the compartment (11)

wherein a third section of the compartment (11 ;106) has a cross-sectional area which is larger than the

cross-sectional area of the first section, and that the third section is arranged between the opening (7; 105) and the first section."

VI. The arguments of the appellants/opponents can be summarised as follows:

Admissibility of request I

This request was late filed and was not to be admitted into the appeal proceedings. Nothing happened in the proceedings justifying a change of case, and, moreover, the subject-matter of the claim was prima facie still not novel in view of the same document D7.

Novelty

Claim 1 defined a sub-compartment by defining a tangential plane. The precise position of this plane around the axis of the package was however not mentioned. Therefore, the broadest definition of the plane had to be taken into account, and when that was done, the subject-matter of claim 1 was not novel in view of the embodiment according to Figure 5 of D7.

Inventive step

The subject-matter of claim 1 was not inventive when starting from D7 in combination with D4. D4 was about avoiding spilling and taught the use of very small amounts of water in packages containing a urinary catheter to hydrate the hydrophilic coating, so that spilling was avoided. The person skilled in the art would apply this teaching to the embodiment of Figure 5 of D7, in which the small amount of water would be

retained behind the flange, and arrive in an obvious way at the subject-matter of claim 1.

VII. The arguments of the respondent/patent proprietor are essentially those underlying the present reasons for the decision.

Concerning novelty, the patent as a whole taught that the word "bottom" used in the claim had to be understood as meaning a surface on which the container was able to stand vertically, and the very function of the smaller cross-sectional area of the first section of the compartment described in paragraph [0008] of the patent had to be taken into consideration when reading the claim. Moreover, the function of the smaller cross-sectional area of the first section was indicated in paragraph [0008] of the patent as granted and was to function as a stop for the liquid in case the container is placed in a horizontal orientation. This function had to be read into claim 1, and such a function was not mentioned at all for the flange shown ion Figure 5 of D7.

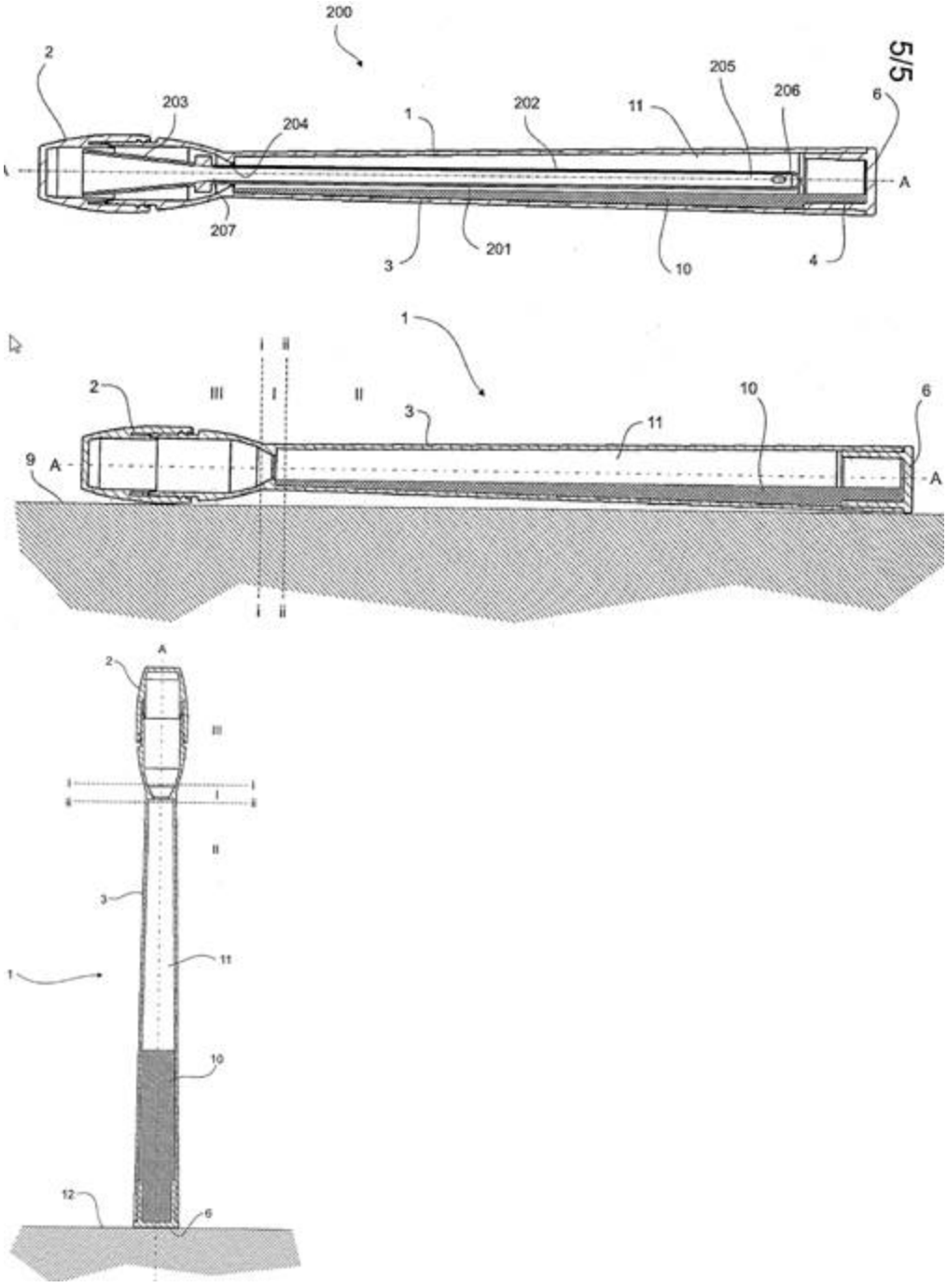
Reasons for the Decision

1. Both appeals are admissible.

2. The invention

The invention is a package comprising a container defining a compartment for containing a liquid and a catheter. In order to avoid spilling out the liquid, in particular when the package is open and in a horizontal position, the container has a specific shape with the free cross-section close to the opening being smaller than the free cross-section towards the bottom of the

container. In that way, the liquid remains in the container even when the latter is in a horizontal position.



3. Admissibility of request I

The appellants/opponents regarded this request as late filed and thus it should not be admitted into the appeal proceedings. According to them, the respondent/ patent proprietor gave no explanation as to the reasons for late filing. Moreover, it was the first time that the newly added features were brought forward; before, these features were not considered important by the respondent/patent proprietor. Nothing happened in the proceedings justifying a change of case, in particular there was no new document on file, and the objection of lack of novelty was on file right from the start of the proceedings. In addition, the new request did not solve the problems at stake, since the subject-matter of the claim was prima facie still not novel in view of the same document D7.

The Board does not share this opinion. In the opposition proceedings and in the decision of the Opposition Division, the key question for the lack of novelty objection was the interpretation of the word "bottom" present in claim 1. In the communication of the Board annexed to the summons to oral proceedings, the Board noted that the problem the invention intended to solve was the possible spilling out of liquid when the open container was put, either voluntarily or by mischance, in the horizontal position (paragraph [0005] of patent as granted), and that in this context the fact that the container should be able to stand vertically on a horizontal surface (as interpreted by the Opposition Division) did not seem to play any role. For that reason, the word "bottom" had to be given a broader meaning than that given by the Opposition Division.

By adding the features of granted claims 2 and 5 into claim 1, which define more precisely the "sub-

compartment" meant to hold the liquid in the container, the respondent/patent proprietor directly addressed the point raised by the Board in its communication. Therefore, the Board considers this request as a direct reaction to the said communication. Moreover, the features added to claim 1 were present in claims 2 and 5 of the patent as granted, and these claims were opposed in the opposition proceedings by the appellants/opponents, so that no new matter was inserted into claim 1 which could have taken the appellants/opponents by surprise.

Therefore, request I is admitted into the proceedings pursuant to Article 13(1) RPBA.

4. Novelty (Article 54 EPC)

Novelty was disputed in view of D7.

Figure 5 of D7 describes a container 2 having a compartment 9 containing a catheter 1. At the opening zone 10, a flange 12 is arranged to avoid that the head or enlarged part of the catheter 6 slips or otherwise enters the compartment 9 (page 12, lines 17 to 23). Water for activating the coating can be present in the compartment 9, as explained for instance on page 10, lines 15 to 17 and lines 34 and 35. The flange 12 creates a section with a smaller cross-section between the opening (closed by tear off flap 4) and the rest of the container. There is a "bottom" opposite the opening.

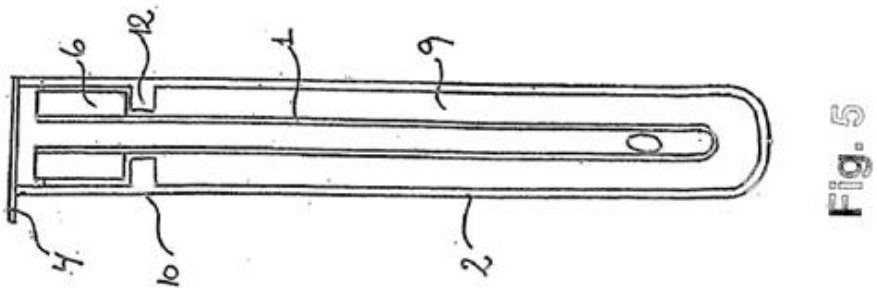


Fig. 5

4.1 The respondent/patent proprietor considered that in the context of the patent the wording "bottom of the container" should be understood as a part on which the container can stand vertically when on a horizontal surface, as could be understood for example from paragraphs [0032], [0036] and [0039] of the patent. None of the embodiments shown in D7 were able to stand vertically.

The Board does not share the opinion of the respondent/ patent proprietor.

Paragraph [0032] cited by the respondent/patent proprietor effectively mentions: "*This allows the container to be more stable when placed in the vertical position*", but this sentence is in the context of a conical container, as the preceding sentence shows: "*Such decrease of the circumference may for example be obtained by shaping a part of the container in a conical shape, where the base of the cone is arranged at the bottom of the container.*"

Paragraph [0036] refers specifically to Figure 2. The first sentence reads: "*Fig. 2 shows the container placed in a vertical position where the bottom 6 is placed on a level or horizontal surface 12, such as a table or a bathroom sink.*"

In paragraph [0039], a link is made again between the conical shape and the stability when the container is in a vertical position: "*As can be seen in Fig. 2 the second section II has an outer circumference, which increases towards the bottom 6. This creates a larger base for the container whereby it is more stable when placed in a vertical position on a leveled surface.*"

For the following reasons, the Board is not convinced that the skilled person after having read the whole of the patent would consider the possible vertical position of the container as essential for the invention.

Indeed, the problem the invention intends to solve is the possible spilling out of liquid when the open container is put, either voluntarily or by mischance, in the horizontal position [0005]. The solution proposed by the invention is to have a container with a closed end on one side (bottom), an opening on the other side, and close to the opening the (free) cross-section is diminished. As can be seen in Figures 3a and 3b, and as explained in paragraph [0008] and paragraph [0040], lines 51 to 58, this allows the liquid to remain in the open container even when it is in the horizontal position. In the first place, the fact that the container can stand vertically does not play any role for that function.

Hence, in the Board's opinion, the word "bottom" as used in claim 1 refers to nothing more than the closed end opposite the opening.

4.2 Moreover, the respondent/patent proprietor held that the function of the smaller cross-sectional area of the first section was indicated in paragraph [0008] of the

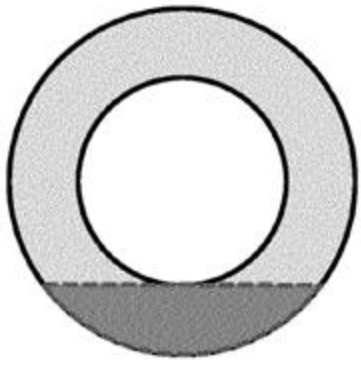
patent as granted and was to function as a stop for the liquid in case the container is placed in a horizontal orientation. This function had to be read into claim 1, and such a function was not mentioned at all for the flange shown on Figure 5 of D7. On the contrary, the function of the flange as indicated in D7 was to retain the catheter head in order to prevent it from being introduced too far into the compartment. Hence, there was no reason for the flange to even be continuous in that case. This interpretation was confirmed by the fact that on page 8 of D7, in the paragraph going from lines 21 to 29, the exclusion means were mentioned to be of the shape of shoulders, which demonstrated that the flange could be made of several parts.

The Board does not agree with the respondent/patent proprietor. While it is true that, from a mechanical point of view, in order to fulfil the function of preventing the catheter head from entering the compartment 9 it would not be necessary for the flange 12 to be continuous in the circumferential direction, nothing in D7 points to such an option. On the contrary, on page 12, when the embodiment of Figure 5 is described, it is indicated that "*the opening zone (10) comprises a flange (12)...*" (emphasis added). A similar statement is present on page 8, in the paragraph beginning line 31: "*...the exclusion means comprises an inwardly extending protrusion, e. g. a flange...*" (emphasis added). The Board sees no reason to believe that the author of D7 meant a discontinuous flange when mentioning the presence of such a flange, in particular for the embodiment of Figure 5.

Moreover, even if D7 does not mention any liquid retaining function of the flange 12, it is technically self-evident that when the container of Figure 5 lies

open in a horizontal position on a levelled surface, the flange will retain some liquid, avoiding its spilling out of the container.

4.3 The appellants/opponents argued that since several planes as required by claim 1 (tangential to the smallest circumference of the first section of the compartment and parallel to the longitudinal axis of the compartment) could be defined, the broadest definition had to be taken into account (Figure below submitted by the appellants/opponents). Considering this broad definition of the volume (light grey zone) which had to be larger than the volume of the liquid contained in the compartment, this condition was also satisfied in the embodiments disclosed in D7. Indeed, it was self-evident that the compartment 9 in Figure 5 was not completely filled with liquid, and that at least in some cases the volume of liquid was smaller than the volume defined by the broadest definition of the sub-compartment.



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

The Board does not share the appellants/opponents' opinion. It is true that the wording of the claim taken alone does not precisely define the position of the

plane meant, and mathematically an unlimited number of planes could be defined which would be tangential to the smallest circumference of the first section of the compartment and parallel to the longitudinal axis of the compartment. However, in the Board's opinion, the claim has to be read with a mind willing to understand after consideration of the description of the patent as a whole. As already mentioned above, the problem the invention intended to solve was the possible spilling out of liquid when the open container was put, either voluntarily or by mischance, in the horizontal position (paragraph [0005] of patent as granted). The solution proposed is to have a first section having a smaller cross-sectional area than the cross-sectional area of the second section so that the first section will function as a stop for the liquid in case the container is placed in a horizontal orientation (paragraph [0008] of the patent). With the additional features of claim 1, in particular the sub-compartment defined by the tangential plane, it is made sure that no liquid is spilled when the open container is in a horizontal position, since the volume defined by the sub-compartment is larger than the volume of liquid in the container (last sentence of paragraph [0009] and paragraph [0010]).

In the Board's opinion, the fact that the sub-compartment should be able to contain all the liquid contained in the container in order to avoid spilling can only mean that the tangential planes defining the smallest volume should be considered when reading claim 1 (the dark grey zone in the above Figure). Indeed, considering the other planes would mean accepting that liquid could still be spilled when the container is in a horizontal position (because it would flow over the flange), which is precisely what the invention intends

to avoid. This interpretation was shared by the respondent/patent proprietor.

4.4 Taking into consideration this definition of the sub-compartment in relation to the liquid present in the container, this feature is novel in view of D7. Indeed, in D7 neither the size of the flange nor the volume of liquid used is precisely defined. Such a relationship is also not implicit, since for instance the size of the flange is only important in so far as the latter must be able to prevent the catheter head from entering farther into the container.

Thus, the subject-matter of claim 1 of request I is novel over D7.

No other lack of novelty objections were maintained against claim 1 of request I.

Hence, the ground for opposition of lack of novelty pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent according to request I.

5. Inventive step (Article 56 EPC)

The appellants/opponents alleged that the subject-matter of claim 1 was not inventive when starting from D7 in combination with D4.

They considered the only differentiating feature as the feature of the sub-compartment, and that the objective problem to be solved by this feature was to avoid the risk of spilling. D4 showed how to avoid spilling either by using a reduced quantity of loose water or by sequestering the water within the package. With the above problem in mind it was obvious for the person

skilled in the art to introduce the teaching of D4 to reduce the loose activating liquid quantity present in the container for the activation of the hydrophilic coating to, for instance, less than 5% of the total volume of the tube receiving portion of the catheter receiving cavity of the package as advised on page 20, line 9 and following, and arrive without inventive step at the subject-matter of claim 1. Such a small quantity remained in the open container behind the flange even when the container was in a horizontal position and, thus, avoided spilling exactly in the same way as required by the feature of the sub-compartment of claim 1. Therefore, the subject-matter of claim 1 was not inventive.

As explained above, the embodiment according to Figure 5 of D7 does not disclose the sub-compartment feature, namely that a sub-compartment of the main compartment is defined by a plane, tangential to the smallest circumference of the first section of the compartment and parallel to the longitudinal axis of the compartment, and the second section of the compartment, the sub-compartment having a volume that is larger than the volume of the liquid contained in the main compartment.

The effect of this feature is to retain the liquid present in the container behind the flange when the container is placed in a horizontal position.

The objective problem can, thus, be seen as one of avoiding spilling when the container according to Figure 5 of D7 is open and in a horizontal position.

D4 addresses improvements of hydrophilic catheter packages containing the activating liquid or swelling

medium in which the catheter is, or has to be, immersed before use. In particular, the author of D4 wishes to avoid the tendency of spillage as the user handles the catheter and tries to remove it from the package for subsequent insertion (page 2, lines 20 to 22). The concept disclosed in D4 is that instead of immersing the catheter in a significant amount of swelling medium, the hydrophilic catheter is vapour hydrated with a vapour swelling medium, such as water vapour, within the catheter package in such a manner that it is ready for use when it reaches the user with little or no possibility of liquid spillage (page 4, lines 12 to 15; page 18, lines 18 to 23).

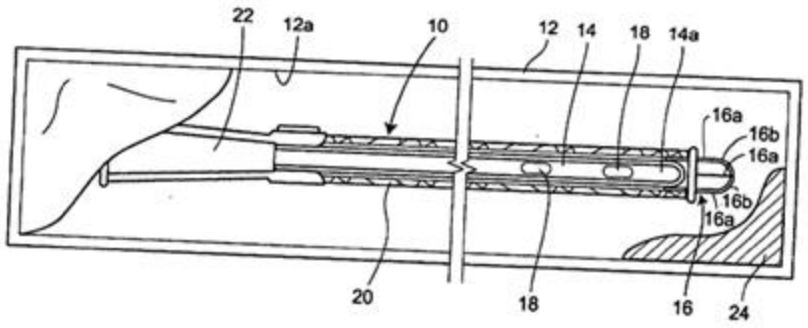


FIG. 1

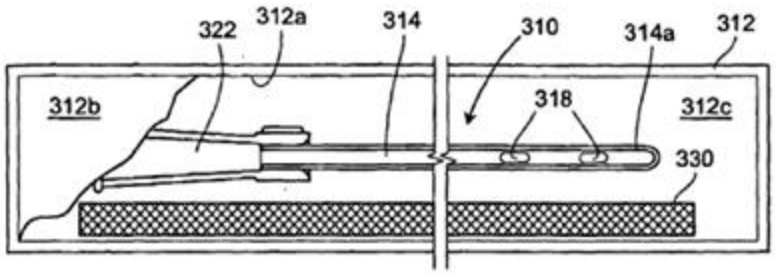


FIG. 3a

The small amount of water is introduced into the package during manufacturing and is either loose as in the embodiment of Figure 1 or sequestered in a sequestering element 330 as, for instance, in the embodiment of Figure 3a. Since the catheter is hydrated

by vapour generated within the package during a predetermined period of incubation, the distribution of the catheter following manufacture has to be delayed for a predetermined period of time to permit the vapour to complete hydration of the hydrophilic coating (page 18, lines 23 to 28).

According to page 20, lines 9 to 31, the amount of water to be used can be as small as less than 20% of the volume of the cavity of the package receiving the portion of the catheter coated with hydrophilic layer; even 5% of the volume is said to be sufficient.

As explained above, according to the appellants/ opponents, the person skilled in the art wishing to solve the spilling problem appearing with the embodiment of Figure 5 of D7 in the horizontal position would change the amount of hydrating liquid used according to the teaching of D4 and arrive in an obvious way at the subject-matter of claim 1. 5% of the volume was such a small amount that it always stayed behind the flange. The condition of claim 1 relative to the sub-compartment was therefore fulfilled, and the subject-matter of claim 1 was not inventive.

The Board does not share this opinion.

D4 does not specifically address the problem of spilling when the open container or package is in the horizontal position, but, more generally, spilling when the catheter is removed from the package before use (page 2, lines 20 to 22). For that reason already it is not established that the person skilled in the art would consider this document when seeking a solution to its problem.

Secondly, even if the person skilled in the art were to consider the teaching of D4, this would not lead to the subject-matter of claim 1. As explained above, while using a small amount of water, D4 proposes two options: either to put the water loose in the package or to put it in a sequestering material. Obviously with the second option there would be no loose water at all in the package, or said differently, the risk of spilling would be completely absent, or still said differently, the option with the sequestering material is the better option of the two. Therefore the Board does not see why the person skilled in the art would choose the option with the loose water when the other option is better.

Finally, even if the person skilled in the art were to choose, for whatever reason, the option with the small amount of loose water, this still would not lead to the subject-matter of claim 1. As explained above, the flange shown in Figure 5 of D7 has the function of avoiding that the head of the catheter enters too deeply into the container. In order to fulfil that function, it does not need to have a specific height, it does not even have to be continuous, let alone to have a specific height in relation to the volume of liquid present in the container as required by the sub-compartment feature of the claim. Even if in some instances the small amount of liquid chosen in accordance with D4 remained behind a flange having the necessary height, on the basis of the teaching of D4, the person skilled in the art does not have any reason to adapt the height of the flange in relation to the amount of liquid used in the container. There is no teaching along this line in D4. If the teaching of D4 is applied to the embodiment of Figure 5 of D7, there will be no or little spilling when removing the catheter from the container or package, but depending

on the amount of liquid chosen and the height of the flange, there can still be spilling when the container is put in a horizontal position. No teaching as to a relationship between the amount of loose water present in the package and the height of the flange is present in D4, and consequently cannot be recognised by the person skilled in the art or be transferred without an inventive step into the container of D7.

For the reasons above, the subject-matter of claim 1 is inventive in view of a combination of D7 with D4. No other lack of inventive-step objection was maintained against the subject-matter of claim 1 of request I.

Hence, the ground for opposition of lack of inventive step pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent according to request I.

6. The appellants/opponents had no objections against the adapted description, and neither does the Board.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance, with the order to maintain the patent on the basis of:

   - claims 1 to 9 of request I, filed with the letter dated 7 May 2019;

   - adapted description, paragraphs [0001] to [0051], filed during the oral proceedings; and

   - Figures 1 to 6 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated