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**Datasheet for the decision
of 7 October 2021**

Case Number: T 2060/17 - 3.2.08

Application Number: 12711556.6

Publication Number: 2686054

IPC: A61M25/00, B65D83/02, A61M25/01

Language of the proceedings: EN

Title of invention:
A CATHETER ASSEMBLY

Patent Proprietor:
Coloplast A/S

Opponents:
Hollister Incorporated
Dentsply IH AB

Headword:

Relevant legal provisions:
EPC Art. 123(2), 84, 54, 56, 111(1)

Keyword:

Amendments - added subject-matter (no)

Claims - clarity (yes)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

T 1575/18

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2060/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 7 October 2021

Appellant: Hollister Incorporated
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
11 July 2017 concerning maintenance of the
European Patent No. 2686054 in amended form.**

Composition of the Board:

Chairwoman P. Acton
Members: A. Björklund
 C. Schmidt

Summary of Facts and Submissions

- I. The appeal was filed by opponent 2 (appellant) against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request C (then on file), the patent in suit (hereinafter "the patent") met the requirements of the EPC.
- II. The former opponent 1 withdrew its opposition by letter of 6 October 2020.
- III. Oral proceedings were held before the Board on 7 October 2021.
- IV. At the end of the oral proceedings the parties' requests were as follows:

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

The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained on the basis of request C (main request) or on the basis of one of auxiliary requests B, H, H1, I, I1, J or J1, all filed with the reply to the appeal dated 9 April 2018. It also requested that the novelty objections raised by the appellant with the letter setting out the grounds of appeal not be admitted into the proceedings.

- V. Claim 1 of the main request (request C), with the feature designations used by the respondent, and with additions compared with claim 1 as granted underlined, reads as follows:

0 "A catheter assembly (1, 101) comprising
a - a catheter (8, 109) having a proximal end
(10) adapted to be inserted into a bodily
cavity and a distal end (11) having a
drainage outlet,
b - a catheter package (2) having
c a cavity (7, 104) for accommodating the
catheter and
d an opening (6, 103) for withdrawing the
catheter from the package,
d1 said package having a proximal end storing
the proximal end of the catheter and a distal
end being the opposite end; and
e - extracting means (17, 111) that are coupled
to the catheter (8, 109) for extracting the
distal end of the catheter out of the
package,
e1 prior to the complete extraction of the
catheter from the package (2),
characterised in that
f the extracting means (17, 111) are coupled to
a part of the catheter that is distal to the
proximal end (10) and proximal to the distal
end (11);
g wherein the extracting means (17, 111) are
arranged in a distal end (5, 102) of the
catheter package and
h wherein the extracting means (17, 111) is in
the form of a strip
i1 that has at least a length that extends from
a proximal end coupled to a coupling area of
the catheter and a distal end abutting the
opening (6, 103) of the catheter package,

i2 or extending beyond the opening (6, 103) of the catheter package.

VI. The appellant's arguments, insofar as they are relevant to the decision, can be summarised as follows:

Article 123(2)

Feature **e1** had been isolated out of context from the paragraph bridging pages 2 and 3 of the application as filed. This was an unallowable intermediate generalisation extending beyond the content of the application as filed.

Article 84 EPC

Feature **e1** did not relate to the structure of the extracting means, but was a method step defining the order in which the catheter was removed from the package. Claim 1 defined a catheter, i.e. a product, and the use of a method step thus rendered the claim not clear.

Even if feature **e1** was considered to be a functional feature, it was not allowable since it could have been defined by the structural features of the passage bridging pages 2 and 3 of the application as filed.

Feature **i2** was also not clear, since the skilled person would not have understood what was meant by the distal end of the strip extending beyond the opening of the package.

Article 54 EPC

The term "strip" defined something which was thin, long and elongate, but it was not excluded that a strip was tubular. This was underlined by paragraphs [0040] and [0041] of the patent, which described the strip as being looped around an insertion aid or arranged around the catheter.

Consequently, the catheter assemblies in D8, D9, D12 and D14 deprived the subject-matter of claim 1 of request C of novelty.

Article 56 EPC

The subject-matter of claim 1 differed from the catheter assembly in D2 only on account of feature **e1**, which specified that the distal end of the catheter was extracted out of the package prior to the complete extraction.

This difference had no particular advantage, but solved the problem of providing an alternative catheter assembly. Modifying the catheter assembly of D2 such that the distal end instead of the proximal end was extracted first was obvious to the skilled person in view of D2 itself, or in view of the catheter assemblies in D8 or D9, and thus did not involve an inventive step.

VII. The respondent's arguments, insofar as they are relevant to the decision, can be summarised as follows:

Article 123(2) EPC

Feature **e1** had a basis in the paragraph bridging pages 2 and 3 of the description as filed. The features of the paragraph which the appellant alleged were inextricably linked to feature **e1** were either implicit in claim 1 or optional.

Article 84 EPC

Feature **e1** was a functional feature which was to be read together with feature **e** and specified which end of the catheter became available to the user. The limitations introduced by feature **e1** were clear to the skilled person and did not require any structural definitions.

Feature **i2** was to be read in conjunction with features **e**, **e1** and **i1**. The skilled person would have had no difficulty understanding what it meant.

Article 54 EPC

The skilled person would not have understood a tube as a strip. Therefore, none of the catheter assemblies in D8, D8, D12 and D14 had extraction means in the form of a strip. The subject-matter of claim 1 was therefore novel.

Article 56 EPC

The skilled person would have had no reason to modify the catheter assembly of D2 such that the distal end of

the catheter was extracted first, and this would have gone against the entirety of the teaching of D2.

Reasons for the Decision

1. Article 123(2) EPC

1.1 The appellant submitted that feature **e1** constituted an unallowable intermediate generalisation since it had been extracted out of context from the paragraph bridging pages 2 and 3 of the application as filed.

This paragraph disclosed feature **e1** in context with a package in which the "*opening only partly exposed the distal end of the urinary catheter*", and with "*extracting means ... readily accessible to the user, so the user may pull the distal end out of the package*" such that "*the distal end becomes fully accessible to the user*". All of these features were missing from the claim.

1.2 The appellant argued that the feature according to which "the distal end is only partly exposed" had been unallowably omitted from the claim.

This feature is disclosed on page 3, line 3 of the application as originally filed. This sentence describes the disadvantages of the prior art, according to which, if the distal end was only partly exposed, further bending, cutting or folding of the package was required. It does not describe an embodiment of the invention. Therefore, the partial exposure of the distal end is not linked to feature **e1**.

- 1.3 Furthermore, the appellant argued that the feature according to which the extracting means must be readily accessible had been unallowably omitted.

Feature **e1** has to be read in combination with feature **e**, which specifies that the "*extracting means [...] are coupled to the catheter for extracting the distal end of the catheter out of the package*", and with features **i1** and **i2**, which specify that the extracting means is a strip having a distal end abutting or extending beyond the opening of the package. These features imply that the extracting means are "readily accessible" to the user. Therefore, the feature relating to the readily accessible extracting means did not need to be introduced explicitly into the claim.

- 1.4 Moreover, the appellant argued that lines 7 and 8 on page 3 of the application as originally filed described that the distal end of the catheter was pulled out of the package prior to the complete extraction of the catheter from the package. On the contrary, feature **e1** together with feature **e** required that the distal end was extracted from the package; however, the term "extract" was not a synonym for "pull". Therefore, substituting pulling with extracting corresponded to an unallowable intermediate generalisation.

It is correct that the term extracting itself is not synonymous with pulling; however, feature **h** specifies that the extracting means are in the form of a strip. It is well known to the skilled person that, in this context, strips can only apply pulling forces. Hence, in the claim, extracting can only be interpreted to mean pulling. Therefore, the use of the term extracting instead of pulling does not lead to an unallowable intermediate generalisation.

1.5 Finally, the appellant argued that the extracting means had to be such that it rendered the distal end of the catheter fully accessible, as was described in the last sentence of the paragraph bridging pages 2 and 3 of the application as originally filed.

Feature **e1** is based on the sentence in lines 6 to 8 on page 3. The following sentence, which states that the distal end of the catheter becomes fully accessible, is formulated as a consequence of the previous sentence, i.e. as a consequence of feature **e1**, and not as an additional feature of the catheter assembly. Therefore, the allegedly omitted feature is implicit in feature **e1** when read together with the remaining features of the claim and it is not necessary to introduce it into the claim.

1.6 The features of the paragraph bridging pages 2 and 3 of the application as filed, which, according to the appellant, should have been introduced into claim 1 together with feature **e1**, are thus either implicitly defined in claim 1 or are not inextricably linked to feature **e1**.

The introduction of feature **e1** into claim 1 therefore does not constitute an unallowable intermediate generalisation. Claim 1 of request C thus meets the requirements of Article 123(2) EPC.

2. Article 84 EPC

2.1 Feature **e1**

2.1.1 The appellant submitted that feature **e1** was a method step specifying the sequence of taking the catheter

from the package: extraction before complete withdrawal. The use of a method step in a device claim rendered the claim not clear.

If feature **e1** was considered to be a functional feature, it was not allowable since it could and should have been defined by the structural features in the paragraph bridging pages 2 and 3 of the application as filed, which had been discussed under Article 123(2) EPC.

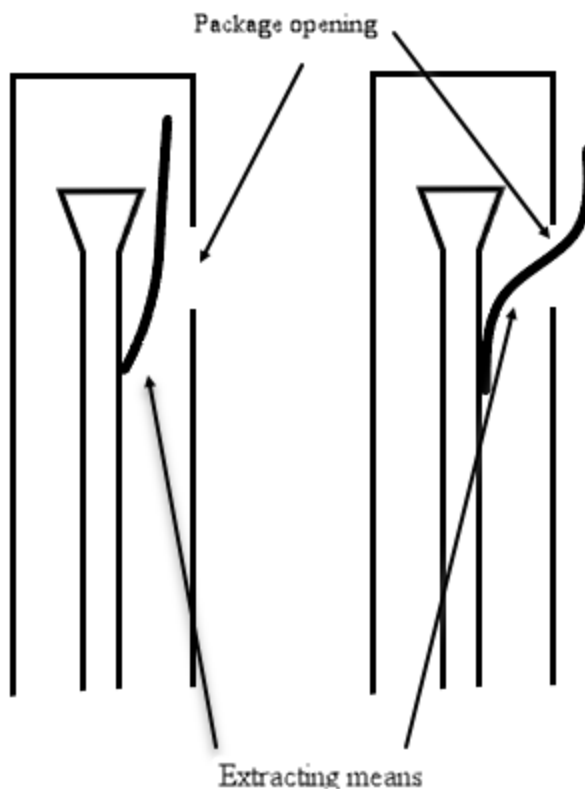
2.1.2 Feature **e1** directly follows feature **e** without any comma or conjunction. Therefore, the skilled person would read feature **e1** in conjunction with feature **e**. In doing so, feature **e1** would be understood as a further functional limitation of the extracting means in feature **e**.

2.1.3 As set out in points 1.3 to 1.5 above, the skilled person would read the "structural features", which, according to the appellant, should have been used instead of feature **e1**, as already being implicitly defined in the claim. It is also noted that these features are functional, just like feature **e1**, rather than structural.

2.2 Feature **i2**

2.2.1 The appellant submitted that the skilled person would not have understood what was meant by the strip of the extracting means having an end extending beyond the opening of the catheter package. This could, for example, have meant that the end of the strip protruded outside of the package or, if the opening was on the side of the package, the strip could have extended across the opening on the inside of the package such

that the distal end of the strip was beyond the opening (see the drawing). The skilled person thus would not have understood what was meant by this definition.



2.2.2 It is true that feature **i2** does not precisely specify the manner in which the distal end of the strip extends beyond the opening of the catheter package. This feature thus encompasses several possibilities for how the distal end of the strip can extend beyond the opening, including it protruding from the package or the strip extending across a side opening of the package. While this renders the scope of feature **i2** broad, it does not mean that the skilled person cannot understand what is encompassed by this feature.

2.3 Claim 1 of request C thus fulfils the requirements of Article 84 EPC.

3. Article 54 EPC

3.1 The appellant submitted that the term "strip" in feature **h**, which was "a long narrow piece, usually of uniform width" (American Heritage Dictionary of the English Language, 5th edition) or "long narrow piece of material" (Webster's College Dictionary), did not mean that a strip was necessarily flat, but that it could also be tubular, contrary to the opposition division's understanding of the term.

This was underlined by paragraphs [0040] and [0041] of the disputed patent, which described that the strip was looped around the insertion aid or arranged around the catheter.

Consequently, the protective sleeve 17 of the catheter assembly in Figures 2 and 4 of D8, the tubular insertion aid 10 of the catheter assembly in Figure 4 of D9, the sleeve S of the catheter assembly in Figure 2 of D12 and the cuff 40 of the catheter assembly in Figure 1b of D14 were also strips according to feature **h**.

3.2 The patent does not contain an explicit definition of the term "strip", nor do paragraphs [0040] and [0041], cited by the appellant, describe that a tube could be considered a strip. These paragraphs specify that the end of the strip may be looped around an insertion aid or arranged around the catheter or the connector of the catheter, not that the overall geometry of the strip is looped or arranged around the catheter.

Since the patent specification does not contain any particular definition of the meaning of the term strip,

it should be interpreted within the common understanding of the skilled person. Moreover, as pointed out in T 1575/18 (point 3.3), a term should not be given an interpretation going against the common use of the language in the absence of a clear and unambiguous indication in the patent that such an interpretation was meant.

- 3.3 The appellant is correct that none of the cited dictionaries defines a strip as being flat, but, while a strip may not necessarily need to have a strictly flat geometry, the skilled person would not consider a tubular member having a lumen throughout its length which encircles a catheter to be a strip.
- 3.4 The skilled person thus would not consider the protective sleeve 17 in Figures 2 and 4 of the catheter assembly of D8, the sleeve S of the catheter assembly in D12 or the cuff 40 of the catheter assembly in D14 to be a strip in the sense of feature **h**.
- 3.5 With regard to the tubular insertion aid 10 of the catheter assembly in Figure 4 of D9, the appellant pointed out that it has a slit, and hence is not a tube. Paragraph [0037], cited by the appellant, describes this slit as having dimensions which are such that there should be no risk of the tubular insertion aid being detached from the catheter unintentionally. Although it has a slit, the insertion aid thus has an inherent tubular shape and encircles the catheter to prevent it being touched during insertion. The skilled person would not understand this tubular insertion aid to be a strip either.
- 3.6 The subject-matter of claim 1 of request C thus differs from the catheter assemblies disclosed in D8, D9, D12

and D14 at least on account of feature **h** and is therefore novel.

4. Article 56 EPC

4.1 According to the appellant, the subject-matter of claim 1 differed from the catheter assembly of D2 merely on account of feature **e1**, which specified that the distal end instead of the proximal end of the catheter was extracted prior to the complete extraction of the catheter from the package.

The patent did not disclose any advantages of extracting the distal end of the catheter first. The problem solved by claim 1 was thus merely to provide an alternative catheter assembly.

Even if the embodiment in the figures of D2 showed a catheter guiding element 15, this was only optional, as is evident from its absence from claim 1. There was thus no teaching in D2 which would discourage the skilled person from modifying the catheter assembly such that the distal end was extracted prior to the complete extraction from the package.

The alternative catheter assembly in claim 1 would thus be obvious to the skilled person in view of D2 alone, or in view of D8 or D9, which explicitly disclosed that the distal end of the catheter was extracted before the complete removal of the catheter from the package.

4.2 The appellant is correct that the catheter guiding element is not defined in claim 1 of D2 and thus may be considered to be optional.

However, claim 1 of D2 as well as paragraphs [0003] and [0024] disclose that the proximal end of the catheter should exit the package first. As described in paragraph [0011], pulling the extracting means moves the proximal end of the catheter out of the package and, according to paragraph [0012], this results in a catheterisation aid which allows safer and simpler handling during application of the catheter.

Even if the skilled person could modify the catheter assembly of D2 such that the distal end instead of the proximal end is extracted prior to the complete extraction from the package, this would go against the explicit teaching in D2 since the package would no longer serve as an insertion aid during the extraction of the catheter from the package.

Therefore, irrespective of how the technical problem to be solved is formulated, or whether the assessment is based on D2 alone or in combination with D8 or D9, the skilled person would not modify the catheter assembly of D2 such that the distal end is extracted prior to the complete extraction of the catheter from the package.

The subject-matter of claim 1 of request C therefore involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated