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# Datasheet for the decision of 11 July 2017

**Case Number:** T 0505/15 - 3.3.07

**Application Number:** 02806438.4

**Publication Number:** 1465688

**IPC:** A61M1/28, A61K33/14, A61P13/12

**Language of the proceedings:** EN

**Title of invention:**
Bicarbonate-based solutions for dialysis therapies

**Patent Proprietor:**
Nikkiso Co., Ltd.

**Opponent:**
Fresenius Medical Care Deutschland GmbH

**Headword:**
Bicarbonate solutions for dialysis/NIKKISO

**Relevant legal provisions:**
EPC Art. 114(2), 56

**Keyword:**
Late submitted material - correct exercise of discretion (yes)
Evidence - public prior use (yes)
Inventive step - main request and auxiliary request 1 (no) - auxiliary request 2 (yes)

**Decisions cited:**
T 0152/03, T 0906/01, G 0001/92

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**Case Number: T 0505/15 - 3.3.07**

# D E C I S I O N
# of Technical Board of Appeal 3.3.07
# of 11 July 2017

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Nikkiso Co., Ltd.<br>Yebisu Garden Place Tower<br>20-3, Ebisu 4-chome<br>Shibuya-ku<br>Tokyo 150-6022 (JP) |
| **Representative:** | Grosse Schumacher Knauer von Hirschhausen<br>Patent- und Rechtsanwälte<br>Nymphenburger Strasse 14<br>80335 München (DE) |
| **Appellant:** (Opponent) | Fresenius Medical Care Deutschland GmbH<br>Else-Kröner-Strasse 1<br>61352 Bad Homburg (DE) |
| **Representative:** | Herrmann, Uwe<br>Lorenz Seidler Gossel<br>Rechtsanwälte Patentanwälte<br>Partnerschaft mbB<br>Widenmayerstraße 23<br>80538 München (DE) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 5 January 2015 concerning maintenance of the European Patent No. 1465688 in amended form.** |

**Composition of the Board:**

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|---|---|
| **Chairman** | J. Riolo |
| **Members:** | A. Usuelli |
| | P. Schmitz |
| | R. Hauss |
| | Y. Podbielski |

## Summary of Facts and Submissions

I. European patent No. 1 465 688, based on European patent application No. 02806438.4, was granted on the basis of twenty claims.

Independent claims 1 and 20 read as follows:

"1. A two part dialysis solution comprising:
a first component comprising a bicarbonate concentrate;
a second component comprising an electrolyte concentrate; wherein the two part dialysis solution does not include acetate; wherein the first component and the second component comprise a physiologically acceptable amount of sodium; wherein a mixed solution of the first component and the second component comprises
100 mmol/L to 160 mmol/L sodium,
0 mmol/L to 2.0 mmol/L of calcium,
0 mmol/L to 1.5 mmol/L of magnesium,
0 mmol/L to 5 mmol/L of potassium,
20 mmol/L to 45 mmol/L of bicarbonate,
70 mmol/L to 130 mmol/L of chloride,
0 mmol/L to 45 mmol/L of lactate, and
0 g/L to 2.5 g/L of glucose; and
wherein the first component has a pH ranging from about 8.6 to about 9.5 and the second component has a pH ranging from about 1.7 to about 2.2."

"20. A method of providing a solution for dialysis comprising the steps of: providing a two part dialysis solution as defined in any one of Claims 1 to 3; and mixing the first component and the second component to form a mixed solution."

