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D E C I S I O N
of 26 September 2003

Case Number: T 0087/02 - 3.2.2

Application Number: 91915826.1

Publication Number: 0541715

IPC: A61M 37/00

Language of the proceedings: EN

Title of invention:
Flexible multiple compartment drug container

Patentee:
B. BRAUN MEDICAL INC.

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0087/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 26 September 2003

Appellant: (Proprietor of the patent)	B. BRAUN MEDICAL INC. 824 Twelfth Avenue Bethlehem Pennsylvania 18018 (US)
Representative:	Grünecker, Kinkeldey Stockmair & Schwanhäusser Anwaltssozietät Maximilianstrasse 58 D-80538 München (DE)
Respondent: (Opponent)	Fresenius Kabi Deutschland GmbH Else-Kröner-Strasse 1 D-61352 Bad-Homburg v.d.H (DE)
Representative:	Luderschmidt, Schüler & Partner GbR Patentanwälte John-F.-Kennedy-Strasse 4 D-65189 Wiesbaden (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 27 December 2001 revoking European patent No. 0541715 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

I. The appellant (patentee) appealed against the decision of the Opposition division posted 27 December 2001 to revoke the European patent No. 0 541 715.

II. The reason given for the revocation was that the functional features contained in the independent product claim 1 as granted were not suitable to be distinguished from the prior art, namely document

D3: US-A-4 496 046,

so that the subject-matter of claim 1 lacked an inventive step.

The Opposition Division further stated that the subject-matter of claim 1 arose from an obvious combination of document

D2: US-A-4 629 080

with document D3.

In addition to D2 and D3, the following documents were discussed during the appeal proceedings:

Dl: EP-A-0 345774 (cited with the grounds of opposition), and

D5: US-A-4 465488,

D6: DE-A-3 238 649,

D7: EP-A-0 295 204 (all cited with the grounds of appeal).

III. Following requests from both parties, oral proceedings were held on 26 September 2003.

IV. At the end of the oral proceedings the appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of claims 1 to 16 filed during the oral proceedings.

V. The respondent (opponent) requested that the appeal be dismissed.

VI. The independent claims 1 and 13 of this request read as follows:

"1. A flexible container (10) for combined storage and administration of medicament and diluent for solutions, the container (10) comprising:
a transparent flexible front sheet (12);
a flexible rear sheet (14) sealed to the front sheet (12) at a common peripheral edge (16);
a first peelable seal (24) extending between two sides of the edge (16) and separably joining the front and rear sheet (12, 14) by a partial melting together of polymer present in the rear sheet and front sheet to form a diluent compartment (18) containing a diluent;
a second peelable seal (26) extending between the two sides and separably joining the front and rear sheet (12, 14) by a partial melting together of polymer present in the rear sheet and front sheet to form an outlet compartment (22) and a medicament compartment

(20) containing a powder medicament intermediate the outlet compartment (22) and the diluent compartment (18), the outlet compartment (22) being empty when the diluent and medicament are in their separate compartments (18, 20), a moisture impermeable cover sheet being sealed to the front sheet, said cover sheet being sized to extend over the medicament compartment (20) and being removable therefrom,
wherein the first peelable seal (24) is rupturable by hydraulic pressure generated by manipulation of the diluent compartment (18), the diluent and medicament are mixed by further manipulation of the container (10) after rupture of the first peelable seal (24) and the second peelable seal (26) is rupturable by hydraulic pressure generated by further manipulation of the now joined diluent and medicament compartments, so that the diluent/medicament solution can flow into the outlet compartment (22); and
an outlet port (30) in communication with the outlet compartment (22), the outlet port (30) being adapted for connection to an IV administration device, whereby the diluent/medicament solution is administered to a patient."

