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**Datasheet for the decision
of 23 January 2024**

Case Number: T 1858/21 - 3.3.02

Application Number: 12766821.8

Publication Number: 2731425

IPC: A01N1/02, A61J1/10, B32B27/08,
B32B27/30, B32B27/32, A61K35/18

Language of the proceedings: EN

Title of invention:

RED BLOOD CELL PRODUCTS AND THE STORAGE OF RED BLOOD CELLS IN
CONTAINERS FREE OF PHTHALATE PLASTICIZER

Patent Proprietor:

Fenwal, Inc.

Opponent:

BASF SE

Headword:

Relevant legal provisions:

EPC Art. 123(2), 84

Keyword:

Amendments
Claims - clarity

Decisions cited:

Catchword:



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Case Number: T 1858/21 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 23 January 2024

Appellant: Fenwal, Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 9 August 2021
revoking European patent No. 2731425 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman M. O. Müller
Members: S. Bertrand
B. Burm-Herregodts

Summary of Facts and Submissions

- I. The appeal by the patent proprietor lies from the opposition division's decision to revoke European patent No. 2 731 425 under Article 101(3) (b) EPC.
- II. The impugned decision was restricted to issues under Articles 123(2) and 84 EPC. The opposition division's conclusions made in this decision included the following:
 - Claim 1 of the main request and auxiliary requests 1 to 14 did not fulfil the requirements of Article 123(2) EPC.
 - Claims 1 and 3 of auxiliary request 9 did not meet the requirements of Article 84 EPC.
- III. In the statement of grounds of appeal, the patent proprietor ("appellant") contested the opposition division's reasoning. It submitted sets of claims according to the main request and auxiliary requests 1 to 21.
- IV. In the reply to the grounds of appeal, the opponent ("respondent") provided counter-arguments regarding the admissibility of the appeal, added matter and the admittance of some claim requests.
- V. The board summoned the parties to oral proceedings, as requested by the parties, and issued a communication under Article 15(1) RPBA.
- VI. Oral proceedings before the board were held by videoconference on 23 January 2024. During the oral proceedings, the respondent withdrew its request that the appeal be considered not admissible. The appellant

filed new sets of claims to replace auxiliary requests 17 and 18 filed during the written appeal proceedings.

VII. The parties' requests, where relevant to the decision, were as follows.

The appellant requested that:

- the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution on the basis of the main request filed with the statement of grounds of appeal or any of auxiliary requests 1 to 21, equally filed with the statement of grounds of appeal, should any of these requests meet the requirements of Articles 84 and 123(2) EPC,
- or, alternatively, the decision under appeal be set aside and the patent be maintained in amended form on the basis of the claims of any of these requests.

The respondent requested that:

- the appeal be dismissed, implying that the opposition division's decision to revoke the patent be upheld,
- auxiliary requests 6, 8, 10, 12, 14 and 21 not be admitted into the proceedings, or
- the case be remitted to the opposition division for further prosecution, should one of the requests meet the requirements of Articles 84 and 123(2) EPC.

VIII. The appellant's case and the respondent's case are summarised in the reasons below.

Reasons for the Decision

Auxiliary requests 6 and 8

1. Added subject-matter - Claim 1

1.1 Claim 1 of auxiliary requests 6 and 8 reads as follows (emphasis added by the board; strike through and bold text representing deletions and additions, respectively, compared with claim 1 as filed):

"1. A red blood cell product comprising:

*(a) a container comprising a wall defining an interior chamber ~~wherein at least a portion of the wall is made of a polymeric material combined with a non-phthalate plasticizer~~ **and being made of a polymeric material free of phthalate plasticizer, wherein the polymeric material has a plastic composition including 55%-80%, by weight, PVC and 20%-45% hemolysis-suppressing plasticizer/agent, wherein, as a percentage of the overall composition, 3-5%, by weight, is BTHC as a first hemolysis-suppressing plasticizer/agent, wherein 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH) is a second hemolysis-suppressing plasticizer/agent;***

(b) a suspension of red blood cells contained within said chamber, said suspension comprising:

(i) concentrated red blood cells; and

(ii) a hypotonic solution comprising at least a nutrient, a buffer and having a pH of at

least ~~approximately~~ 8.0, wherein the hypotonic chloride-free solution comprises:

1 mM to 2.2 mM adenine;

20 mM to 110 mM mannitol;

2.2 mM to 90 mM sodium citrate;

*16 mM to 30 mM sodium phosphate dibasic;
and*

20 mM to 140 mM glucose, wherein the pH of the solution is at least 8.0."

In the above, BTHC is n-butyryltri-n-hexylcitrate ester.

- 1.2 The respondent contended that claim 1 of auxiliary requests 6 and 8 added matter beyond the content of the application as filed.
- 1.3 The appellant submitted that the plastic composition as defined in claim 1 of auxiliary requests 6 and 8 was based on the passages on page 13, lines 24 to 28 and page 12, lines 26 to 32 of the application as filed.
- 1.4 The board does not agree with the appellant.

The passages on page 13, lines 24 to 28 and page 12, lines 26 to 32 referred to by the appellant as a basis for the plastic composition of claim 1 of auxiliary requests 6 and 8 disclose the following:

"In another embodiment, the plastic composition may include approximately 55%-80%, by weight, PVC and approximately 20%-45% hemolysis-suppressing plasticizer/agent wherein, as a percentage of the overall composition approximately 3-25% and more

preferably 5%-15%, by weight, is a first plasticizer/agent capable of suppressing hemolysis, such as BTHC." (page 13, lines 24 to 28)

"More preferably, at least the first and second extractable agents or plasticizers are extractable agents or plasticizers, each effective in suppressing hemolysis in RBCs. Thus, in the embodiment where BTHC is one of such extractable hemolysis-suppressing agents, the other of the at least first or second agents or plasticizers may be a non-phthalate plasticizer, such as DINCH, which also is effective in suppressing hemolysis." (page 12, lines 26 to 32)

It is acknowledged that the first passage (page 13, lines 24 to 28 of the application as filed) discloses a plastic composition comprising 55-80% by weight polyvinyl chloride (PVC) and 20-45% hemolysis-suppressing plasticizer/agent, with BTHC being a first hemolysis-suppressing plasticizer/agent, as specified in claim 1 of auxiliary requests 6 and 8. The board further acknowledges that by selecting and combining the two lower limits of the ranges 3-25% and 5-15% disclosed in this passage, a range of 3-5% is obtained for the amount of BTHC, as specified by claim 1 of auxiliary requests 6 and 8. This passage, however, does not disclose the presence of DINCH as a second hemolysis-suppressing plasticizer/agent as required for the plastic composition of claim 1 of auxiliary requests 6 and 8. The second passage (page 12, lines 26 to 32) discloses DINCH as a second hemolysis-suppressing plasticizer/agent, in addition to the BTHC. The second hemolysis-suppressing plasticizer/agent disclosed in this passage is thus as specified by claim 1 of auxiliary requests 6 and 8. However, this passage

does not disclose the remaining features of the plastic composition of claim 1 of auxiliary requests 6 and 8.

The board acknowledges that the claimed plastic composition is obtained by combining the plasticizer mixture of DINCH and BTHC of the second passage with the features disclosed for the plastic composition in the first passage, including the above-discussed combination of the two lower limits of the BTHC amount.

However, the description as filed (page 12, line 16 to page 14, line 2) includes several embodiments of the invention with regard to the plastic composition. As submitted by the respondent, these different embodiments relate to plastic compositions with or without PVC (page 12, lines 17 and 18). Furthermore, the embodiments disclosed on page 13, lines 14 to 18; page 13, lines 18 to 22; page 13, lines 24 to 28; and page 13, line 24 to page 14, line 2 disclose various different plastic compositions with PVC.

It follows that three selections are needed to arrive at the subject-matter of claim 1 of auxiliary requests 6 and 8: a first selection of the specific plastic composition with PVC disclosed on page 13, lines 24 to 28 out of the various plastic compositions disclosed on page 12, line 16 to page 14, line 2 of the application as filed; a second selection of the mixture of DINCH and BTHC disclosed in the passage on page 12, lines 26 to 32 of the application as filed; and lastly a third selection of the BTHC amount out of the different alternatives covered by the two ranges 3-25% and 5-15% disclosed in the above-quoted passage on page 13, lines 24 to 28 of the application as filed (by combining the two lower limits disclosed in that passage). There is,

however, no pointer in the application as filed towards making any of these three selections.

1.5 Since three selections in the description of the application as filed are needed to arrive at the subject-matter of claim 1 of auxiliary requests 6 and 8 and since there is no pointer in the application as filed towards any of these selections, claim 1 of auxiliary requests 6 and 8 introduces subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC.

1.6 Auxiliary requests 6 and 8 are therefore not allowable.

Main request and auxiliary requests 1 to 5 and 7

2. Added matter - claim 1

2.1 Claim 1 of the main request and auxiliary request 1 differs from claim 1 of auxiliary requests 6 and 8 in that one of the hemolysis-suppressing plasticizers/agents is a citrate ester (claim 1 of auxiliary requests 6 and 8 encompasses a specific citrate, i.e. BTHC) and in that the plastic composition further comprises less than 3.0% of stabilizers and lubricants.

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary requests 6 and 8 in that one of the hemolysis-suppressing plasticizers/agents is "another hemolysis-suppressing plasticizer" (BTHC in claim 1 of auxiliary requests 6 and 8) and in that the plastic composition further comprises less than about 3.0% of stabilizers and lubricants.

Claim 1 of auxiliary requests 3 and 4 corresponds to claim 1 of auxiliary request 2 except that the term "about" has been deleted.

Claim 1 of auxiliary requests 5 and 7 differs from claim 1 of auxiliary requests 6 and 8 in that the plastic composition further comprises less than 3.0% of stabilizers and lubricants.

2.2 The respondent contended that claim 1 of the main request and auxiliary requests 1 to 5 and 7 added matter beyond the content of the application as filed.

2.3 The plastic composition with the feature "less than (about) 3.0% of stabilizers and lubricants" in claim 1 of the main request and auxiliary requests 1 to 5 and 7 is disclosed on page 13, lines 14 to 18, i.e. for one of the various different plastic compositions with PVC disclosed in the embodiments on pages 13 and 14 of the application as filed (1.4, *supra*).

Like claim 1 of auxiliary requests 6 and 8, claim 1 of the main request and auxiliary requests 1 to 5 and 7 refers to a range of 3-5% of a hemolysis-suppressing plasticizer (a plasticizer which is specified in the main request and auxiliary requests 1 to 5 and 7 in a more or less restricted way than in auxiliary requests 6 and 8).

For each of the main request and auxiliary requests 1 to 5 and 7, two selections are required to arrive at the subject-matter of claim 1: one for the plastic composition as disclosed on page 13, lines 14 to 18 out of the various plastic compositions disclosed on page 12, line 16 to page 14, line 2 of the application as filed, and one for the range of 3-5% for the amount of the hemolysis-suppressing plasticizer on page 13, lines 24 to 28 of the application as filed (by combining the two lower limits disclosed in that passage). However, like in the context of claim 1 of auxiliary requests 6

and 8, there is no pointer in the application as filed towards these two selections.

3. The main request and auxiliary requests 1 to 5 and 7 are thus not allowable either.

Auxiliary requests 9 and 10

4. Added matter - claim 1

- 4.1 Claim 1 of auxiliary requests 9 and 10 essentially differs from claim 1 of auxiliary requests 6 and 8 on account of:

- the presence of two non-phthalate plasticizers in an amount of 20% by weight (20-45% hemolysis-suppressing plasticizer/agent in claim 1 of auxiliary requests 6 and 8)
- the presence of a citrate ester capable of suppressing hemolysis in an amount of 3% by weight instead of 3-5% by weight of the specific citrate BTHC in claim 1 of auxiliary requests 6 and 8
- the amount of 17% by weight of DINCH (the amount of DINCH is not specified in claim 1 of auxiliary requests 6 and 8)
- the presence of less than 3.0% of stabilizers and lubricants

- 4.2 The respondent contended that claim 1 of auxiliary requests 9 and 10 contravened Article 123(2) EPC.

