BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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File Number: T 111/91 - 3.2.3

Application No.: 84 902 234.8

Publication No.: 0 176 511

Title of invention: A pressure balancing device for sealed vessels

Classification: A61J 1/00

D E C I S I O N
of 2 July 1992

Proprietor of the patent: Gustavsson, Bengt

Opponent: Farmitalia Carlo Erba s.r.l.

Headword:

EPC Articles 54(2), (3), (4); 56; 87(4); 89; 123

Keyword: "Inventive step (yes)"

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Case Number : T 111/91 - 3.2.3

D E C I S I O N
of the Technical Board of Appeal 3.2.3
of 2 July 1992

Appellant : (Proprietor of the patent)
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Decision under appeal :
Decision of Opposition Division of the European Patent Office dated 10 December 1990 revoking European patent No. 0 176 511 pursuant to Article 102(1) EPC.

Composition of the Board :

Chairman : C.T. Wilson
Members : J. du Pouget de Nadaillac
J.H. van Moer

Summary of Facts and Submissions

I. The appeal is directed against the decision of the Opposition Division dated 10 December 1990 revoking the European patent No. 0 176 511 (patent application No. 84 902 234.8) on the ground that Claims 1 of the main and single subsidiary requests filed on 14 February 1990 do not meet the requirements of Articles 123(2),(3) and 84 EPC; that, even if these claims were redrafted to overcome this first objection, their subject-matters would not be novel in view of EP-A-0 091 312 (state of the art under Article 54(3) and (4) EPC) or do not involve an inventive step having regard to FR-A-2 221 121 and US-A-4 161 178.

These patent publications and the others, which were mentioned in the opposition proceedings, are referenced as follows:

1. EP-A-0 091 312
2. FR-A-2 221 121
3. US-A-4 161 178
4. EP-A-0 123 659
5. WO 84/04673.

II. The Appellant (Patentee) lodged an appeal on 5 February 1991 and filed on 9 April 1991, together with his Statement of Grounds, two sets of claims, as main and subsidiary requests. In response to communications of the Board, he submitted on 3 February 1992 new figures and on 5 June 1992 a new description and a new set of five claims, as main and single request.

III. Claim 1 of this last request, once corrected in order to suppress obvious clerical mistakes (particularly: "international" instead of "internal"), reads as follows:

"A device intended to be used in combination with a vessel (1) having a neck fitted with a sealing member (2) and further intended to be able to receive a transfer member comprising a puncturing member, e.g. a needle of an injection syringe, which is able to pierce the sealing member (2) to enter the interior of the vessel for removing or adding material thereto, said device comprising a closed container (7;18;19) and connection means (3) in the form of a cap to which the closed container is firmly attached and which is provided with attachment means (20) for firmly attaching the device to the neck portion of said vessel (1) and further, at its opposite portion, which in use position is facing away from said vessel, with coupling means (4) for said transfer member and with a pierceable sealing member (5) overlying the sealing member (2) of the vessel in use position of said device, said connection means (3) further having an internal passage (10;13;14;15) for ventilating the vessel, said passage communicating with said closed container (7;18;19) by way of a liquid-rejecting filter (9;16) arranged to prevent entry of liquid into the closed container and, in use position of said device, also communicating with the vessel (1), either directly or via the puncturing member of the transfer device, to provide a communication between the closed container and the interior of the vessel in use position of said device for ventilating and pressure balancing the interior of the vessel."

IV. The Appellant requests that the decision under appeal be set aside and that the patent be maintained on the basis of:

- Claims 1 to 5 and description, pages 1 to 4, as submitted on 5 June 1992, and

- Figures 1 to 4, as filed on 3 February 1992.

During the whole appeal proceedings, the Respondent, although invited to file comments, has not responded.

Reasons for the Decision

1. The appeal is admissible

2. Admissibility of amendments (Article 123 EPC)

The amended Claim 1 meets the requirements of Article 123(2) EPC. In, particular, the features of Claim 1 concerning the coupling means (4) for the transfer member, the pierceable sealing member (5) of the connection means, the internal passage and the liquid rejecting filter are respectively supported by page 2, line 14; page 2, lines 18, 19; page 2, line 26, with page 3, line 13; and page 2, line 25 of the description as originally filed, whereas those concerning the attachment means and the cap form of the connection means can be deduced from the original figures. A direct internal passage for the ventilating means is shown in the original Figure 1 (see the needle 10), and an internal passage via the puncturing member of the transfer device is supported by Figure 5. The description and the figures (deletion of the original Figure 3) have been amended by way of adaptation to the modified claims and to acknowledge the closest state of the art.

Furthermore, the features of Claim 1 represent a clear limitation of the scope of protection in comparison with the granted Claim 1. Thus, Claim 1 does not contravene Article 123(3) EPC, either.

3. State of the art

The features of Claim 1 are disclosed in the SE priority document filed on 20 May 1983. Therefore this claim of the patent in suit is entitled to this priority date, which according to Article 89 EPC is to be considered as the filing date. The two EP citations, referenced above 1 and 4, although filed before this date, were published after and hence form part of the state of the art only under Article 54(3) and (4) EPC and, accordingly, can only be cited with respect to novelty. Document 5 constitutes the second priority document, claiming partly priority of the SE document, which is the first priority document of the present invention. As indicated in the description (column 2, first lines) of the contested patent, it relates to a transfer member, which can be coupled to the device of the present invention, and has consequently not the same subject-matter as the present invention (Article 87(4) EPC). It is not a part of the state of the art. Documents 2 and 3, published before the priority dates, are the only documents, which fall under Article 54(2) EPC and are, therefore, to be considered when dealing with the question of inventive step.

4. Novelty

Document 1 does not disclose the provision of either a liquid-rejecting filter or coupling means for a transfer member, which are some of the new features introduced in Claim 1. Thus, one ground of revocation raised by the Opposition Division, namely the lack of novelty of the subject-matter of Claim 1 in view of this prior art, has been overcome.

Document 4 constitutes in the opinion of the Board the closest prior art, having regard to the question of novelty, since it relates to a device comprising a sealed vessel intended to receive simultaneously a transfer member for preparing solutions from toxic substances and a closed container for ventilating the vessel through a liquid-rejecting filter. For this reason, Claim 1 of the patent in suit is drafted in a single part form according to the Guidelines for Examination in the European Office, C-III, 2.3a. However, in this prior art, needles form the connection means, so that there are no connection means in the form of a cap, which, further, has coupling means and a sealing member.

These last features are also not found in Document 2.

Connection means in the form of a cap are shown in Document 3, which, however, does not teach the provision of a closed container for ventilating the vessel, which is attached to this cap. An internal passage of the cap and an additional sealing member are also not described therein.

Therefore, the subject-matter of Claim 1 is novel.

5. Inventive step

5.1 As seen above, Documents 2 and 3 are the only documents relevant to the question of inventive step. Document 2 represents undoubtedly the closest prior art, since it describes - see Figure 2 - two interconnectable elastically deformable containers, one containing a dry ingredient, which is to be mixed with a solvent contained in a sealed vessel, and the other being air-filled. These containers communicate with the interior of the vessel respectively by means of connection means in the form of a

hollow needle, which passes through the sealing member fitted on the neck of the vessel. When pressed, the air-filled container creates an overpressure in the vessel, so that solvent is pressed into the container having the dry ingredient and mixed therewith. The dissolved substance is then re-injected into the vessel for application.

5.2 This prior art device is not suitable for toxic drugs for the following reasons:

(a) The connection means between the vessel and the containers, namely the needles, are not firmly attached to the vessel, so that there is a permanent risk of unintentional withdrawal of the needles from the vessel. The clamp mentioned by the Respondent during the opposition proceedings maintains the sealing member of the vessel and not the needles.

(b) It cannot be avoided that liquid enters the air-filled container during the mixing operation and, since both containers cannot be disconnected from each other when they are disconnected from the vessel, the ambient air can be contaminated with sprays or vapours of the drug escaping from the containers.

Furthermore, the fact that both containers are interconnected makes the handling of this known device complicate.

The purpose of the present invention is to provide a safer and simplified device, particularly suitable for toxic substances.

5.3 To solve this problem, the present invention differs from this known prior art in two main aspects: It pertains to

an intermediate device used between the vessel and either a transferring member or an injection syringe, and it proceeds in a different way, since it is the vessel which contains the drug substance in a dry or liquid form, so that a solvent, when needed, is first injected by means of the transfer member or the syringe into the vessel and, in a subsequent step, the content of the vessel is transferred to the injection syringe. During this last step, the vessel is usually turned upside-down. Moreover, it is not necessary to provide means for creating an overpressure, but only means for ventilating and pressure balancing the interior of the sealed vessel in all positions of the vessel.

5.4 According to Claim 1, a closed system for ventilating and pressure balancing is therefore provided, which additionally to the features known from the closest prior art comprises the following features:

(i) The connection means is in the form of a cap, which is firmly attached to the neck of the vessel and has on its upper surface facing away from said vessel coupling means for a transfer member and an own sealing member, which overlies the sealing member of the vessel.

(ii) The closed container for ventilating and pressure balancing is firmly attached to the cap.

(iii) An internal passage comprising a liquid-rejecting filter is provided in the cap to allow a communication between said closed container and the interior of the vessel.

Various embodiments are disclosed. With these new features, a closed system is achieved, since the air,

which circulates from the vessel to the closed container or vice-versa, is always enclosed in the system and cannot escape into the ambient air. Even if it gets out of the vessel through the sealing member of this vessel, it is stopped by the sealing member of the cap and can only get into the closed container. This container, being attached to the cap, remains with the vessel, that is to say with the toxic component. The liquid-rejecting filter avoids that liquid enters the closed container, particularly when the vessel is turned upside-down, so that pressure balancing of the vessel even occurs in such a situation. Tests provided by the Appellant show great differences in the volume of solution spilled on the gloves or an underlying cloth between an untrained person handling the claimed device and a trained person working with an "open" system, namely a sealed vessel and a syringe.

5.5 Connection means in the form of a cap surrounding the neck of a sealed vessel are known from Document 3, which concerns also an intermediate device for transferring a medicament to a particular flexible container. The cap comprises coupling means for the holder member of a hollow needle, which forms the piercing and connecting means. This document does not disclose any more of the distinguishing features (i) to (iii) of paragraph 5.4 and, particularly, does not deal with the problem of ventilating and pressure balancing a vessel or with the problem of avoiding contaminated air escaping into the ambient air. Consequently, this document cannot lead the skilled person to firmly attach the closed container known from Document 2 to the cap and to provide this cap together with an internal passage for ventilating the vessel and with a sealing member.

5.6 For these reasons, the combination of both Documents 2 and 3 cannot suggest the solution according to Claim 1 and,

therefore, the Board has come to the conclusion that the subject-matter of this claim involves an inventive step.

Order

For these reasons, it is decided:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the documents set out in paragraph IV above, with the following amendments:

Description: page 1, line 36, introduce after the word "application":
"and, therefore, falls under Article 54(3) and (4) EPC";
page 2, line 17, write "overlying" as one word;
page 2, line 19, replace "international" by "internal";

Claim 1: line 19, write "overlying" as one word;
line 21, replace "international" by "internal.

The Registrar: The Chairman:

N. Maslin C.T. Wilson