**BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS**

**BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE**

**CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS**

**Internal distribution code:**
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

# Datasheet for the decision of 4 February 2009

**Case Number:** T 0327/07 - 3.2.02

**Application Number:** 97912114.2

**Publication Number:** 1011605

**IPC:** A61J 1/10

**Language of the proceedings:** EN

**Title of invention:**
Flexible plastic container with three chambers

**Patentee:**
B. BRAUN MELSUNGEN AG

**Opponent:**
Fresenius Kabi Deutschland GmbH

**Headword:**
-

**Relevant legal provisions:**
-

**Relevant legal provisions (EPC 1973):**
EPC Art. 52(1), 54, 56

**Keyword:**
"Novelty (yes)"
"Inventive step (yes)"

**Decisions cited:**
-

**Catchword:**
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0327/07 - 3.2.02

# D E C I S I O N
**of the Technical Board of Appeal 3.2.02**
**of 4 February 2009**

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | B. BRAUN MELSUNGEN AG<br>Carl-Braun-Strasse 1<br>D-34212 Melsungen (DE) |
| **Representative:** | Jönsson, Hans-Peter<br>Patentanwälte<br>von Kreisler Selting Werner<br>Postfach 10 22 41<br>D-50462 Köln (DE) |
| **Respondent:** (Opponent) | Fresenius Kabi Deutschland GmbH<br>Else-Kröner-Strasse 1<br>D-61352 Bad-Homburg v.d.H. |
| **Representative:** | Luderschmidt, Schüler & Partner<br>Patentanwälte<br>Postfach 3929<br>D-65029 Wiesbaden (DE) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted 22 December 2006 revoking European patent No. 1011605 pursuant to Article 102(1) EPC 1973.** |

**Composition of the Board:**

**Chairman:** M. Noel
**Members:** S. Chowdhury
A. Pignatelli

## Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 1 011 605.

II. The opposition was filed against the whole patent and based on Article 100(a) (lack of novelty and inventive step).

III. With its decision posted on 22 December 2006 the Opposition Division held that, although the subject-matter of claims 1 and 2 was novel, it lacked an inventive step and revoked the patent, accordingly.

The following documents cited in the opposition procedure are of interest in the appeal procedure:

D1: EP-A-0 790 051
D4: EP-B1-0 295 204
D6: US-A-4 465 488
D9: US-A-4 458 811.

IV. A notice of appeal against this decision was filed on 15 February 2007 and the appeal fee was paid on the same day. The statement of grounds was submitted on 23 April 2007.

V. Oral proceedings were held on 4 February 2009. The respondent made no written submissions and notified the office that it would not participate in the oral proceedings.

The appellant requested that the decision under appeal be set aside and the patent be maintained as granted with page 3 amended.

VI. Claims 1 and 2 read as follows:

"1. A flexible plastic container (1) for the spatially separated storage and, optionally, selective sterilization of the ingredients of preparations for parenteral or enteral use, consisting of only three compartments a first compartment (3), a second compartment (4) and a third compartment (5), said compartments being separated from each other by means of leaktight welds of the envelope material, said compartments having one closable fill in opening (7), (8), and (9), each; connecting means (10) and (11) which are formed as peelable heat-sealed welds which can be opened sterilely from the outside, by which respective flow connections between compartments (3), (4), and (5) can be provided; wherein the proportions by volume of said three compartments (3), (4), and (5) are selected such that in the working position as resulting from suspendin by the hang up means (12) a rapid and complete mixture of all ingredients within the third compartment (5) is possible by opening the connecting means (10) and (11) characterized in that the first compartment (3) contains carbohydrates, the second compartment (4) lipide and the third compartment (5) amino acids."

2. The use of a flexible plastic container according to claim 1 for the selective sterilization, spatially separated storage, rapid mixing and administration of carbohydrates, lipides, and amino acids."

VII. The appellant argued as follows:

The opposition division's argument, that it was general knowledge that infusing carbohydrates directly into patients could be dangerous, was not correct, there was no evidence of this knowledge and D4 explicitly taught against this. D6 taught to place the most benign liquid in the lower chamber and this was the carbohydrate as in D4. D9 disclosed the use of two chambers only and column 6 of D9 referred to the mixing of an antibiotic and a nutritional material.

By placing the carbohydrates in an upper chamber and amino acid in the lower chamber, according to the invention, the danger of separation of the fat emulsion owing to contact with highly concentrated carbohydrate solution was avoided, and a complete mixing resulting in a homogeneous mixture was possible.

## Reasons for the decision

1. The appeal is admissible.

2. *Amendments*

The amendment to page 3 of the patent was effected in order to clearly restrict the scope of claim 1 to a three compartment container. The amendment was occasioned by a ground of opposition (lack of novelty with respect to D1) and is allowable.

3. *Novelty*

The question of novelty was not an issue for the opposition division. Claim 1 defines a container consisting of only three compartments, which clearly distinguishes the claimed container from that of D1 (cited under Article 54(3) EPC) which consists of more than three compartments. No further novelty objection arises against the subject-matter of the claims.

4. *Inventive step*

4.1 The patent in suit is based on the problem defined in paragraph [0005] as follows: With said plastic containers according to prior art mixing of the separate components of the preparations for parenteral or enteral use is possible without time-consuming kneading of the bags by the hospital personnel after opening the ports. Upon opening the ports, the ingredients of the upper compartments being in working position flow without expenditure of mechanical energy due to gravitational force into the lower mixing chamber. However, the spatial arrangement of the ingredients, in particular according to D4, results in a relatively long mixing time before the solution can be administered to the patient.

4.2 D4 is the closest prior art document, a position with which all parties and the opposition division concur. The container of claim 1 of the patent in suit differs from the container of D4 in that in the claimed container the first compartment (3) contains carbohydrates, the second compartment (4) lipids and the third compartment (5) amino acids, whereas in the

container of D4 the first compartment contains amino acids, the second compartment lipids and the third compartment carbohydrates. Effectively, the position of the amino acids and the carbohydrates of D4 have been exchanged according to present claim 1.

The exchange of the position of the amino acids and the carbohydrates compartments ensures that due to the higher density of carbohydrates in relation to amino acids, a particular simple and rapid mixing of these ingredients without time-consuming pressing and kneading operations by the hospital personnel is possible (paragraph [0017]).

4.3 The above problem and solution combination is not disclosed in the prior art so that the claimed subject-matter involves an inventive step.

4.4 According to the opposition division the document D6 suggests placing the amino acids in the lowermost compartment, which immediately leads to the subject-matter of claim 1. The Board disagrees with this conclusion for the following reasons:

D6 suggests (column 5, lines 8 to 19) placing the fluid having the smaller volume in the top chamber and the fluid having the larger volume in the lower chamber. As a safety precaution it is preferred that the most benign fluid be in the lower chamber so that in the event of inadequate mixing it is the first fluid to be administered to the patient. D6 then goes on to suggest placing in the amino acid in the upper chamber and dextrose in the lower chamber.

The implication is that dextrose is a benign fluid, or at least that its placement in the lower compartment is not unsafe. This of course depends on the concentration of dextrose, but there is no evidence in the prior art that any solution of dextrose would be unsafe for administration to a patient such that precautions in this respect would be necessary. That it is safe to place glucose in the lower chamber is also supported by D4 in which a 40% an aqueous solution of glucose (D4: column 4, lines 5 to 8) is placed in the lowermost compartment.

Therefore, neither of D4 or D6 suggests that there is a safety issue with the placement of a carbohydrate in the lowermost compartment, which would require a re-arrangement of the compartments.

4.5 D9 describes a two chamber container (Figure 2) in which dextrose is placed in the upper compartment and amino acid or fat in the lower compartment. It is stated in column 6, lines 10 to 12 that breaking a frangible member allows free flow in mixing of the two fluids.

This is a two chamber container and there is no reason why a third chamber should be added to this arrangement, or if one is added, there is no indication of how the different fluids should be housed. There is a general disclosure of multiple compartments (column 6, lines 46 to 50) but again there is no indication of how the different fluids should be housed in the different compartments.

Moreover, there is no pointer in either one of D4 or D9 to the other. The reference in D9 to free flow in mixing is merely a gravitational effect, not a density driven effect as used in the patent in suit. Therefore, the combination of D4 with D9 involves an ex post facto consideration.

4.6 The effect of exchanging the arrangement of the carbohydrate and amino acid chambers of D4, and achieving the present invention, is more than merely a rapid mixing of the solutions. The resulting mixture is homogeneous over time (compare Table 1 of the patent and the Comparative example), and the danger, which is present in the container of D4, is avoided that a fat emulsion may separate upon contact with a high concentration carbohydrate.

4.7 For the foregoing reasons claim 1 of the patent in suit involves an inventive step.

5. Since the container of claim 1 involves an inventive step, so does its use. Therefore, claim 2 also meets the inventive step requirement of Article 52(1) EPC 1973.

## Order

**For these reasons it is decided that:**

1. The decision under appeal is set aside.

2. The case is remitted to the department of the first instance to maintain the patent on the basis of the following documents:

   Claims 1 and 2 as granted.
   Description pages 2 and 4 to 6 as granted.
   Description page 3 filed at the oral proceedings.
   Drawings as granted.

The Registrar The Chairman

D. Sauter M. Noel