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**Datasheet for the decision
of 14 November 2018**

Case Number: T 2047/13 - 3.2.02

Application Number: 03723571.0

Publication Number: 1420846

IPC: A61M25/00

Language of the proceedings: EN

Title of invention:
CATHETER ASSEMBLY

Patent Proprietor:
Dentsply IH AB

Opponent:
Hollister Incorporated

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 100(a)
RPBA Art. 13(1)

Keyword:

Novelty - (yes)

Inventive step - (yes)

Late-filed line of attack - admitted (no)

Decisions cited:

T 0414/09

Catchword:



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Case Number: T 2047/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 14 November 2018

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
12 July 2013 concerning the maintenance of
European patent No. 1420846 in amended form.

Composition of the Board:

Chairman E. Dufrasne
Members: S. Böttcher
P. L. P. Weber

Summary of Facts and Submissions

- I. Both the opponent and the patent proprietor lodged an appeal against the interlocutory decision of the Opposition Division, dispatched on 12.07.2013, that, account being taken of the amendments according to the first auxiliary request made by the patent proprietor during the opposition proceedings, European patent No. EP 1 420 846 and the invention to which it related met the requirements of the EPC.
- II. Opposition was filed against the patent as a whole based on the grounds for opposition of lack of novelty and lack of inventive step pursuant to Article 100(a) EPC.
- III. Notice of appeal was filed by the appellant/opponent (hereinafter "the opponent") on 20 September 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 22 November 2013.
- IV. Notice of appeal was filed by the appellant/patent proprietor (hereinafter "the proprietor") on 20 September 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 22 November 2013.
- V. Oral proceedings took place on 14 November 2018.

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

The proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of

auxiliary requests I to X filed by letter of 7 April 2014.

VI. The following documents are referred to in this decision:

D1: WO-A-98/11932
D2: WO-A-00/16843
D3: US-A-3,967,728
D6: WO-A-01/52763

VII. Claim 1 of the patent as granted reads as follows:

"A catheter assembly comprising:

a catheter (630;830) having on at least part of its surface a hydrophilic surface layer intended to produce a low-friction surface character of the catheter by treatment with a wetting fluid prior to use of the catheter;

a catheter receptacle (620;820) forming a cavity for accommodation of at least part of the catheter; and
a compartment (650; 850) accommodating said wetting fluid, wherein said compartment forms an integrated part of the receptacle (620; 820), but being separated from said cavity,

characterised by an additional outer layer (660; 860) attached to the receptacle, said layer being arranged to at least partly cover the part of the receptacle forming said wetting fluid compartment."

VIII. The opponent's arguments can be summarised as follows:

Main request

Novelty over D1

The embodiment shown in Figure 11 of D1 and described on page 13, line 35 to page 14, line 17, comprised all the features of the preamble of claim 1 of the patent as granted, namely, a catheter (1) having a hydrophilic surface layer; a catheter receptacle (48) forming a cavity; and a compartment (47) accommodating a wetting fluid and forming an integrated part of the receptacle, but being separate from said cavity. In addition, the sheet member (49) closing the two compartments could be regarded as the additional outer layer specified in the characterising portion of claim 1 since this layer covered at least part of both the compartment (47) and the cavity (48). In fact, claim 1 did not require that the additional outer layer covered the whole receptacle. Therefore, the common sheet closing the two container parts could be considered the additional outer layer.

According to another interpretation, the outermost layer in the multiple layer material mentioned in D1 (page 7, line 33 to page 8, line 7, Figures 1 and 2) could be considered the additional outer layer, since a laminate of layers such as the multiple layer film inherently comprised an outer layer attached to the remainder of the layers. The claim did not say anything about how the receptacle was built before the outer layer was added. Furthermore, the embodiment shown in Figures 1 and 2 also had a compartment for the wetting fluid that is separate from the cavity, namely, the widened end section (12). Hence, the embodiment shown in Figures 1 and 2 of D1 was also novelty-destroying.

Hence, the subject-matter of claim 1 of the patent as granted was anticipated by D1.

Novelty over D6

D6 also disclosed a catheter assembly comprising a catheter (11) having on at least part of its surface a hydrophilic surface layer intended to produce a low-friction surface character of the catheter by treatment with a wetting fluid prior to use of the catheter (Figure 1 and page 3, last three lines); a catheter receptacle (12) forming a cavity for accommodation of at least part of the catheter (11) (page 3, last paragraph); a compartment (17) accommodating said wetting fluid, wherein said compartment (17) forms an integrated part of the receptacle (12), but being separated from said cavity, (page 5, first paragraph and Figures 1 and 2); and an additional outer layer attached to the receptacle, said layer being arranged to at least partly cover the part of the receptacle forming said wetting fluid compartment. As shown in Figures 1 and 2, the compartment (17) was covered by the additional layer (24) of the receptacle.

Thus, D6 disclosed all the features of claim 1 of the patent as granted.

For the same reasons as given for claim 1, the subject-matter of claim 36 was not novel over both D1 and D6.

Inventive step in view of D2 in combination with D3 and common general knowledge

The subject-matter of claim 1 did not involve an inventive step when combining D2 with the common general knowledge and D3. D2 could be considered the closest prior art as it disclosed a catheter assembly

comprising:

a catheter (1) having on at least part of its surface a hydrophilic surface layer intended to produce a low-friction surface character of the catheter by treatment with a wetting fluid prior to use of the catheter (page 5, lines 3 to 5);

a catheter receptacle (2) forming a cavity for accommodation of at least part of the catheter (1) (page 5, lines 5 to 9); and

a compartment (8) accommodating said wetting fluid, wherein said compartment (8) formed an integrated part of the receptacle (2), but being separated from said cavity (page 4, line 29 to page 5 line 2, the wetting fluid "is integrated into the package").

The subject-matter of claim 1 differed from D2 in that an additional outer layer was attached to the receptacle and that this layer was arranged to at least partly cover the part of the receptacle forming said wetting fluid compartment.

The problem to be solved could be understood to be how to provide a stronger wetting fluid compartment (opposed patent, column 2, lines 41 to 43).

Adding an additional layer in order to provide a stronger product was commonly known. Additionally, the inclusion of an additional outer layer was merely a design option that required no inventive skill (T 414/09). In any case, this problem was solved in D3, which disclosed, in column 2, lines 45 to 50, that an additional outer layer (of, for example, metal or aluminium) could be laminated to a catheter package.

Inventive step in view of D1 in combination with D3 - admissibility of a new line of attack

The subject-matter of claim 1 also lacked an inventive step in view of D1 in combination with D3. In particular, the claimed catheter assembly differed from D1 in that it comprised an additional outer layer attached to the receptacle. The provision of such an additional outer layer was rendered obvious by the teaching of D3.

The new line of attack was presented for the first time at the oral proceedings because the claimed subject-matter was considered to lack novelty in view of D1. Only after it was clear that this attack would not succeed before the Board could it have been expected that the opponent would make an inventive-step attack on the basis of this document.

- IX. The proprietor's arguments are essentially those underlying the reasons for this decision.

Reasons for the Decision

1. The appeal is admissible.
2. The invention as defined in claim 1 of the patent as granted relates to a catheter assembly comprising a hydrophilic catheter (e.g. a urinary catheter) that is to be treated with a wetting fluid prior to use. The assembly further comprises a catheter receptacle forming a cavity for accommodating the catheter and a compartment accommodating the wetting fluid and forming an integrated part of the receptacle but being separated from the cavity.

Such catheter assemblies are costly to produce when gas-impermeability is required and the compartment accommodating the wetting fluid may be weak.

According to the invention, an additional outer layer is attached to the receptacle, the outer layer being arranged to at least partly cover the part of the receptacle forming the wetting fluid compartment.

This allows the use of gas-impermeable material to be limited to essentially the compartment and makes the latter stronger (paragraph [0010] of the patent).

Claim 36 as granted relates to a method for producing such a catheter assembly.

3. *Novelty over D1*

3.1 D1 relates to a catheter assembly comprising a hydrophilic urinary catheter and a catheter receptacle. Figure 11 shows an embodiment with a two-part container (46) having a cavity (48) for the catheter and a compartment (47) for the wetting fluid, wherein the compartment is an integrated part of the receptacle but is separated from the cavity. A sheet member (49) of gas-impermeable film material forms a common closure for the two container parts (page 13, line 35 to page 14, line 6).

3.2 In the opponent's view, the container (46) could be considered the receptacle and the common sheet (49) closing the two container parts could be considered the additional outer layer covering the receptacle.

The Board does not agree with this interpretation since this would imply that the terms "additional" and

"outer" have no technical meaning. Hence, while the sheet (49) can be regarded as a layer attached to the receptacle, it cannot be regarded as an additional outer layer since it is the only layer on that part of the assembly. Furthermore, the sheet member of D1 covers both the compartment for the wetting fluid and the cavity. However, claim 1 requires the outer layer to be arranged so as to at least partly cover the part of the receptacle forming the wetting fluid compartment, and not at least partly cover the whole receptacle.

- 3.3 According to another interpretation, the opponent referred to a passage on page 7, line 33 to page 8, line 7 of D1 disclosing a catheter package formed by two sheets of a multiple layer film material. The opponent considered the outermost layer of this multiple layer film to be the additional outer layer of claim 1. Hence, according to this interpretation, the receptacle would be formed by the multiple layer film without the outermost layer.

The Board cannot concur with this interpretation. The wording "additional outer layer attached to the receptacle" means, in the Board's view, that the receptacle is formed and that the outer layer is attached to it. In contrast, D1 discloses using a multiple layer film material to form a package for a catheter. Although this multiple layer film material inherently has an outermost layer, this layer cannot be regarded as an additional outer layer attached to the receptacle.

Moreover, the passage referred to by the opponent relates to the embodiment of Figures 1 and 2 of D1. Contrary to the opponent's view, the Board does not

consider the widened end section (12) to be a compartment separated from the cavity. Since there is no separation between the cavity and the widened end section, the liquid swelling medium has to be confined in a spongy or gel-like material in order to keep it in the compartment (page 8, lines 17 to 22). Hence, this embodiment is also not novelty-destroying for the subject-matter of claim 1 since it does not comprise a separate compartment for the wetting fluid.

It follows that neither the embodiment of Figures 1 and 2 nor the embodiment of Figure 11 of D1 anticipates the subject-matter of claim 1 of the patent as granted.

The same considerations apply, *mutatis mutandis*, to independent claim 36, the subject-matter of which is also novel over D1.

4. *Novelty over D6*

4.1 D6 discloses (page 3, last paragraph; Figure 1) a hydrophilic catheter package comprising an envelope (12) housing the catheter (11) and a liquid pouch (17) containing a wetting fluid. The liquid pouch may be rendered easily burstable by weakened areas around its perimeter (page 4, 2nd paragraph). Applying pressure to the liquid pouch causes the liquid to escape into the chamber (19) in order to activate the lubricious coating of the catheter.

4.2 In the opponent's view, the pouch (17) could be regarded as a compartment accommodating the wetting fluid and forming an integrated part of the receptacle. The envelope (12), and in particular its end (24), was

considered as an additional outer layer covering this compartment.

The Board cannot concur with this view. The pouch (17) is arranged inside the envelope that accommodates the catheter (page 2, last paragraph), but it does not form an integrated part of the envelope (12).

Furthermore, the end (24) of the envelope (12) is a part of the envelope that can be removed by tearing at tear points (22), (22') (page 5, 2nd paragraph; Figure 1), and cannot be regarded as an additional outer layer attached to it. Basically, no additional layer is attached to the pouch.

4.3 Hence, the subject-matter of claim 1 is novel over D6.

4.4 The same considerations apply, *mutatis mutandis*, to independent claim 36, the subject-matter of which is also novel over D1.

5. *Inventive step in view of D2 in combination with D3 and common general knowledge*

5.1 D2 discloses, similarly to D6, a hydrophilic catheter assembly comprising a receptacle (2) in which a catheter (1) is arranged together with a container (8) comprising a wetting fluid (page 7, line 25 to page 8, line 5; figure 1).

In the Board's view, the subject-matter of claim 1 differs from D2 in that:

- the compartment for accommodation of the wetting fluid is an integrated part of the receptacle and

- an additional outer layer is attached to the receptacle.

- 5.2 The opponent alleged that the container for the wetting fluid is an integrated part of the package (2), and referred to the passage on page 4, line 29 to page 5, line 2 of D2.

According to this passage, the wetting fluid is integrated into the package. However, this surely does not mean that the compartment for the wetting fluid forms an integrated part of the receptacle. In the context of the cited passage of D2, "integrated into" means "included" or "inside".

- 5.3 The opponent first argued that the addition of an additional layer was merely a design option that did not require inventive skill, and referred to decision T 414/09.

Since the cited decision T 414/09 does not deal with any additional outer layer, this decision does not appear relevant for the present case.

The opponent further argued that it is commonly known to add an additional layer to a product to make it stronger and alleged that this problem was also solved in D3.

The Board does not concur with the argumentation in relation to D3. D3 discloses a catheter assembly wherein a pouch (17) containing sterile lubricant and a catheter (12) are arranged in an envelope (40) (Figures 1 and 2).

The Board observes that D3 does not disclose an

additional outer layer attached to the receptacle. The passage referred to by the opponent (column 2, lines 45 to 50) relates to a laminated material that is used to form the pouch (Figure 4). Thus, even when considering the teaching of D3 in order to solve the alleged problem of making the catheter assembly of D2 stronger, the skilled person would not be prompted to attach an additional outer layer to the receptacle of the package (2).

5.4 Moreover, like D2, D3 does not disclose a compartment for the wetting fluid forming an integrated part of the receptacle (envelope).

5.5 Hence, in the Board's opinion, a combination of the teachings of D2 and D3 would not lead to a catheter assembly according to claim 1 or to a method according to claim 36.

Thus, the subject-matter of claim 1 and claim 36 involves an inventive step.

6. *Inventive step in view of D1 in combination with D3 - admissibility of a new line of attack*

6.1 During the oral proceedings before the Board, the opponent raised for the first time a further objection of lack of inventive step of the subject-matter of claim 1 in view of a combination of D1 with D3.

6.2 The proprietor requested that this attack not be admitted into the proceedings.

6.3 During the appeal proceedings, the opponent exclusively relied on D2 as the closest prior art for the assessment of inventive step. In view of this, the

opponent's new inventive-step attack based on D1 as closest prior art, filed at such a late stage of the proceedings, came as a surprise to both the proprietor and the Board. This attack therefore represents an amendment to the appellant's case that should only be introduced into the proceedings at the discretion of the Board under Article 13 RPBA.

- 6.4 The opponent argued in this respect that it could not pursue this inventive-step attack earlier in the proceedings because it considered D1 to be novelty destroying.

However, in the communication annexed to the summons to the oral proceedings, the Board had already expressed its preliminary view that the subject-matter of claim 1 was novel over D1. Consequently, the opponent should have envisaged the possibility that the novelty attack on the basis of D1 would not be successful and should have submitted its inventive-step attack on the basis of D1 at least within the time limit given in that communication. The opponent's argument in this respect is therefore not convincing.

- 6.5 Moreover, the Board notes that, according to the above analysis, neither D1 nor D3 discloses an additional outer layer as required in claim 1. Hence, a combination of D1 with D3 would prima facie not lead to the subject-matter of claim 1.

It follows that the prima facie relevance of the new line of attack is not given.

- 6.6 Therefore, pursuant to Article 13(1) RPBA, the Board decided not to admit the amendment to the opponent's

case based on this new attack.

7. Hence, the grounds for opposition of lack of novelty and lack of inventive step pursuant to Article 100(a) EPC do not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated