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**Datasheet for the decision
of 4 August 2021**

Case Number: T 1327/15 - 3.2.08

Application Number: 06706103.6

Publication Number: 1858575

IPC: A61M25/00

Language of the proceedings: EN

Title of invention:

A PACKAGE FOR A MEDICAL DEVICE

Patent Proprietor:

Coloplast A/S

Opponents:

Dentsply IH AB
Medical Service GmbH

Relevant legal provisions:

EPC Art. 84, 123(2)
RPBA Art. 13(3)

Keyword:

Claims - clarity - main request (no)
Late-filed auxiliary requests - admitted (no)



Beschwerdekammern

Boards of Appeal

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Case Number: T 1327/15 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 4 August 2021

Appellant: Dentsply IH AB
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Appellant: Medical Service GmbH
(Opponent 2) Luisenstrasse 8
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Representative: Grünecker Patent- und Rechtsanwälte
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Respondent: Coloplast A/S
(Patent Proprietor) Høltedam 1
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
4 May 2015 concerning maintenance of the
European Patent No. 1858575 in amended form.**

Composition of the Board:

Chairwoman P. Acton
Members: G. Buchmann
 C. Schmidt

Summary of Facts and Submissions

- I. With the decision of 4 May 2015 the opposition division decided to maintain the opposed patent on the basis of the then valid auxiliary request 1.
- II. Both opponents filed an appeal against that decision.
- III. Oral proceedings took place before the Board on 4 August 2021.
- IV. The appellants 1 and 2 (opponents 1 and 2) requested
- that the decision under appeal be set aside and the patent be revoked, and
- that auxiliary request 1, filed during the oral proceedings on 4 August 2021, should not be admitted.
- V. The respondent requested that the patent be maintained on the basis of the request which formed the basis of the decision of the opposition division, or, as an auxiliary measure, auxiliary request 1 as filed during the oral proceedings on 4 August 2021.
- VI. **Claim 1 of the main request reads as follows**
(Amendments with respect to claim 1 as granted are underlined).

"1.

An assembly (1) for wetting a medical device (5) with a fluid medium,

2.

said assembly comprising a package (2, 3, 4) accommodating the medical device,

3.

the assembly further comprising at least one

compartment (6) accommodating the fluid medium

3.1

so that the fluid medium is incapable of interacting with the medical device until the compartment is opened,

characterized in that

4.

the assembly comprises opening means

4.1

adapted for a combined opening action whereby the package as well as the compartment are opened,

5.

the package comprises a container (3, 4)

6.

and a closure (2)

6.1

which can be detached from the container for making the medical device accessible and

6.2

which interacts with the compartment to open the compartment upon movement of the closure relative to the container,

7.

wherein the compartment is emptied as an integrated part of the opening procedure."

VII. **Claim 1 of auxiliary request 1 reads as follows**

(Amendments with respect to claim 1 as filed are indicated).

"1.

An assembly (1) for wetting a medical device (5) with a fluid medium,

2.

said assembly comprising a package (2, 3, 4)

accommodating the medical device,

3.

the assembly further comprising at least one compartment (6) accommodating the fluid medium

3.1

so that the fluid medium is ~~not in contact with the medical device~~ incapable of interacting with the medical device until the compartment is opened, characterized in that

~~**4.**~~

~~the assembly comprises opening means~~

~~**4.1**~~

~~adapted for a combined opening action whereby the package as well as the compartment are opened,~~

~~**5'**~~

the package comprises a container (3, 4) with an opening

6.

and a closure (2)

6.1

which can be detached from the container for making the medical device accessible and

6.2

which interacts with the compartment to open the compartment upon movement of the closure relative to the container,

7.

wherein the compartment is emptied as an integrated part of the opening procedure,

8.

wherein the medical device is a catheter."

VIII. The arguments of the appellants can be summarised as follows:

Main Request

The subject-matter of claim 1 lacked clarity because it was unclear whether the opening means and the closure were the same element or not, or whether the closure was a part of the opening means. The interrelation of the opening means and the detachable closure was not clear. It was also ambiguous whether opening of the compartment was a result of manipulation of the opening means, the closure or both.

Auxiliary Request 1

Auxiliary request 1 should not be admitted because no new issues had been presented which would provide a reason for filing an amended request at this late stage of the proceedings.

Furthermore, the request was prima facie not allowable. In claim 1, the essential feature of the combined opening action had been deleted. The added Feature 7 had been taken in isolation from the context of the description, page 2, lines 4-10, where this feature was described as a direct result of the combined opening action. Therefore, the feature including the combined opening action by the opening means had been omitted in an unallowable way.

IX. The arguments of the respondent can be summarised as follows:

Main Request

"Opening means" was a generic term and encompassed the container, the closure and an additional opening feature (seal 16). The description, page 6, line 28 - page 7, line 2, clarified the relationship between the opening means and the closure, the latter being a part of the opening means.

The combined opening action of Feature 4.1 was specified in more detail in Features 6.1 and 6.2. A link was thus provided between the opening means and the closure. This link also became clear from the description, page 6, line 28 - page 7, line 2.

Auxiliary Request 1

Feature 7 was derived from the description, page 2, lines 8-9. This feature was present in each of the embodiments and its inclusion in the claim did not therefore represent new information.

The "combined opening action" had not been omitted from the claim. Indeed, the claim specified both that the closure is detached for making the medical device accessible and that the closure interacts with the compartment to open and empty it.

Reasons for the Decision

1. Main Request - Article 84 EPC

According to the wording of claim 1, the

assembly comprises

- a package (Feature 2)
- a compartment (Feature 3)
- opening means for a combined opening action whereby the package as well as the compartment are opened (Features 4, 4.1).

The package comprises

- a container and
- a closure (Features 5, 6) which interacts with the compartment to open it (Feature 6.2).

Therefore, the opening means (separate from the package) and the closure (part of the package) are not only named differently, but they also form part of different components of the assembly. From the functional viewpoint, the claim does not describe any relationship between the combined opening action of the opening means and the function of the closure.

On the other hand, both the opening means and the closure open the compartment (Features 4.1 and 6.2).

It thus becomes unclear whether the opening means and the closure are the same element or not, or whether the closure is a part of the opening means. The claim is completely silent as regards any technical or functional correlation of these two components with each other.

Consequently, it is also unclear whether the compartment is opened by the opening means, by the closure or by both elements.

The respondent argued that "opening means" was a generic term, and that the opening means of the claim comprised the container and the closure. However, this contradicts the claim wording, according to which the package comprises the container and the closure, and, at the same time, the opening means and the package form two different parts of the assembly. Furthermore, the respondent's submission that the opening means comprised a further "opening feature", represented by a seal 16 (page 9, lines 7-11), does not solve the contradiction between the respondent's interpretation and the claim wording.

The respondent also referred to the description, page 6, line 28 - page 7, line 2, to explain the relationship between the opening means and the closure.

The first sentence of the cited passage discloses that release of the closure from the container requires opening of the compartment. This means that the opening of the compartment is a prerequisite for release of the closure. The subsequent sentence discloses that "the opening means may thus be adapted to open the compartment at the latest at the time when the package is opened". This does not provide, however, any clear technical or functional relationship between the opening means and the closure.

Even if said passage of the description provided clear information, this would still not be sufficient, because the requirement of clarity refers to the claims

rather than to the description.

The respondent suggested that the making-accessible of the medical device and the opening of the compartment, as specified in Feature 6.2, constituted the same "combined opening action" as specified in Feature 4.1. Even assuming that this was correct, it does not lead to any clarification of the technical relationship between the opening means and the closure.

Therefore, claim 1 of the main request lacks clarity (Article 84 EPC).

2. **Auxiliary Request 1**

2.1 In claim 1 of auxiliary request 1, Feature 7 has been added, according to which "the compartment is emptied as an integrated part of the opening procedure". According to the respondent, this feature had been taken from page 2, lines 8-9, of the original application. However, the sentence from which Feature 7 was extracted reads: "Due to the combined opening action, the compartment is emptied as an integrated part of the opening procedure". Therefore, in the context of this passage, the emptying of the compartment is directly caused by the combined opening action of the opening means. This constitutes a direct and inextricable link between Feature 7 and the combined opening action by the opening means.

Therefore, Feature 7 may not be taken from the description in isolation without including the opening means which causes the combined opening action in the claim, as this would infringe Article 123(2) EPC.

Features 4 and 4.1, which were present in claim 1 as

filed and which referred to the opening means and the combined opening action, are, however, no longer present in claim 1 of auxiliary request 1.

- 2.2 The wording of the claim does not even implicitly require a combined opening action. Indeed, the claim specifies that
- a closure can be detached from the container to make the medical device accessible, and
 - the closure opens the compartment upon movement of the closure relative to the container.

These two features do not imply that the opening of the compartment is a consequence of the detachment of the closure from the container. They do not clearly imply any other "combined opening action" either.

- 2.3 Finally, even if Feature 7 as such was present in all embodiments - as argued by the respondent -, this would not allow this feature to be taken in isolation and inserted into the claim.

- 2.4 Therefore, auxiliary request 1 is prima facie not allowable under Article 123(2) EPC, and is not admitted into the proceedings under Article 13(1) and (3) RPBA 2007.

Order

For these reasons it is decided that:

The patent is revoked.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated