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**Datasheet for the decision  
of 18 September 2014**

**Case Number:** T 0112/10 - 3.3.07  
**Application Number:** 00950792.2  
**Publication Number:** 1131077  
**IPC:** A61K33/10, A61M1/16, A61M1/28,  
A61P13/12, A61K33/14  
**Language of the proceedings:** EN

**Title of invention:**

BICARBONATE-BASED SOLUTION IN TWO PARTS FOR PERITONEAL  
DIALYSIS OR AS A SUBSTITUTION SOLUTION IN CONTINUOUS RENAL  
REPLACEMENT THERAPY

**Patent Proprietor:**

Baxter International Inc.

**Opponent:**

Fresenius Medical Care Deutschland GmbH

**Headword:**

BICARBONATE-BASED SOLUTION IN TWO PARTS FOR PERITONEAL  
DIALYSIS OR AS A SUBSTITUTION SOLUTION IN CONTINUOUS RENAL  
REPLACEMENT THERAPY/Baxter International

**Relevant legal provisions:**

EPC Art. 123(2), 54, 111(1)

**Keyword:**

Amendments - added subject-matter (no)  
Novelty - (no)  
Remittal to the department of first instance - (yes)

**Decisions cited:**

G 0002/10, T 1186/05, T 0234/09

**Catchword:**



**Beschwerdekammern  
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Case Number: T 0112/10 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 18 September 2014**

**Appellant:** Baxter International Inc.  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
26 November 2009 concerning maintenance of the  
European Patent No. 1131077 in amended form.

**Composition of the Board:**

**Chairman** J. Riolo  
**Members:** D. Boulois  
P. Schmitz

## Summary of Facts and Submissions

I. European patent No. 1 131 077 based on application No. 00 950 792.2 was granted on the basis of a set of 22 claims. Independent claims 1 and 8 read as follows:

"1. A two-part bicarbonate containing solution, the solution comprising:

a first part housed in a first container, the first part including an alkaline bicarbonate concentrate having a pH ranging from about 8.6 to 10.0;

a second part housed in a second container, the second part including an acidic concentrate having a pH ranging from about 1.0 to less than 3.0, the pH of the acidic concentrate effective to obtain, when the first part and the second part are mixed together, a mixed solution having a pH ranging from 6.5 to 7.6."

"8. A multi-chamber container for storing a bicarbonate solution, the container comprising:

a first chamber housing an alkaline bicarbonate concentrate, the alkaline bicarbonate concentrate having a pH ranging from about 8.6 to 10.0; and

a second chamber housing an acidic concentrate, the acidic concentrate having a pH ranging from 1.0 to less than 3.0."

II. An opposition had been filed against the granted patent. The patent had been opposed under Article 100 (a) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step and extended beyond the content of the application as filed.

III. The documents cited during the opposition proceedings included *inter alia* the following:

(1): WO 97/041902

(4): DE 19748290

- IV. The present appeal lies from the decision of the opposition division to maintain the patent as amended. The decision was based on 12 sets of claims, namely the claims as granted as main request, auxiliary requests 1-9 filed with letter of 7 August 2009 and auxiliary requests 10 and 11 filed during the oral proceedings of 8 October 2009.
- V. According to the decision under appeal, Claim 1 of the main request did not meet the requirements of Article 123(2) EPC, since the wording "less than 3.0" had no basis in the application as filed.

The subject-matter of all claims 1 of auxiliary requests 1-9 had been modified by the introduction of the term "with the proviso that the pH of 3 is excluded" instead of "less than 3.0".

The subject-matter of auxiliary requests 1-9 did not meet the requirements of Article 123(2) EPC, since this wording still resulted in a deletion of an end value of a range, this inherently creating a new pH range which was not originally disclosed in the application as filed.

Claim 1 of auxiliary request 10 was based on claim 8 as granted, with the new feature, "**wherein each of the chambers is constructed from a gas-permeable material**". No basis could be found in the application as filed for a multi-chamber container as defined in claim 1 without being associated with a frangible connector and a heat seal, leading thus to the infringement of Article 123(2) EPC.

The subject-matter of claim 1 of auxiliary request 11 differed from the subject-matter of claim 8 as granted in that "*the acidic concentrate **having a pH ranging from 1.3 to 2.5***" and "*wherein each of the chambers is constructed from a gas-permeable material*".

The subject-matter of claim 1 of auxiliary request 11 met the requirements of Article 123(2) EPC and was novel over document (1).

The problem to be solved was to provide a system that stabilised high concentration of gas bicarbonate without the need of a gas barrier.

As regards inventive step, document (4) was considered as the closest prior art, since it sought to solve the same problem, by sticking to a specific pH range, i.e. below 3,2, preferably 2,8 to 3,2.

The opposition division considered that document (4) taught away the solution.

VI. The opponent and the patent proprietor filed an appeal against the decision.

With the letter dated 1 April 2010, the appellant-proprietor submitted a new main request, an alternative main request, and auxiliary requests 1, 1A, 2, 2a, 3, 3A, 4, 4A, 5, 5A, 6, 6A, 7, 7A, 8, 8A, 9, 9A, and 10.

The subject-matter of claims 1 and 5 of the main request read as follows:

"1. A multi-chamber container for storing a bicarbonate solution, the container comprising:

a first chamber housing an alkaline bicarbonate concentrate, the alkaline bicarbonate concentrate having a pH range of 8.6 to 10.0; and

a second chamber housing an acidic concentrate, the acidic concentrate having a pH ranging from 1.0 to less than 3.0, wherein the acidic concentrate has a pH effective to obtain, when the alkaline concentrate is mixed with the acidic concentrate, a mixed solution having a pH ranging from 6.5 to 7.6 wherein each of the chambers is constructed from a gas-permeable material."

"5. A method for stabilising bicarbonate solutions, the method comprising the steps of: housing an alkaline bicarbonate concentrate in the first container, adjusting the pH of the alkaline bicarbonate concentrate to a range of 8.6 to 10.0, housing an acidic concentrate in the second container, and adjusting the acidic concentrate to a pH ranging from 1.0 to less than 3.0, wherein the step of adjusting the acidic concentrate is further defined by adjusting the acidic concentrate to a pH effective to obtain, when the alkaline concentrate is mixed with the acidic concentrate, a mixed solution having a pH ranging from 6.5 to 7.6 and wherein the first container is a first chamber of a multi-chamber container and the second container is a second chamber of the multi-chamber container and wherein the first and second containers are constructed from a gas-permeable material."

The alternative main request differed from the main request by the suppression of some dependent claims, which were objected during the opposition procedure under Article 123(2) EPC.

The subject-matter of claim 1 of the auxiliary request 1 differed from claim 1 of the main request by the further addition of the feature "wherein both chambers are separated by a peel seal".

- VII. With a letter dated 9 August 2010, the appellant-proprietor filed auxiliary requests 12 and 13.
- VIII. With a letter dated 13 August 2010, the appellant-opponent contested the admissibility of the A versions of the auxiliary requests and filed a new document:  
(25): Versuchsbericht - Gaspermeabilität von Kunststofffolien
- IX. A Board's communication dated 25 July 2014 was sent to the parties.  
In this it was stated in particular that the subject-matter of the main request appeared to meet the requirements of Article 123(2) EPC, especially in view of the term "*less than 3.0*", and that document (1) appeared to be relevant for novelty.
- X. Oral proceedings took place on 18 September 2014.
- XI. The arguments of the appellant-opponent, as far as relevant for the present decision, may be summarized as follows:

*Main request - Article 123(2) EPC*

The subject-matter of claim 1 did not meet the requirements of Article 123(2) EPC, in view of the absence in the application as originally filed of the disclaiming term "*less than*" and this feature defined a new pH range not originally disclosed. This feature was neither implicitly nor explicitly in the original



application. It was also not possible to see in the term "*less than*" a disclosed disclaimer allowable under decision G 2/10, since no basis for the remaining subject-matter could be found.

The exclusion of the pH value of 3.0 constituted a novel technical information, as the technical problem of the patent was not solved anymore for the pH value of 3.0. It was also not clear what a pH range of "*1.0 to less than 3.0*" would encompass. It was unclear for instance whether a pH value of 2.9999 might be comprised within the claimed range.

#### *Novelty*

Document (1) disclosed a multi-chamber bag comprising two bags bound together (see Fig. 3, and page 11, lines 24-32). All the possible materials used for the films of the bags were made from gas permeable materials ( see page 14, line 32- page 15, line 15). Document (25) showed further that the polymers used for forming the multi-layer membrane of document (1) were all gas permeable.

In any case where a membrane was not specifically designed for being gas-impermeable, such as by the addition of an aluminium coated film, said membrane had gas permeability properties.

The solutions contained in the bag of document (1) had the same composition and pH as the claimed solutions (see Tables 2 and 3).

Consequently, document (1) was relevant for novelty.

- XII. The arguments of the appellant-proprietor, as far as relevant for the present decision, may be summarized as follows:

*Main request - Article 123(2) EPC*

The application as originally filed defined the pH value of the acidic concentrate as "*about 1.0 to about 3.0*". In order to further distinguish the claimed subject-matter from the prior art, it was deemed appropriate to restrict the scope of protection by excluding the pH value of 3.0, through the introduction of the feature "*a pH ranging from 1.0 to less than 3.0*".

The term "*less than*" was not disclosed verbatim in the application as originally filed and was seen as an introduction of a disclosed disclaimer according to G 2/10. The subject-matter remaining in the claim after the introduction of the disclaimer was explicitly or implicitly, directly and unambiguously disclosed for the skilled person using common general knowledge. In this case, there was no singling out, no intermediate generalisation and no creation of unclarity. Finally, disclaiming the upper limit of a range did not add any subject-matter or technical information.

#### *Novelty*

Document (1) was not seen as a novelty destroying document since it did not disclose a multi-chamber container but a substitute to a multi-chamber container, as confirmed by the term "*the present invention may be utilized as a substitute for multiple chamber containers*" (see document (1), page 15, lines 16-19).

Moreover, it was not possible to arrive at the conclusion that the non-PVC material disclosed in Table 2 of document (1) was the multi-layer film disclosed on page 15, and that this film was gas-permeable. The description lacked information on the multi-layer film, as regards its thickness or the commercial nature of

the polymers used for it. Document (25) could not be used to support the existence of the gas-permeability property for these reasons.

- XIII. The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked.
- XIV. The appellant-proprietor requested that the decision under appeal be set aside and the patent be maintained according to the main request or alternatively on the basis of the alternative main request, auxiliary requests 1, 1A, 2, 2A, 3, 3A, 4, 4A, 5, 5A, 6, 6A, 7, 7A, 8, 8A, 9, 9A, and 10 all filed with letter of 01 April 2010, auxiliary request 11 as maintained by the opposition division and filed during oral proceedings before the opposition division on 8 October 2009 and auxiliary requests 12 and 13 filed with letter dated 9 August 2010

Additionally, the appellant-proprietor requested to remit the case to the first instance in case that inventive step of auxiliary requests 1, 1A, 5, 5A, 12 or 13 was to be discussed.

On a further auxiliary basis the appellant-proprietor requested that the patent be maintained on the basis of the requests as indicated under point 27 of his letter dated 9 August 2010.

## **Reasons for the Decision**

### *1. Main request - Article 123(2) EPC*

The subject-matter of claims 1 and 5 has been objected

to by the appellant-opponent on the basis of the feature "to less than 3.0".

1.1 The subject-matter of claims 1 and 5

1.1.1 The subject-matter of claims 1 and 5 of the main request relates, respectively, to a multi-chamber container comprising *inter alia* a chamber housing an acidic concentrate, "*having a pH ranging from 1.0 to less than 3.0*" and to a method for stabilising bicarbonate solutions by the use *inter alia* of the same acidic concentrate with a "*pH ranging from 1.0 to less than 3.0*".

Independent claims 1 and 7 of the application as filed related however to an acidic concentrate "*having a pH ranging from about 1.0 to 3.0*".

The subject-matter of claims 1 and 5 of the main request comprises thus a further restriction as far as the pH value of the acidic concentrate is concerned, namely the exclusion of the specific value of pH 3.0.

1.1.2 The question must be answered whether a person skilled in the art would derive the exclusion of the specific value directly and unambiguously from the application as originally filed.

It is clear that the restriction of the claimed pH range does not have a literal basis in the application as originally filed.

However, the replacement of the feature "3.0" by "*less than 3.0*" does not imply a different technical teaching and does not constitute a new technical feature as regards the claimed pH range. There is indeed no way to distinguish the specific pH value of 3.0 from a pH value of "*less than 3.0*".

The true value of the pH value of "*less than 3.0*" might indeed be expressed by a different degree of accuracy, from one decimal place to more than one. In the present case, the appellant-proprietor had chosen to use one decimal place to define the pH. However, the term "*less than 3.0*" also includes pH values with more than one decimal from which the accuracy of the measurement techniques or the simple application of the rules on rounding up numbers would give as a true pH value 3.0. In other words, it is not possible to distinguish a pH value of less than 3.0, such as for instance 2.999, from the exact value of 3.0.

This ruling is consistent with the Board of Appeal case law as regards novelty and rounding up of values (see T 1186/05 or T 234/09).

It appears therefore that the subject-matter remaining in this claim after the modification is directly and unambiguously derivable from the application as filed.

#### 1.1.3 Further arguments

Both appellants saw in the introduction of the term "*less than*", the introduction of a disclosed disclaimer, with the consequence that the principles established in decision G 2/10 applied.

The Board does not share this view.

As explained above, it is not possible to distinguish the upper limit of a pH value of "*less than 3.0*" from the value of "*3.0*". It is evident that the true meaning of the feature "*less than 3.0*" includes values which would anyway be rounded up to "*3.0*" and would not be distinguishable from the rounded value.

Accordingly, there is no value excluded, and consequently this is not to be seen as a disclaimer or

proviso, and decision G 2/10 is not relevant for the present case.

1.2 The subject-matter of the main request meets the requirements of Article 123(2) EPC.

2. *Main request - Novelty*

2.1 Document (1) relates to a dual-filled twin bag included in a package, useful for administering a solution used in a peritoneal dialysis (see page 3, lines 13-21). Figure 3 shows two bags inter-connected by a tubing set and included in an overpouch (see page 11, lines 24-32). The system of document (1) comprises thus a receptacle comprising two sub-units, which is seen as a container with multiple chambers.

Document (1) further discloses in Tables 2 and 3 the solutions to be used for the dual-filled bag system. The solutions comprise a first acidic composition and a second bicarbonate solution. In particular, Table 2 discloses a first acidic solution of pH 2.0 and a second bicarbonate composition at pH 9.0, which form when mixed a composition with a pH of 7.36-7.42 (see Table 3).

The bags of the solution system of Table 2 are made from a "*non-PVC material*", for which the description of document (1) offers only a unique preferred possibility, namely the multilayer film disclosed on page 15. The non-PVC material of Table 2 is thus inevitably the only possibility disclosed on page 15 of the description of document (1). The passage on page 15 mentions that the preferred "*non-PVC material is a multilayer film*", made from polypropylene for the first layer, ultra-low density PE, polypropylene-ethylene copolymer and styrene-ethylene butylene-styrene copolymer for the second layer, and a blend of ultra-

low density PE, polypropylene-ethylene copolymer and modified styrene-ethylene butylene-styrene copolymer for the third layer.

Document (25) shows that a multi-layer film made from the same polymers and copolymers in the multilayer film of document (1) is permeable to carbon dioxide. In view of these results, it becomes clear that the multi-layer film surrounding each bag of document (1), is permeable to gas.

## 2.2 Further arguments from the appellant-proprietor

According to the appellant-proprietor, the system described in document (1) cannot be considered as a multi-chamber container, as confirmed by the statement in said document (1), namely that "*the present invention may be utilized as a substitute for multiple chamber containers*" (see document (1), page 15, lines 16-19). Moreover, the teaching of document (25) is not sufficient to establish that the multi-layer film of document (1) is gas-permeable, since some specifics of said multi-layer film, such as the thickness or the exact type of copolymer or polymer, were not given in document (1), and thus cannot be reproduced.

The Board could not follow these arguments:

- (a) The term "*multi-chamber container*" is a broad term encompassing a great number of enclosing systems. The term suggests indeed at first a rigid receptacle with several subunits, but also encompasses any receptacle, package or enclosure for holding another product inside, such as bags. Said term additionally encompasses also flexible systems, as confirmed by the significance of a multi-chamber system given in the contested patent. The description of the contested patent

describes indeed a multi-chamber system in the form of a flexible compressed bag comprising a first and a second separated chamber (see Figure 1 and par. [0039]).

There is thus no reason to question that a packaging system such as the overpouch of document (1) constitutes also a container. The two internal bags comprised within the overpouch constitute *de facto* the multi-chamber system.

As to the fact that the system of document (1) is presented as a substitute of a multi-chamber container, there is no further detail given in document (1) what was meant by it, in particular if it meant a system as presented in the contested patent, or any other system. This statement does thus not exclude in any manner that the system of document (1) might not be seen by the skilled person as a "*multi-chamber container*", even if was not considered as such in document (1).

- (b) As to the term "*a gas-permeable material*" present in the independent claims of the main request, this term represents a functional feature. The required property or quality of gas-permeability is however not specified in the claims and is not further defined or illustrated in the description of the contested patent, which mentions a unique possibility of gas-permeable material, namely polypropylene (see par. [0039]).

As regards the experiments of document (25), even if the tested multi-layer structure tested therein is not exactly the same as the one used in document (1), the teaching of the experiments illustrates clearly the character of gas-



permeability of said multi-layer films. The fact that the structure of the multi-layer film of document (1) is undefined as regards the thickness or the brand name of the products cannot occult the reality of the gas-permeability of the polymers and copolymers used to form the multi-layer film.

2.3 Consequently, the main request does not meet the requirement of novelty.

3. *Alternative main request - Novelty*

Since the subject-matter of this request differs only by the suppression of dependent claims, the conclusions reached above for the main request apply *mutatis mutandis* for the subject-matter of claim 1 of this request, which lacks novelty over document (1).

4. *Auxiliary request 1 - Remittal to first instance*

4.1 The subject-matter of claim 1 has been amended by the addition of the feature "*wherein both chambers are separated by a peal seal*".

This feature has been added to restore novelty over document (1), since there is no peal seal disclosed therein.

The discussion on this unexamined feature constitutes a shift to a different technical field and presents a particular complexity especially with regard to inventive step.

4.2 Although Article 111(1) EPC does not guarantee an absolute right to have all the issues of the case considered by two instances, it is well recognised that any party should, whenever possible, be given the

opportunity to said consideration by two instances of the important elements of the case. The essential function of an appeal in inter partes proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is taken into consideration by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against a party and leaves other essential issues outstanding, but also in cases the decision of the opposition division was reversed and the remaining issues to discuss constitute a new case. In both situations, the case should normally be remitted to the first instance department for consideration of the undecided or fresh issues.

The observations and comments made above apply fully to the present case. In view of the reversal of the decision of the opposition division as regards Article 123(2) EPC and novelty over document (1), the subject-matter of claim 1 of auxiliary request 1 constitutes a fresh case. Especially more, since the subject-matter of claim 1 further comprises an unexamined feature, namely "*wherein both chambers are separated by a peel seal*".

These issues must be considered as essential substantive issues in the present case.

Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, the case is to be remitted to the

Opposition Division for further prosecution on the basis of auxiliary request 1.

**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 first instance for further prosecution.

The Registrar:

The Chairman:



N. Schneider

J. Riolo

Decision electronically authenticated