"13. A method for forming a flexible container (10) for combined storage and administration of medicament and diluent for solutions, the method comprising the steps of:
providing a flexible, transparent, front sheet (12);
providing a flexible, vapor impermeable, rear sheet (14);
sealing the front and rear sheets (12, 14) together at a common peripheral edge (16), wherein the surface of the front sheet (12) adjoining the rear sheet (14)

comprises a blend of thermoplastic elastomer and polymer and the surface of the rear sheet (14) adjoining the front sheet (12) comprises a polymer selected from the group consisting of polypropylene, polyethylene and a polypropylene-polyethylene copolymer; heating the front and rear sheets (12, 14) in a first localized area to fuse together the heated portions of the adjoining surfaces, thereby forming a first peelable seal (24) extending between two sides of the common peripheral edge (16), said first peelable seal separably joining the front and rear sheets to thereby form a first compartment (18) for containing a diluent;

heating the front and rear sheets in a second localized area to fuse together the heated portions of the adjoining surfaces, thereby forming a second peelable seal (26) extending between the two sides of the common peripheral edge (16), said second peelable seal (26) separably joining the front and rear sheets to thereby form an outlet compartment (22) and a compartment (20) for containing a medicament, the medicament compartment (20) being between the outlet compartment (22) and the diluent compartment (18);

filling the diluent compartment (18) with a diluent solution and filling the medicament compartment (20) with a medicament, while leaving the outlet compartment (22) empty;

installing a moisture and light impermeable foil (54) covering the medicament compartment (20), wherein at least a portion of the foil (54) is removable for visual inspection of the medicament compartment (20);

wherein the first peelable seal (24) is rupturable by hydraulic pressure generated by manipulation of the diluent compartment (18), and wherein after rupture of

the first peelable seal (24), the diluent and medicament are mixed together by further manipulation of the container to form a diluent/medicament solution and thereafter the second peelable seal (26) is rupturable by hydraulic pressure generated by further manipulation of the now joined diluent and medicament compartments so that the diluent/medicament solution can flow into the outlet compartment (22); and forming an outlet port (30) in communication with the outlet compartment (22), the outlet port (30) being adapted for connection to an IV administration device."

VII. The appellant (patentee) argued essentially as follows:

The newly filed documents D5, D6 and D7 should not be introduced into the procedure because they were late filed and not relevant.

The amendments applied to the claims invalidated the arguments of the Opposition Division with respect to the mere function, and therefore not distinguishing, nature of certain features. The fact that now in claim 1 the contents of each compartment were specified did not represent any significant departure from the granted subject-matter, being such feature already contained in the granted method claim 14.

Regarding the inventive step, document D3 did not disclose a container having peelable seals, delimiting the compartments. Whenever the containers disclosed in document D3 were intended to contain a powdered drug and a diluent in respective adjacent compartments for intravenous administration additional barriers forming a buffer chamber between the compartments had be to

provided to avoid any transfer between the compartments (see Figures 20 to 24). The different compartments were put in communication by tearing the separation walls and not by peeling the seals. There was no reason to believe that the person skilled in the field would necessarily replace these double separation walls of document D3 by a single peelable sealing as disclosed by document D1. Document D3 did not disclose the spatial disposition of the compartments claimed by the invention either. Such relationship had the advantage that only correctly mixed medicaments could be delivered through the outlet. The third (outlet) compartment of the invention was necessary in order to assure complete mixing of medicament and diluent prior to delivery to the patient.

In its letter of appeal the appellant rigorously contested that a person skilled in the art would even have considered a nursing container with an unsafe single breakable seal between the powder and diluent compartments as disclosed in document D2, Figure 18, and combine its teaching with the one of D3 or any other document to arrive at a drug container intended for intravenous use according to the patent in suit.

VIII. The respondent argued as follows:

Among the newly filed documents at least document D7 should be introduced into the procedure because it disclosed an easy to peel seal. Documents D5 and D6 represented the general state of the art.

The new version of the claims submitted during the oral proceedings represented a shift in the claimed subject matter which was not acceptable at such a late stage.

Novelty was acknowledged. Regarding inventive step, the third compartment of the container according to the invention was not necessary in order to guarantee that only completely mixed medicaments could be delivered to the patient, because the barrier provided by closing the outlet valve was already sufficient for this purpose. It followed that the claimed invention was made obvious by the embodiment with two compartments of Figure 23 of document D3 in combination with the teaching of document D1. This known embodiment comprised a compartment (278) for the powder medicament and a compartment (280) for the diluent. Alternatively to the embodiment of Figure 23, also the one of Figures 11 to 14, in combination with the teaching of document D1, rendered the claimed invention obvious.

The container disclosed in Figure 20 of document D3 comprised three compartments like the claimed container, and it was at the discretion of the user to fill the compartments according to the claimed specification. Moreover, document D1 explicitly cited at page 3, line 19, that the known container was divided into compartments to hold plural contents and that the compartments were isolated from each other by a seal having easy-to-peel openability. The opening method disclosed by document D1 was twisting and squeezing the container with the hands (page 7, line 3); pulling tabs could be provided to facilitate peeling (page 5, last line). It was obvious for a skilled person who wanted to increase the cleanliness

of the container to replace a breakable junction as disclosed in Figure 3, reference number 58, of document D3 by a peelable seal according to document D1.

Reasons for the Decision

1. The appeal is admissible.

2. *Late filed documents*

Documents D5 and D6 represent the background state of the art. Document D7 discloses a container with three compartments separated by a seam which seam comprises tubular passages closed by breakable seals or by weldings rupturable by lateral pressure. This document does, however, not disclose a peelable seal extending from one side of the container to the other. All the three documents do not contain any relevant feature beyond those already known by the documents D3 and D1. Accordingly they are disregarded according to Article 114(2) EPC.

3. *Amendments*

The newly filed claim 1 meets the requirements of Article 123(2) and (3) EPC. The subject-matter added in claim 1 consists essentially of the specification that the diluent compartment contains a diluent, that the medical compartment contains a powder medicament and that the peelable seals are made by a partial melting together of polymer present in the front and rear sheet. All the new features of claim 1 are originally contained in the claims 13 and 14 as granted and are -

undisputedly - covered by the content of the application as filed.

Claims 2 to 12 correspond to the granted claims 2 to 12, claims 13 to 16 correspond to the granted claims 14 to 17.

4. *Novelty*

Novelty of the newly filed claims has not been challenged and the Board sees no reason to doubt it.

5. *Inventive step*

5.1 The patent as granted, see EP-B-0 541 715, page 2, lines 30 to 41, designates document D2 as the closest prior art. Although the title of that document could suggest a more general use not excluding IV administration, its claims and the whole description exclusively refer to a nursing container, i.e. administration via the mouth into the digestive tract of a baby patient. It is clear to any person skilled in the art that the safety requirements for storage and preparation of a substance intended for nutritional use are less severe than they are for an intended IV administration. In fact, there is only one diaphragm (24) in the container disclosed in document D2 to separate the fluid containing chamber from the powder containing one (see Figures 6 to 8, and 18) which according to document D3 is too unsafe a solution which therefore suggests a buffer chamber (214) construction defined by two breakable diaphragms (196A and l96B) to separate the two chambers for IV application (see Figures 22 and 23).

Therefore, it has been common ground that for the amended claims not D2 but document D3 represents the closest state of the art. Of the various flexible containers disclosed therein two are of particular relevance with respect to the claimed subject-matter.

5.1.1 The embodiment of a flexible container illustrated in Figure 20 and described in column 15, lines 10 to 61, of document D3 comprises a transparent flexible front sheet (240), a flexible rear sheet (244) sealed to the front sheet (24) at a common peripheral edge; a first seal (246, 248) extending between two sides of the edge and separably joining the front (240) and the rear (244) sheet to form a first compartment (228) containing a first component (234); a second seal (256, 258) extending between the two sides and separably joining the front and rear sheet (240, 244) to form a third compartment (232), adjacent the outlet, containing a third component (238); and a second compartment (230) containing a second component (236), intermediate the first compartment (228) and the third compartment (232); an outlet port (266C) in communication with the third compartment (232), the outlet port being adapted for connection to an IV administration device, whereby the medicament solution is administered to a patient.

The seals of this known device (see the paragraph bridging columns 10 and 11, and the paragraph bridging columns 14 and 15)) are made of a third sheet (40, 194, 196) and joined to them along two lines of securement (34, 222, 224). By grasping the front and the rear sheets and manually separating them, pulling them in opposite directions, the seal will be ruptured along

the line of securement. Since the container is intended for IV administration it is provided with a double barrier of two seals forming between them a buffer chamber which prevents, or at least makes visible, any leakage and unintended mixing of the contents of two adjacent compartments during storage.

All the three compartments of this known embodiment are filled with components, about the consistency and nature of which (fluid, powdered drug, diluent) document D3 is silent. There is not any moisture impermeable cover sheet sealed to the front sheet.

5.1.2 The embodiment of a flexible container illustrated in Figures 23 to 26 and described in column 16, line 2, to column 17, line 34, deals with the problem to store a powdered and a fluid drug safely side by side in adjacent compartments without any moisture transmission occurring. The container (268) for this purpose consists of only two compartments (278 and 280), the one (280) adjacent the outlet being filled with the diluent and the one (278) remote from the outlet containing the powdered drug. The two compartments (278 and 280) are again safely separated by a buffer chamber comprising the two breakable seals (312 and 314). The powder compartment (278) comprises a moisture impermeable cover sheet peelably sealed over the front sheet of the powder compartment (278).

5.1.3 Considering the fact, that the embodiment described in paragraph 5.1.2 above envisages the same purpose as the claimed subject-matter of the patent in suit, this embodiment is given the preference over the embodiment analysed in paragraph 5.1.2 to serve as the closest

prior art from which to start inventive step considerations.

The subject-matter of Claim 1 differs from this state of the art by the following features:

(i) There is a second seal extending between the two sides ... to form an outlet compartment, the outlet compartment being empty when the diluent and medicament are in their separate compartments.

(ii) Both, the first and the second, seals are peelable seals such that they are rupturable by hydraulic pressure generated by manipulation of an adjacent fluid containing compartment. A precise definition of a "peelable seal" in the meaning of the patent is given on page 5, lines 5 to 14, of EP-B-0 541 715. When opening of a peelable seal in the meaning of the patent in suit the two sheets which have been joint by welding are disengaged along their welded surfaces. In contrast thereto, the seal disclosed in document D3 is opened by traction which causes breaking across the material of the diaphragm (196) adjacent the welding line.

5.2 The container according to the closest state of the art as defined in paragraph 5.1.2 above suffers from the drawback that the rupture of the two diaphragms defining the buffer chamber may produce particles of the diaphragm material which float in the infusion solution. Moreover, if not particular care is taken by the nursing person, who may be a medical lay person in a case of emergency, undissolved powder material may inadvertently accumulate in the outlet port and cause

harm to the patient. Since the seal lines of the known container are ruptured by pulling apart the external sheets of the container the grasping position, the manner of use is not unambiguous. But even when grasped at the right position a considerable traction force has to be applied to rupture the two seals defining the buffer chamber which may result in the unintended vulneration of neighbouring seams.

The problem underlying the patent in suit is, therefore, to find a container for safe combined storage of a powdered medicament and a diluent for solutions which warrants that a ready-to-use infusion solution may be safely prepared even by an inexperienced person and under emergency conditions.

This problem is solved by the features (i) and (ii) above. The use of the peelable seals, which respond on the action of hydraulic pressure, in combination with the particular sequence of the contents of the chambers involves the effect that seals between the chambers of the container according to the patent in suit can only be opened in a predetermined sequence starting with the seal between the diluent containing and the powder containing chambers. This is the consequence of the fact that hydraulic pressure only propagates in a liquid but not in a powder medium.

5.3 Document Dl discloses plural chamber containers which are adapted to mix two or more substances, The seal between two adjacent containers is called to have "easy-to-peel openability" and has been acknowledged by the appellant to qualify for a "peelable seal" in the meaning of the patent in suit.

In their empty state the disclosure of document Dl, therefore, may cover three-chamber containers which are separated by a first and a second peelable seal. In their storage condition, which is claimed by the patent in suit, document Dl exclusively discloses containers all the chambers of which are filled with liquids. Consequently, document Dl fails to deliver any hint to the unidirectional operability which is crucial to the claimed invention.

Although the container illustrated in Figure 18 of document D2 comprises a sequence of three chambers having the same contents as claimed, the fact that the rupturable seal disclosed therein is opened by grasping and pulling apart implies that the seals can also be opened in sequences other than the intended one. Therefore, document D1 equally fails to deliver a hint to unidirectional operability.

6. Since, therefore, neither a combination of documents D3 and Dl, nor of D3 with D2 as asserted by the Opposition Division, leads to the container according to claim 1 in an obvious manner, claim 1 is allowable.

The method according to independent claim 13 inevitably produces a container as specified in claim 1. Claim 13 is, therefore equally allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form on the basis of the following documents:

   – Claims 1 to 16 as submitted during the oral proceedings;

   – description as granted with the proviso that on page 3, line 10, the expression: "claim 14" is replaced by: "claim 13";

   – figures as granted.

The Registrar: The Chairman:

V. Commare W. D. Weiß