- 4.3 The appellant submitted that claim 1 of auxiliary requests 9 and 10 was based on the disclosure on page 13, lines 14 to 18 and page 13, lines 24 to 28.

- 4.4 The board disagrees with the appellant.

The passage on page 13, lines 14 to 18 reads as follows: "*In an embodiment, containers of the type described above may include approximately 55-80%, by weight, PVC resin and approximately 20-45%, by weight, of at least first and second phthalate plasticizer(s) wherein a preferred plasticizer is BTHC and/or DINCH, and less than about 3% of stabilizers and lubricant.*" This embodiment discloses a plastic composition as required by claim 1 of auxiliary requests 9 and 10, except that the amount of the at least first and second phthalate plasticizer(s) is approximately 20-45% by weight rather than the specific value of 20% by weight of two non-phthalate plasticizers in claim 1 of auxiliary requests 9 and 10, and that the only plasticizers disclosed are DINCH and/or BTHC (DINCH and a citrate ester capable of suppressing hemolysis in claim 1 of auxiliary requests 9 and 10).

Furthermore, this passage does not directly disclose the further features of claim 1 of auxiliary requests 9 and 10 that (i) 3% by weight of the plastic composition is the citrate ester capable of suppressing hemolysis and (ii) 17% by weight of the plastic composition is DINCH.

The passage on page 13, lines 24 to 28, also referred to by the appellant as a basis, discloses a plastic composition including 55-80% by weight PVC and approximately 20-45% hemolysis-suppressing plasticizer/agent, with approximately 3-25% and more preferably 5-15% by weight of the overall composition being a first plasticizer/agent capable of suppressing hemolysis, such as BTHC.

This passage discloses that the amount of the hemolysis-suppressing plasticizer/agent is approximately 20-45% by weight rather than the specific value of 20% by weight of two non-phthalate plasticizers in claim 1 of auxiliary requests 9 and 10. Furthermore, this passage discloses that the only plasticizer is a first plasticizer/agent capable of suppressing hemolysis, such as BTHC (claim 1 of auxiliary requests 9 and 10 requires DINCH and a citrate ester capable of suppressing hemolysis). Lastly this passage does not disclose the presence of less than 3.0% of stabilizers and lubricants.

The combination of the above passages on page 13, lines 14 to 18 and page 13, lines 24 to 28 does not disclose the combination of the plasticizers required by claim 1 of auxiliary requests 9 and 10, namely DINCH and a **citrate ester** capable of suppressing hemolysis. For this reason alone, claim 1 of auxiliary requests 9 and 10 does not meet the requirements of Article 123(2) EPC.

Furthermore, at least two selections are required to arrive at the claimed subject-matter: a first selection of the specific plastic composition on page 13, lines 14 to 18 in combination with the specific plastic composition on page 13, lines 24 to 28 (out of the various plastic compositions disclosed on page 12, line 16 to page 14, line 2 of the application as filed), and a second selection of the specific amount of 3% of a plasticizer/agent capable of suppressing hemolysis on page 13, lines 24 to 28 of the application as filed.

There is, however, no pointer towards either of these two selections.

Claim 1 of auxiliary requests 9 and 10 does not meet the requirements of Article 123(2) EPC for this reason too.

4.5 Auxiliary requests 9 and 10 are not allowable.

Auxiliary requests 11 to 14

5. Added matter - claim 1

5.1 Claim 1 of auxiliary requests 11 to 14 essentially differs from claim 1 of auxiliary requests 6 and 8 on account of:

- the amount of 5% of BTHC (3-5% in claim 1 of auxiliary requests 6 and 8)
- the amount of 15-30% of DINCH (the amount of DINCH is not specified in claim 1 of auxiliary requests 6 and 8)
- the presence of 2-12% epoxidized oil and 0.5-3.0% of additional co-stabilizers and lubricants

5.2 The respondent contended that claim 1 of auxiliary requests 11 to 14 did not fulfil the requirements of Article 123(2) EPC.

5.3 The appellant submitted that claim 1 of auxiliary requests 11 to 14 was based on the disclosure on page 13, line 28 to page 14, line 2 and page 12, lines 26 to 32 of the application as filed.

5.4 The board disagrees with the appellant.

The passage on page 13, line 28 to page 14, line 2 of the application as filed discloses the "polymeric material" specified in claim 1 of auxiliary requests 11 to 14, except that the amount of BTHC is 5-15% (5% in

claim 1 of auxiliary requests 11 to 14) and one of the hemolysis-suppressing plasticizers/agents is one or more of ATBC, DINCH or other extractable agents (DINCH in claim 1 of auxiliary requests 11 to 14).

The passage on page 12, lines 26 to 32 of the application as filed refers to the combination of BTHC and DINCH as the hemolysis-suppressing plasticizers/agents, as required by claim 1 of auxiliary requests 11 to 14.

The board acknowledges that, by selecting the lower amount of the range 5-15% disclosed in this passage, a value of 5% is obtained for the amount of BTHC, as specified by claim 1 of auxiliary requests 11 to 14.

The board also acknowledges that the claimed "polymeric material" is obtained by combining the plasticizer mixture of DINCH and BTHC (second passage on page 12, lines 26 to 32 of the application as filed) with the features disclosed for the plastic composition (first passage on page 13, line 28 to page 14, line 2 of the application as filed), including the above-discussed selection of 5% of BTHC.

However, to arrive at the "polymeric material" required by claim 1 of auxiliary requests 11 to 14, three selections are required: a first selection of the specific plastic composition with PVC disclosed on page 13, line 28 to page 14, line 2 out of the various plastic compositions disclosed on page 12, line 16 to page 14, line 2 of the application as filed; a second selection of the mixture of DINCH and BTHC disclosed on page 12, lines 26 to 32 of the application as filed; and lastly a third selection of the specific amount of 5% of BTHC on page 13, line 28 to page 14, line 2 of

the application as filed. However, there is no pointer in the application as filed towards each selection. Consequently, claim 1 of auxiliary requests 11 to 14 does not meet the requirements of Article 123(2) EPC.

5.5 Auxiliary requests 11 to 14 are not allowable.

Auxiliary request 15

6. Added matter - claim 1

6.1 Claim 1 of auxiliary request 15 essentially differs from claim 1 of auxiliary requests 9 and 10 in that the term "a citrate ester capable of suppressing hemolysis" present in claim 1 of auxiliary requests 9 and 10 has been replaced with the specific citrate ester "n-butryltri-n-hexyl citrate (BTHC)" in claim 1 of auxiliary request 15.

6.2 During the oral proceedings, the appellant did not dispute that the conclusion drawn regarding the at least two selections needed to arrive at claim 1 of auxiliary requests 9 and 10 also applied to claim 1 of auxiliary request 15.

6.3 Thus, claim 1 of auxiliary request 15 does not meet the requirements of Article 123(2) EPC.

6.4 Auxiliary request 15 is not allowable.

Auxiliary request 16

7. Added matter - claim 5

7.1 Claim 5 of auxiliary request 16 reads as follows
(emphasis added by the board; strike through and bold

text representing deletions and additions, respectively, compared with claim 17 as filed):

"5. A container for storing red blood cell compositions comprising: one or more container walls defining an interior chamber, said container wall(s) ~~comprising a~~ **being made of** polymeric material that ~~is~~ (a) **is at least substantially free of phthalate,** (b) **is free of PVC,** (c) **comprises a non-PVC material** and (d) comprises at least a first plasticizer and a second plasticizer **wherein one of said first and second plasticizers comprises a citrate ester, and wherein the other of said first and second plasticizers comprises 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH),** wherein each of said at least first and second plasticizer is effective in suppressing hemolysis in red blood cells."

7.2 The respondent contended that claim 5 of auxiliary request 16 contained added matter.

7.3 The appellant submitted that claim 5 of auxiliary request 16 was based on the combination of claims as filed, more particularly claims 17, 18, 20 and 27 as filed.

7.4 The board disagrees with the appellant.

Claim 18 as filed discloses that "at least one of said first and second extractable agents comprises a citrate ester". Claim 18 as filed represents a basis for the feature "wherein one of said first and second plasticizers comprises a citrate ester" as specified in claim 5 of auxiliary request 16.

Claim 20 as filed discloses that "*another of said at least first and second agents comprises DINCH or acetyltri-n-butyl citrate*". A first selection of DINCH is thus needed within this claim to arrive at "*the other of said first and second plasticizers comprises 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH)*", as specified in claim 5 of auxiliary request 16.

Claim 27 as filed discloses that "*said polymeric material comprises a non-PVC composition*". This represents the same disclosure as the feature "*c) comprises a non-PVC material*" found in claim 5 of auxiliary request 16.

However, claim 27 as filed is not the only claim directed to the type of polymer (non-PVC in this claim) present in the plastic material. On the contrary, the immediately preceding claim 26 as filed defines this polymer as polyvinyl chloride (i.e. PVC). Since there are thus different alternatives regarding the polymeric material in the claims dependent on independent claim 17 as filed, a second selection of "*a non-PVC composition*" is needed to arrive at "*a non-PVC material*" as required by claim 5 of auxiliary request 16.

Since two selections in the claims as filed are needed to arrive at the subject-matter of claim 5 of auxiliary request 16 and since there is no pointer in the application as filed towards combining both selections, claim 5 of auxiliary request 16 adds matter.

7.5 For these reasons, claim 5 of auxiliary request 16 does not meet the requirements of Article 123(2) EPC and auxiliary request 16 is not allowable.

Auxiliary request 17

8. Added matter - claim 2

8.1 Claim 2 of auxiliary request 17 reads as follows:

"2. The product of claim 1, wherein the entire container is made of said non-PVC polymeric material free of phthalate plasticizer and combined with a non-phthalate plasticizer comprising DINCH."

8.2 The respondent contended that claim 2 of auxiliary request 17 did not comply with the requirements of Article 123(2) EPC.

8.3 The appellant submitted that claim 2 of auxiliary request 17 was based on the combination of study 6 on page 19, lines 4 to 6; page 8, lines 9 to 11; and page 10, lines 14 to 20.

8.4 The board disagrees with the appellant.

First, the application as filed does not include any literal disclosure of *"the entire container"* referred to in claim 2 of auxiliary request 17. This was not disputed by the appellant.

As regards the passages cited by the appellant, the board notes the following.

Page 19, lines 4 to 6 of the application as filed discloses that: *"The other container was made of the same non-PVC polyolefin with DINCH plasticizer coated thereon and gamma irradiated."*

The passage on page 8, lines 9 to 11 discloses that:
"In one embodiment, containers useful in the storage of RBCs as described above include container walls that are made in whole or at least in part of a plastic material that may include at least one or more polymeric compounds."

The passage on page 10, lines 14 to 20 discloses that:
"Of course, even in containers where the walls 12 are made without any PVC, some PVC may be present in small amounts. For example, ports 16 may include plasticized PVC. In any event, as used herein, the terms 'substantially PVC-free' or 'substantially free of PVC' refer to containers in which the walls that are in contact with the RBC composition, i.e., that part of the container that makes up a part of the storage environment, are made from a material that is free of PVC."

None of the above passages, which refer only to the walls of the container, explicitly or implicitly discloses that the **entire container** is made of non-PVC polymeric material.

8.5 For this reason, claim 2 of auxiliary request 17 does not meet the requirements of Article 123(2) EPC.

8.6 Auxiliary request 17 is not allowable.

Auxiliary request 18

9. Auxiliary request 18 contains only one claim - claim 1 - which reads as follows (emphasis added by the board; strike through and bold text representing deletions and additions, respectively, compared with claim 1 as filed):

"1. A red blood cell product comprising:

(a) a container comprising a wall defining an interior chamber ~~wherein at least a portion of the wall is made of a polymeric material combined with a non-phthalate plasticizer~~ **and being made of polymeric material free of phthalate plasticizer and free of PVC and comprising a non-PVC material combined with a non-phthalate plasticizer comprising 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH);**

(b) a suspension of red blood cells contained within said chamber, said suspension comprising:

(i) concentrated red blood cells; and

(ii) a hypotonic solution comprising at least a nutrient, a buffer and having a pH of at least ~~approximately~~ 8.0, **wherein the hypotonic chloride-free solution comprises:**

1 mM to 2.2 mM adenine;

20 mM to 110 mM mannitol;

2.2 mM to 90 mM sodium citrate;

**16 mM to 30 mM sodium phosphate dibasic;
and**

20 mM to 140 mM glucose, wherein the pH of the solution is at least 8.0."

10. Article 123(2) EPC

10.1 The respondent contended that claim 1 of auxiliary request 18 added matter.

10.2 The board does not agree with the respondent. As submitted by the appellant, claim 1 of auxiliary request 18 is based on the combination of claims 1, 2, 3 and 5 as filed with the passages on page 3, lines 24 to 28 and page 10, lines 4 to 8.

Claim 1 as filed discloses the part of claim 1 of auxiliary request 18 which is not highlighted above.

Claim 2 as filed discloses that the non-phthalate plasticizer comprises 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH), as specified in claim 1 of auxiliary request 18.

Claim 3 as filed discloses the hypotonic chloride-free solution referred to in claim 1 of auxiliary request 18.

Claim 5 as filed discloses that the polymeric material comprises a non-PVC composition, as required by claim 1 of auxiliary request 18.

Furthermore, the passage on page 3, lines 24 to 28 discloses a polymeric material that is substantially free of phthalate. This provides a basis for the term "being made of polymeric material free of phthalate plasticizer" found in claim 1 of auxiliary request 18.

Finally, the passage on page 10, lines 4 to 8 discloses a material that is free of PVC, as required by claim 1 of auxiliary request 18.

10.3 The respondent submitted that claims 3 and 5 as filed were dependent only on claim 1 as filed and not on claim 2 as filed. Thus the combination of the features of those claims was not directly and unambiguously disclosed in the application as filed.

The board disagrees. First, the board notes that claim 1 as filed requires *inter alia* the combination of a polymeric material, a non-phthalate plasticizer and a hypotonic solution.

The non-phthalate plasticizer of claim 2 as filed (DINCH) is the only non-phthalate plasticizer defined in the claims as filed. The fact that DINCH is the only specific non-phthalate plasticizer specified in the dependent claims as filed represents a clear pointer towards this plasticizer.

In the same way, the hypotonic composition of claim 3 as filed is the only hypotonic composition defined in the claims. In the same way as set out in the preceding paragraph, this represents a clear pointer to this hypotonic composition.

Lastly, the fact that a non-PVC composition is singled out as the polymeric material in claim 5 as filed also provides a pointer towards this feature of claim 1 of auxiliary request 18. Irrespective of this, the entire application is directed to either PVC or non-PVC as the polymeric material, and there is nothing in the application as filed that would lead the skilled reader to assume that certain features disclosed in the application as filed applied only to PVC compositions and others only to non-PVC compositions. Hence, it is clear that any feature disclosed in the application as filed, including those of claims 1 to 3 as filed, apply to both PVC and non-PVC compositions.

Thus, contrary to the respondent's submission, the features of claims 1, 2, 3 and 5 can be combined without contravening Article 123(2) EPC. Thus, the sole claim of auxiliary request 18, claim 1, does not contain any added matter.

11. Article 84 EPC

The respondent did not object to the clarity of claim 1 of auxiliary request 18 and the board sees no reason to find otherwise.

12. The board concludes that claim 1 of auxiliary request 18 meets the requirements of Articles 123(2) and 84 EPC.

Admittance of auxiliary requests 6, 8, 10, 12, 14 and 21

Since it was found that auxiliary requests 6, 8, 10, 12 and 14 were not allowable and since there was no need to discuss the allowability of auxiliary request 21, a decision on their admittance was not required.

Remittal

13. The parties requested that the case be remitted to the opposition division if one of the requests is found to meet the requirements of Articles 123(2) and 84 EPC.

13.1 In line with the parties' requests and since the opposition division decided solely on Articles 123(2) and 84 EPC, there are special reasons to remit the case to the opposition division for a further examination of auxiliary request 18.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



M. Schalow

M. O. Müller

Decision electronically authenticated