II. The patent was opposed on the grounds that its subject-matter lacked inventive step and extended beyond the content of the application as filed. The following documents were among those cited during the first-instance proceedings:

D1: WO 01/17534 A1
D2a: Fresenius Medical Care Deutschland GmbH, handling of the HF-Bic solutions
D3a: Interkantonale Kontrollstelle für Heilmittel; HF-Bic 35-010, letter of 21 December 2001
D7: WO 99/27885 A1
D8: Letter from company B. Braun, September 2000
D9: Technical information regarding SH-Bic of 6 October 2000 - fax date
D12: Document signed by Dr Gömpel-Klein, 25 February 2014
D13a: Delivery note 24469534 for HF-Bic 35-410
D13b: Fax from Zentralapotheke des Universitätsklinikums Magdeburg dated 10 May 2000
D13c: Certificate of analysis No.: 200000020423/0004 by Fresenius Medical Care Deutschland GmbH

III. By an interlocutory decision posted on 5 January 2015, the opposition division decided that the patent in amended form met the requirements of the EPC. The decision was based on the granted patent as main request, on auxiliary request 1 filed on 26 March 2014 and on auxiliary requests 2 and 3 filed during the oral proceedings held on 26 June 2014.

During the oral proceedings before the opposition division Dr Gömpel-Klein was heard as witness (Minutes of the hearing on file).

The decision of the opposition division can be summarised as follows:

(a) Documents D3a and D8 to D13c had been filed early enough before the oral proceedings to allow the patent proprietor to analyse them. Moreover, these documents were *prima facie* relevant. Accordingly, these documents were admissible.

(b) The public prior use of the product HF-Bic 35-410 (delivery from the opponent to the Universitätsklinikum Magdeburg (documents D13a-D13c)) was not sufficiently proven and therefore did not constitute prior art. The same conclusion applied to the alleged prior use of the product HF-Bic 35-210. In contrast, the bicarbonate-based solution SH-BIC disclosed in D9 was available to the public.

(c) The patent met the requirements of Article 123(2) EPC. However, the subject-matter of claim 1 was obvious in view of the combined teachings of D9 and D1 or D1 and D7.

(d) The subject-matter of auxiliary request 1 did not comply with Article 123(2) EPC and Rule 80 EPC. The subject-matter of auxiliary request 2 was not inventive for the same reasons as that of the main request.

(e) The dialysis solution defined in claim 1 of auxiliary request 3 differed from the solution disclosed in document D1 in that sodium and potassium were present in both components. This had the effect of increasing the safety of the two-part dialysis solution. The technical problem was the

provision of a dialysis solution with improved safety. The prior art did not suggest providing compositions in which each component contained both sodium and potassium in physiologically acceptable amounts. The subject-matter of auxiliary request 3 was therefore inventive.

IV. Appeals were filed against the decision of the opposition division by the patent proprietor (hereinafter: appellant-patent proprietor) and by the opponent (hereinafter: appellant-opponent).

With the statement setting out the grounds of appeal the appellant-patent proprietor submitted five auxiliary requests.

Claim 1 of auxiliary request 1 differed from claim 1 as granted in that the feature "0 mmol/L to 45 mmol/L of lactate" was replaced by "0 mmol/L lactate".

Claim 1 of auxiliary request 2 differed from claim 1 as granted in the addition of the feature:

"wherein the first component and the second component each comprise a physiologically acceptable amount of potassium;"

and in the replacement of the feature "0 mmol/L to 5 mmol/L of potassium" by the feature "up to 5 mmol/L of potassium".

Auxiliary request 2 contained a second independent claim (claim 17) substantially identical to claim 20 as granted.

V. In a communication pursuant to Article 15(1) RPBA issued on 29 May 2017, the Board commented *inter alia* on the issue of the alleged public prior uses. It expressed the view that neither the product specified in D9 (SH-BIC) nor document D9 itself formed part of the state of the art. In relation to product HF-Bic 35-410 it stated that the certificate of analysis contained a link to documents supporting delivery of the product to the Universitätsklinikum Magdeburg and observed that, in view of decision G 1/92, whether the certificate of analysis was available to the public was immaterial. It furthermore affirmed that the prior use of HF-Bic 35-410, if acknowledged, could represent a suitable starting point for the assessment of inventive step.

VI. Oral proceedings were held on 11 July 2017.

VII. The arguments of the appellant-patent proprietor can be summarised as follows:

(a) Admissibility issues
The opposition division had been wrong to admit documents D3a and D8 to D13c into the proceedings. None of these documents appeared to be *prima facie* sufficiently relevant to justify their admission. Furthermore, some of these documents had been filed as evidence of prior uses that were not mentioned in the notice of opposition. The late filing of these documents was not justified.

(b) Public prior uses
There were some inconsistencies among the documents submitted by the appellant-opponent as evidence for the prior use of product HF-Bic 35-410. D13a made reference to a double chamber with compartments of 3500 and

1000 ml, whereas D13c referred to a single bag of 4500 ml. Also, the chemical analysis of product HF-Bic 35-410 had a number of flaws. The document itself was not public. Furthermore, it appeared that the product had been analysed 14 years after its manufacture. An analysis made after such a long storage period was not reliable. Additionally, the signature of the person who had made the analysis was missing. A further problem in connection with the prior use of HF-Bic 35-410 concerned the confidentiality of the alleged prior use. The product had not yet received a marketing authorisation. Accordingly, it had been delivered to the Universitätsklinikum Magdeburg while clinical studies were still ongoing. Under these circumstances there was a *prima facie* assumption that any person involved in the use of the product was obliged to maintain confidentiality. The witness testimony was not suitable to corroborate the information of documents D13a to D13c because it contained various contradictory assertions. The fact that the witness was an employee of the appellant-opponent had to be borne in mind when assessing the credibility of the testimony.

(c) Inventive step

The two-part dialysis solution defined in claim 1 of the patent differed from product HF-Bic 35-410 on account of the higher pH of the bicarbonate solution. This had the effect of increasing its long-term stability. Document D1 described a two-part solution in which the bicarbonate solution had the same pH as the solution according to the patent in suit. However, the two-part solution of D1 was characterised by the presence of lactate and of high amounts of glucose. Product HF-Bic 35-410 was quite different in that respect. Thus, the skilled person had no reason to modify the pH of the bicarbonate solution of HF-Bic

35-410 in the light of the teaching of D1. Furthermore, a modification of the pH would have also involved an increase of the total amount of sodium. There was no teaching on how to modify the pH of the bicarbonate solution without increasing the sodium concentration. The subject-matter of claim 1 of the patent was therefore inventive.

The same argument and conclusion applied to the subject-matter of claim 1 of auxiliary request 1.

Claim 1 of auxiliary request 2 was characterised by the requirement that potassium was present in both components. This was an additional difference over product HF-Bic 35-410 which had the effect of improving the safety of the dialysis solution by ensuring that the right amounts of potassium were administered at all times. Since none of the prior-art documents suggested distributing potassium over both components, the requirement of inventive step was met.

VIII. The arguments of the appellant-opponent can be summarised as follows:

(a) Prior uses
The two-part dialysis solutions HF-Bic 35-210 and HF-Bic 35-410, very similar to the product claimed in the patent, had been produced by the opponent and distributed to various hospitals before the priority date of the patent in suit. Delivery of product HF-Bic 35-410 to the Universitätsklinikum Magdeburg was shown by documents D13a to D13c. The product had not been distributed in the context of a clinical study. Thus, there was no reason to assume that there had been a secrecy agreement between the opponent and the Universitätsklinikum Magdeburg. This was in line with

the witness testimony given by Dr Gömpel-Klein before the opposition division. As shown by documents D8 and D9, a further two-part dialysis solution had been available to the public before the priority date of the patent, namely product SH-Bic.

(b) Inventive step

The dialysis solution of claim 1 of the patent as granted and of auxiliary request 1 differed from product HF-Bic 35-410 only in the pH of the bicarbonate solution. The skilled person knew from document D1 that the stability of the bicarbonate solution could be improved by adjusting its pH in the range 8,6 to 10,0. Thus, by modifying the pH of the bicarbonate solution of HF-Bic 35-410 in the light of the teaching of D1 the skilled person would have arrived at the subject-matter of claim 1 of the main request and of auxiliary request 1 without any inventive effort.

The requirement that potassium was distributed over both components of the solution did not render the subject-matter of auxiliary request 2 inventive. In product HF-Bic 35-410 potassium was present in the electrolyte component. In formulation 2 of D1 (page 22) it was in the buffer component. The skilled person therefore knew that potassium was compatible with the substances present in both components. Furthermore, D7 suggested distributing the total amount of sodium over all the components of the solution. It would have been obvious for the skilled person to extend this concept also to potassium. After all there were only three ways of distributing potassium, namely in the electrolyte component, in the buffer component or in both. The mere selection of one these alternatives had no inventive merit.

IX. The appellant-patent proprietor requested that the decision under appeal be set aside and that the opposition be rejected (i.e. maintenance of the patent as granted) or that the patent be maintained in accordance with one of auxiliary requests 1 to 5 submitted with the grounds of appeal. It furthermore requested that documents D3a and D8 to D13c not be admitted into the appeal proceedings.

X. The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked.

## Reasons for the Decision

*Public prior use of product HF-Bic 35-410*

Admissibility issues in relation to the prior use

1. The appellant-patent proprietor requested not to admit into the proceedings some documents that were submitted by the appellant-opponent during the first-instance proceedings and were admitted by the opposition division. These include *inter alia* documents D12 and D13a to D13c which are relevant in relation to the prior use of the product HF-Bic 35-410.

1.1 The admission of these documents is a discretionary decision of the opposition division pursuant to Article 114(2) EPC. The decision was mainly based on the view that the documents appeared to be *prima facie* relevant and that the patent proprietor had had sufficient time to analyse them (point 3.4 of the decision).

1.2 The Board agrees on the *prima facie* relevance of documents D12 and D13a to D13c as supporting evidence for the prior use of the product HF-Bic 35-410. It furthermore considers that the appellant-patent proprietor had sufficient time in opposition and appeal proceedings for a thorough consideration of these documents and for presenting its comments.

Accordingly, documents D12 and D13a to D13c are part of the proceedings.

Assessment of the prior use

2. HF-Bic 35-410 is a product that the appellant-opponent says it delivered to the Zentralapotheke of the Universitätsklinikum Magdeburg before the priority date of the patent in suit.

As evidence of this prior use it relied on the witness testimony given by Dr Gömpel-Klein before the opposition division, her written declaration (document D12), and documents D13a-D13c.

2.1 Dr Gömpel-Klein, an employee of the appellant-opponent, explains in her declaration (D12, fourth paragraph) that HF-BIC 35-410 received a marketing authorisation only after the priority date of the patent. Nevertheless, it was already sold before that date upon specific requests by medical doctors and after approval of the responsible authority (Regierungspräsidium; see minutes of the testimony, in particular pages 3 to 8). Delivery did not take place in the context of a clinical study or research project (minutes of the testimony, sentence bridging pages 10 and 11). Instead, the product was used in emergency cases for patients in intensive care who were unable to tolerate the products

which were available on the market. HF-BIC 35-410 was delivered *inter alia* to the Universitätsklinikum Magdeburg (minutes of the testimony, in particular pages 23 to 31).

2.2 D13a is a delivery note from the appellant-opponent numbered 24469534 and dated 8 May 2000 addressed to the Zentralapotheke of the Universitätsklinikum in Madgeburg. The product identified on this delivery note is "HF-Bic 35-410" bearing article number 9673591 and batch number ADK191. The note gives a delivery date of 9 May 2000. It bears a signature and the date 9 May 2000 on the part of the note requesting confirmation that the product has been received.

2.3 D13b is a fax dated 10 May 2000 from the Zentralapotheke of the Universitätsklinikum Magdeburg to the appellant-opponent. It states that the hospital wishes to return product HF-Bic 35-410 with batch number ADK191 and delivered with note 24469534 dated 8 May 2000, and ask for a new product to be delivered.

2.4 D13c is a certificate of analysis, by the opponent, of the product described as Multibic 4K+ with article number 9673591 and batch number ADK191. The batch number and article number identify the product as the one which was delivered to the Universitätsklinikum Magdeburg.

2.5 The matching of the delivery note number, article number and batch number in documents D13a to D13c proves in the Board's view without any doubt that:

(a) product HF-Bic 35-410 with article number 9673591 and batch number ADK191 was sent by the appellant-

opponent to the Zentralapotheke Universitätsklinikum in Madgeburg (see D13a);

(b) this product was received by the recipient (see D13a and D13b) on 9 May 2000 (see D13a);

(c) the product has the composition disclosed in D13c.

The fact that D13c designates the product with the name Multibic 4K+, whereas in D13a and D13b the name HF-Bic 35-410 is used, does not invalidate this conclusion. Indeed, Dr Gömpel-Klein explained that the products of the HF-Bic series were also referred to as Multibic (minutes of the testimony, page 20).

2.6 According to the appellant-patent proprietor (and the opposition division) there is an inconsistency between D13a and D13c in that D13a makes reference to compartments of 3500 ml and 1000 ml, whereas D13c only refers to one bag of 4500 ml. Therefore, it could not be concluded that the documents relate to the same product. The Board does not agree. It is of the view that the reference to "1x4500ML" in D13c refers to the total volume contained in the analysed product. D13c refers to a solution A and a solution B and thus to a two-part product. There is therefore no inconsistency between D13a and D13c. On the contrary, the article and batch numbers identified in D13c are identical to those in D13a. Thus, in the Board's view there is no doubt that the product sent by the appellant-opponent to the Universitätsklinikum Magdeburg as per the delivery note D13a is the product of the certificate of analysis D13c.

2.7 The appellant-patent proprietor furthermore argued that it was unclear on which date the analysis certified in D13c was carried out. The document bore the date 26 February 2014 and this was thus the probable date of

the analysis. An analysis carried out on a product about 14 years after its manufacture was unreliable. A further reason for the results being unreliable was that the document was not signed, contrary to the legal obligation to do so. The appellant-patent proprietor furthermore observed that D13c was not a public document.

2.8 In this respect the Board notes that the date of 26 February 2014 printed on D13c precedes the filing of this document in the opposition proceedings by one month. The appellant-opponent's explanation that the document was printed for the purpose of submitting it during the opposition proceedings and that the date of 26 February 2014 had been added automatically to the document by the computer on printing therefore appears credible. Also credible is the appellant-opponent's argument that the original printed document was no longer available about 14 years after its creation, given that there was no obligation to keep the original paper version for more than 10 years. Furthermore, the idea that the appellant-opponent analysed a product 14 years after its manufacture appears far-fetched to the Board. A chemical analysis of a product for the purpose of quality control is usually performed on or around the time of manufacture; otherwise it does not serve any useful purpose.

The Board also does not regard the lack of a signature as casting doubt on the content of the document. Firstly, the allegation of a legal requirement for signing such documents has not been substantiated. Secondly, even if the printed document was originally signed, it is unlikely that the electronically stored version of the document would contain such a signature.

As to the appellant-patent proprietor's observation that D13c was not a public document, the Board observes that in view of decision G 1/92 the chemical composition of a product is state of the art if the product as such is available to the public and can be analysed and reproduced by the skilled person (see Headnote). Thus, the relevance of the certificate of analysis D13c is that it reveals what the skilled person would have observed by an analysis of product HF-BIC 35-410. In that respect the question whether D13c was available to the public (before the priority date of the patent) is immaterial.

2.9 In summary, on the basis of documents D13a and D13b and the witness statements the Board is convinced that product HF-Bic 35-410 was delivered to the Zentralapotheke of the Universitätsklinikum Madgeburg on 9 May 2000 and that the chemical composition of the product was as specified in the certificate of analysis D13c. The product was delivered in the context of a commercialisation that occurred before the granting of the marketing authorisation (see D12).

The question whether the product was used is immaterial, since the fact that the product was delivered to the Universitätsklinik Madgeburg would in principle already suffice to make the product available to the public.

It remains to be decided whether the delivery to the Universitätsklinik Madgeburg was subject to any obligation to maintain confidentiality.

2.10 In this respect, the appellant-patent proprietor argued that the Boards of Appeal had reasoned that in the medical field there was a *prima facie* assumption that

any person involved in the medical process is obliged to maintain confidentiality, given the need for patient confidentiality and the need to protect the development and testing of prototype devices (see T 152/03, point 3.4 of the Reasons, confirmed by T 906/01, point 3.5 of the Reasons). The appellant-opponent had failed to provide evidence that no confidentiality agreement existed. Furthermore, the failure to provide invoices led to the inference that delivery for test purposes had to be assumed.

2.11 As reported in point 2.1 above, according to the witness the delivery of HF-Bic 35-410 did not take place in the context of a clinical study. Moreover, she had no knowledge of an explicit or implicit confidentiality agreement.

2.12 The opposition division considered the witness as credible and the Board has no reason to depart from this assessment. The appellant-patent proprietor attempted to cast doubt on the witness's credibility by referring to the fact that she was an employee of the appellant-opponent and that there was a bonus element to her remuneration. The Board is of the view that the credibility of a witness cannot be put into doubt by the mere fact that he or she is an employee of one of the parties to the proceedings. Bonus payments are not unusual and the witness has confirmed that these have for years not been related to a project concerning HF-Bic 35-410 (see page 42 of the witness testimony).

2.13 The appellant-proprietor also sought to cast doubt on the reliability of what the witness recalled, suggesting that the witness statement contained contradictory assertions, for example with regard to the size of the individual bag compartments. While

stating initially that the bags with the peel-seam had not changed up to the date of the marketing authorisation (witness testimony, page 6), the witness stated later on that the new sizes of the individual bag compartments had been introduced around the year 2000 (witness testimony, page 25). The Board is of the view that the discrepancies pointed out do not call into question the reliability of the overall assertions made by the witness.

2.14 Therefore, the Board has no reason to doubt the witness's assertion that HF-Bic 35-410 was not delivered in the context of a clinical trial. In this regard the Board furthermore considers that the delivery of a medicinal product for emergency cases (see point 2.1 above) is almost certainly not compatible with it being delivered for test purposes or being part of a clinical trial, unless there are clear indications to the contrary. No such indications exist. The mere absence of invoices dating back to the year 2000 does not permit the inference that the deliveries were made for test purposes, as suggested by the appellant-patent proprietor. Instead, the delivery of the product in emergency cases suggests that it was made for a commercial purpose, albeit with a special regulatory approval as it related to a product which had not yet received marketing authorisation.

In this context it is also noted that the delivery note D13a, which clearly looks like a commercial document, was issued by the "Vertrieb Dialysetechnik Zentraleuropa". The word "Vertrieb" (in English "marketing" or "distribution") clearly shows that the note was issued by a commercial department rather than a department responsible for clinical trials.

2.15 The sale of a product for a commercial purpose is not compatible with the concept of an implied obligation to maintain confidentiality. The Board notes that the boards in cases T 152/03 and T 906/01 (cited by the appellant-patent proprietor) referred to a *prima facie* assumption that any person involved in the medical process is obliged to maintain confidentiality, given the need for patient confidentiality and the need to protect the development and testing of prototype devices. The present case differs from that in that the prior use occurred in a commercial context.

2.16 For the reasons set out above, the Board concludes that there was no obligation to maintain confidentiality.

It follows that product HF-Bic 35-410 is part of the state of the art pursuant to Article 54(2) EPC.

*Main request (patent as granted) - Inventive step*

3. The invention underlying the patent in suit relates to bicarbonate-based solutions for use during dialysis therapies such as hemofiltration (see paragraphs [0001] and [0029] of the patent). The solution consists of two components, a bicarbonate concentrate and an electrolyte concentrate, which are mixed before use (paragraph [0012]).

3.1 Closest prior art

3.1.1 Product HF-Bic 35-410 is a bicarbonate-based solution for hemofiltration (see D12, fourth and fifth paragraphs). The Board regards this product as a suitable starting point for the assessment of inventive step.

3.1.2 The certificate of analysis D13c shows that HF-Bic 35-410 is constituted of two solutions named A and B. Solution A is an electrolyte concentrate having a pH value of 2,15. Solution B is a bicarbonate-based buffer solution having a pH value of 7,55.

The two-part solution of the patent in suit differs from product HF-Bic 35-410 in that the pH of the buffer solution is in the range of about 8,6 to about 9,5.

3.2 Technical problem

3.2.1 In the appellant-patent proprietor's opinion the higher pH value of the buffer component has the effect of increasing the long-term stability of the two-part solution of the patent in suit. This position was not disputed by the appellant-opponent.

In view of the above, the technical problem can be formulated as the provision of a two-part dialysis solution with an increased stability.

3.3 Obviousness

3.3.1 Document D1 addresses the problem of stabilizing bicarbonate-based two-part solutions useful for peritoneal dialysis or hemofiltration (page 6, lines 1 to 3). As observed by the appellant-patent proprietor, some of the solutions disclosed in D1 contain lactate and high amounts of glucose. However, the presence of these substances is not mandatory and indeed D1 also discloses compositions which do not contain lactate and the amount of any glucose present is within the range of claim 1 of the patent in suit (see formulations 1 and 2 of page 21).

The solution proposed in D1 to the problem of increasing the stability of the two-part solution is to adjust the pH of the bicarbonate composition to about 8,6 to 10,0 (page 6, line 13 to 30).

3.3.2 Hence, the skilled person confronted with the problem of increasing the stability of product HF-Bic 35-410 would find in D1 a clear incentive to increase the pH of the bicarbonate solution to a value of about 8,6 to 10,0 which largely overlaps with the range recited in claim 1 of the patent in suit.

The appellant-patent proprietor argued that the addition of a basic substance such as sodium bicarbonate in order to increase the pH of the bicarbonate solution would result in an increase also of the amount of sodium. In this respect the Board notes that claim 1 covers a broad range of sodium concentration (100 mmol/L to 160 mmol/L) whereas the concentration of sodium in product HF-Bic 35-410 is 140,0 mmol/L. Thus, an addition of sodium bicarbonate would not necessarily result in an amount of sodium exceeding the upper limit of 160 mmol/L defined in claim 1. Furthermore, it appears that the total sodium concentration could be adjusted, if necessary, by modifying the amount of sodium chloride. Thus, in the Board's view, the skilled person would have no difficulty in increasing the pH of the bicarbonate solution whilst maintaining the sodium concentration within the range defined in claim 1.

3.4 It follows from the above that the subject-matter of claim 1 does not fulfil the requirements of Article 56 EPC.

*Auxiliary request 1 - Inventive step*

4. The two-part solution of this request is characterised in that it does not contain lactate. This, however, does not represent a further distinguishing feature over product HF-Bic 35-410 which is also lactate-free. Thus, the considerations set out in respect of the main request apply also to this request. Hence, auxiliary request 1 does not meet the requirements of Article 56 EPC.

*Auxiliary request 2 - Inventive step*

5. Claim 1 of this requests specifies that both the first and the second components comprise a physiologically acceptable amount of potassium.

5.1 Product HF-Bic 35-410 is again the closest prior art. Document D13c indicates that solution A of this product contains ca. 18,00 mmol/L of potassium whereas solution B, i.e. the bicarbonate-based buffer solution, does not contain any potassium.

Thus, the subject-matter of claim 1 of auxiliary request 2 differs from the closest prior art in the pH of the bicarbonate solution and in the requirement that potassium is present in physiologically acceptable amounts in both components.

5.2 The distribution of potassium in the two components ensures that safe amounts of this electrolyte are administered all the time. This can prevent the patient, for instance in the event of accidental administration of only one of the two components, from receiving a solution containing high amounts of potassium or no potassium at all. The risks associated

with accidental errors occurring during the preparation and administration of a two-part dialysis solution are discussed in the patent (paragraphs [0049] to [0053]).

5.3 As explained in the witness testimony (page 7 of the protocol), the two-part solution HF-Bic 35-410 was packaged in a double-chamber bag container which is described in document D2a. This container consists of two chambers: a small one containing the electrolyte solution and a larger one with the bicarbonate solution. The two solutions are mixed by pressing the small chamber in such a way as to open the peeling seam separating the two chambers, thereby allowing the content of the small chamber to enter into the larger one (see page 7 of the witness testimony). The mixed solution in the larger chamber can then be administered to the patient.

5.4 The double-bag system of product HF-Bic 35-410 cannot prevent, for instance, the accidental administration of the bicarbonate solution before its mixing with the electrolyte solution. This could occur for instance because of inattentiveness on the part of the caregiver or because of a malfunctioning of the peeling seam system. In that case the patient would receive a solution that does not contain potassium.

Thus, the two-part solution of claim 1 offers the advantage that, with regard to potassium's administration, it guarantees a level of safety that is not subject for instance to the carefulness of the professionals using it. Hence, the Board agrees with the appellant-patent proprietor that the two-part dialysis solution defined in auxiliary request 2 is safer than product HF-Bic 35-410.

The technical problem underlying the subject-matter of auxiliary request 2 is therefore the provision of a two-part dialysis solution having increased stability and improved safety.

5.5 None of the available prior-art documents discloses a two-part dialysis solution in which potassium is contained in both components.

As observed by the appellant-opponent, in product HF-Bic 35-410 potassium is present in the electrolyte component whereas in formulation 2 of D1 it is in the bicarbonate component. In the Board's view, this would possibly lead the skilled person to the conclusion that potassium is compatible with the substances present in both components. However, contrary to the appellant-opponent's position, this would not be a suggestion to distribute it in the two components.

Nor does document D7 provide any relevant teaching. The appellant-opponent observed that this document discloses solutions in which sodium is distributed in all the components. In its opinion the skilled person would consider applying this concept also to the potassium. The Board notes that D7 relates to a container for peritoneal dialysis which comprises three components. The distribution of sodium in the three components is not associated with safety issues. D7 rather concerns the problem of avoiding bicarbonate precipitation in the presence of calcium and magnesium ions (page 2, lines 2 to 6). Thus, the skilled person addressing the problem defined in point 5.4 above would have no reason to consider the teaching of this document.

The Board also finds unconvincing the appellant-opponent's argument that dividing potassium in both components is only one of the three ways of distributing potassium, the other two being to include it only in the electrolyte component or only in the buffer component. As mentioned above, none of the available prior art documents discloses a two-part dialysis solution in which potassium is contained in both components. Thus, the appellant-opponent's argument is made with hindsight of the invention. Furthermore, only the distribution of auxiliary request 2, in which both the first and the second components comprise a physiologically acceptable amount of potassium, ensures that safe amounts of potassium are administered all the time. Thus, the potassium distribution characterising auxiliary request 2 offers an advantage which is not suggested in the prior art.

Thus, the subject-matter of claim 1 meets the requirements of Article 56 EPC. Claim 17 is inventive as well since it relates to a method involving the use of the solution of claim 1.

5.6 The conclusions set out in point 5.5 above would still apply if also products HF-Bic 35-210 and SH-Bic were considered to be part of the state of the art. In these bicarbonate-based solutions too, the potassium ion is present only in the electrolyte component. Thus, these products would not provide any relevant teaching in relation to the key feature of auxiliary request 2, namely the distribution of potassium in the two components.

In view of this, there is no need to decide whether or not products HF-Bic 35-210 and SH-Bic were available to

the public before the priority date of the patent in suit, as maintained by the appellant-opponent.

## 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 with the order to maintain the patent on the basis of the set of claims of auxiliary request 2 and a description to be adapted.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated