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D E C I S I O N
of 9 May 2001

Case Number: T 0162/98 - 3.3.5

Application Number: 91100559.3

Publication Number: 0443324

IPC: B01F 5/10

Language of the proceedings: EN

Title of invention:
System for preparing a concentrate solution

Patentee:
Gambro Lundia AB

Opponent:
Fresenius AG

Headword:
Solution preparation system/GAMBRO

Relevant legal provisions:
EPC Art. 100(b), 56

Keyword:
"System claim - sufficiency of disclosure (yes) - skilled person"
"Inventive step (yes) non-obvious alternative"

Decisions cited:
-

Catchword:
-

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Case Number: T 0162/98 - 3.3.5

D E C I S I O N
of the Technical Board of Appeal 3.3.5
of 9 May 2001

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 21 November 1997 rejecting the opposition filed against European patent No. 0 443 324 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: R. K. Spangenberg
Members: B. P. Czech
M. B. Günzel

Summary of Facts and Submissions

I. The appeal is from the decision of the opposition division rejecting the opposition against European patent No. 0 443 324. The sole independent claim 1 of the contested patent reads as follows:

"System for preparing a concentrate solution for use as a medical solution, for example, dialysis fluid or replacement fluid for hemofiltration or a concentrate fluid for preparation of such fluids, comprising

a container (21);

water supply means (17) for supplying a predetermined amount of water to said container;

recirculation means (22) for recirculating said predetermined amount of water in a recirculation path including said container (21);

characterized by

a plurality of vessels (27, 28, 29), each containing an in water dissolvable solid substance;

said recirculation means (22) recirculating said predetermined amount of water in said recirculation path including said container (21) and a first of said vessels (29), for at least partially dissolving the substance of said first vessel until a predetermined concentration is obtained for providing a partially prepared solution;

said recirculation means further comprising valve means (24, 25) for connecting said container (21) to a further of said plurality of vessels (27,28) for including each vessel one by one in the recirculation path replacing the previous vessel, for recirculating said partially prepared solution in said recirculation path for at least partially dissolving the substance of each of said vessels until a predetermined

concentration is obtained for providing said concentrate solution."

II. The opposition was based on the grounds of Article 100(b) EPC and lack of inventive step (Article 100(a) EPC).

In it's decision, the opposition division considered seven documents, and more particularly

D1: US-A-4 202 760,

D2: EP-A-0 278 100, and

D7: US-A-4 848 916.

Concerning the opponent's objection under Article 100(b) EPC, the opposition division came to the conclusion that "from claim 1 in combination with the patent specification sufficient information is provided to the skilled person that concentrate medical solutions can be prepared with the apparatus defined in claim 1".

Concerning inventive step, the opposition division reached the conclusion that, irrespective of whether D1, D2 or D7 was considered as the closest prior art, the other two of these documents would not give any suggestion or hint to the skilled person for solving the respective objective problem with the respective distinguishing features of claim 1.

III. During the written appeal procedure, the appellant (opponent) argued that, in the case of only partial dissolution of salt components, the control of

pre-determined concentrations of the various salts to be dissolved by means of conductivity measurements would be very complicated and/or not precise enough. However, the patent in suit did not comprise sufficiently clear and complete information concerning the way these measurement were to be carried out and the avoidance of precipitations of dissolved salts. He submitted two further documents for further substantiating and as evidence for his objection under Article 100(b) EPC.

Concerning inventive step he identified different cases (full or partial dissolution of the solids) falling under claim 1 of the main request. In both cases, the technical problem indicated in the patent would not be solved by the claimed system, and the claimed system would be disadvantageous, in terms of speed and precision, in comparison to the systems disclosed in D1 and D2. Under these circumstances, the combination of constructional features taken from D1 and D2 or D2 and D7 and leading to the claimed system could not be considered as being inventive.

IV. Concerning sufficiency of the disclosure, the respondent (proprietor) stated that the skilled person would operate the claimed system at concentrations below the saturation limit. With a proper use of the system at such concentrations, there would be no problems with precipitation, re-crystallization or conductivity measuring.

Concerning inventive step, he pointed out the differences between the devices disclosed in D1, D2 and D7 and the claimed system. If combined, these documents would not lead to the claimed subject-matter at all, or

only by ex-post facto reconstruction.

V. Oral proceedings took place on 9 May 2001.

During the oral proceedings, the appellant no longer raised an objection under Article 100(b) EPC. He essentially based his objections concerning inventive step on documents D2 and D7 and the general knowledge of the skilled person.

When asked, the respondent confirmed that the wording of claim 1 as granted covered a system wherein at least some of the vessels (27, 28, 29) would contain a same substance, possibly in predetermined amounts.

VI. The appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety.

The respondent requested that the appeal be dismissed. As an auxiliary request, he requested that the patent be maintained on the basis of the amended claims submitted with his letter dated 24 October 1998.

Reasons for the Decision

1. *Scope of claim 1*

During the oral proceedings, the appellant acknowledged that claim 1 was to be considered as directed to an apparatus. It was undisputed that the apparatus as claimed does not exclude the following possible modes of it's use:

(i) full dissolution of weighted quantities of substances comprised in at least some of the vessels (27, 28, 29) and

(ii) partial dissolution of excess quantities of substances comprised in at least some of the vessels (27, 28, 29).

Moreover, the board takes the view that - as pointed out by the respondent during the oral proceedings - even the use of the claimed apparatus with

(iii) full or partial dissolution of only one type of substance comprised in at least a plurality of the vessels (27, 28, 29)

is covered by the wording of claim 1, although it is not specifically addressed in the description. Means for determining the concentration are not necessarily part of the apparatus of claim 1, nor are any such means restricted to conductivity measuring means (see also description of the patent, column 2, line 33 to 38).

2. *Sufficiency of the disclosure (Article 100(b) EPC)*

Concerning the sufficiency of the disclosure, the board agrees with the conclusion reached by the opposition division. During the oral proceedings before the board, the appellant no longer relied upon the objection under Article 100(b) EPC. In particular, he did not challenge that medical concentrate solutions can be obtained by operating the claimed apparatus according to the mode (i) and (iii) identified here above. The manufacture of the apparatus poses no apparent problems

and the apparatus can be put into use by a skilled person. Therefore, it is sufficiently disclosed within the meaning of Article 100(b) EPC.

The board wishes to indicate that even if the claimed apparatus may be used in a way leading to technical problems, this does not necessarily mean that sufficiency of the disclosure of the claimed apparatus as such is challenged. Carrying out partial dissolution of certain salts (according to mode ii) referred to here above) at relatively high concentrations using conductivity measuring means merely constitutes a special way of using the preferred embodiment of the apparatus according to dependent claim 3. If, in this case, the skilled person was confronted with technical problems as alleged by the opponent, he/she would disregard this particular modus operandi of the claimed apparatus.

3. The board is satisfied that the claimed apparatus is novel over the cited prior art. Novelty of the claimed subject-matter has not been challenged. The differences between the claimed apparatus and the disclosures of the cited documents emanate from the following assessment of inventive step.

4. *Inventive step*

4.1 Closest prior art

D2, which is considered to represent the closest prior art, discloses an apparatus for the preparation of medical solutions, which comprises means for dissolving two salts (NaCl and $NaHCO_3$) present in solid form. Water is passed in parallel through two independent flowpaths

each comprising a salt containing vessel. Conducting the water through the vessels leads to a relatively high and constant level of concentration of the dissolved salts (see page 13, line 42 to 44). For forming a multi-component medical solution, the two relatively concentrated salt solutions obtained are independently but implicitly simultaneously admixed in controlled amounts to a main water stream. In order to obtain predetermined concentrations of the two salts in the multi-component solution, their concentrations in the latter are measured after their admixture to the main stream, e.g. by conductometers. Depending on the measured values, flow restriction means arranged in the two separate flowpaths, e.g. dosing pumps, are operated to admix controlled amounts of concentrated salt solutions to the main stream. The two salts are preferably arranged in cartridges in amounts suitable for one treatment. Different medical treatments may be carried out with the disclosed apparatus. See Figure 8, claims 1, 16, 27, 34 and 35, page 4, lines 9 to 32 and lines 43 to 52, page 5, lines 2 to 15, page 10, line 37 to page 11, line 32, page 13, lines 11 to 57. The working principle of the arrangement shown in Figure 8 for controlling the salt concentration in the mixed stream is the same as the one of Figure 1, which is explained at page 6, lines 23 to 37. Irrespective of varying extents or degrees of dissolution, the concentrations in the mixed stream can be adequately controlled. Although the amount of salt comprised in the cartridges is preferably the amount required for a single treatment, D2 does not clearly specify whether the dissolution of the salts within the cartridges is taking place continuously during flow-through or upon filling the cartridge with water (batch-like).

In contrast with the apparatus according to claim 1, the apparatus disclosed in D2 does not disclose

- recirculation means and a recirculation path through a container and further solid containing vessels, and hence

- no valve means for including the different vessels into such a recirculation path one by one.

4.2 Technical problem

According to the respondent the apparatus as claimed is constructionally simpler and/or more flexible than the ones of the prior art. It can thus be used more effectively in preparing medical solutions from solid substances, including substances which are difficult to dissolve, according to the individual patient's needs. The appellant did not accept these alleged advantages, since in his view the techniques and devices disclosed in any of D1, D2 and D7 would also allow for a simple preparation of solutions tailored to individual patients.

Irrespective of any such advantages, the board takes the view that the technical problem to be solved by the claimed apparatus with respect to D2 can in any case be seen in the provision of a further system (apparatus) suitable for preparing a concentrate medical solution of predetermined concentration(s) for individual patients from at least one type of component present as a water-soluble solid substance.

4.3 The claimed apparatus undisputedly solves this problem and provides an apparatus suitable for the flexible

preparation of various solutions from various solid starting materials. As will appear from the following, the claimed apparatus is not suggested by or derivable from the cited prior art.

4.4 Although the preparation of medical solutions with concentrations dependent on an individual patient's need are not addressed in D2, the apparatus disclosed therein is clearly suitable for that purpose. Moreover, the use of interchangeable solid containing cartridges makes the apparatus of D2 quite flexible. However, the apparatus and method disclosed in D2 is based on a different approach to the formulation of a medical solution, comprising a rather uncontrolled dissolution of the two salts, followed by controlled metering of the solutions obtained into a main aqueous stream, depending on the concentration in the mixed stream obtained. A measurement or control of the exact salt concentrations reached during their dissolution is not described. Considering the different approach adopted in D2, this document cannot by itself suggest the constructional modifications required to arrive at the apparatus of claim 1, i.e. the inclusion of recirculation means for fast dissolution of substances difficult to dissolve, and the valve means for sequential dissolution of the solids, wherein part of the recirculation path (container, conduits) is shared during recirculation through the different vessels.

4.5 D7 discloses an apparatus for bulk mixing a sodium bicarbonate solution in order to provide a dialysis solution for multiple patients. A mixing tank is filled with a pre-determined amount of water, and then a predetermined amount of bicarbonate, e.g. in the form of pre-measured packages, is introduced into the

container by means of an open top portion (see claim 1). Mixing and complete dissolution of the bicarbonate is carried out by pumping the mixture through an external recirculation loop conduit for a sufficient time. See column 1, lines 6 to 14, column 2, lines 52 to 57, column 4, lines 1 to 16 and Figures 1 and 2 of D7. Mixing/dissolution of multiple substances in water is not addressed. Moreover, D7 does not refer to individual patient's needs.

Thus D7 cannot by itself suggest the use of multiple additional vessels comprising bicarbonate or another water soluble solid substance, and of valve means including each of these vessels into the recirculation path one by one.

4.6 A combination of the teaching of D7 with the teaching of D2 would require ex-post facto reconstruction of the apparatus and would go against the general approach to dissolution and metering of the substances as taken in D2 (simultaneous and controlled addition of solutions prepared in a relatively uncontrolled way).

Moreover, such a combination would still not comprise the required valve means enabling sequential dissolution. This finding also applies to a combination of the teaching of D2 with the teaching of D7, if the latter was considered as closest prior art. The applicant's allegation, according to which the further constructional modifications necessary to arrive at the claimed apparatus from a combination of these two documents would be trivial for a skilled person, cannot be accepted in the absence of any evidence concerning the relevant common general knowledge.

4.7 The appellant's allegation that the use of the apparatus of claim 1 would be more complicated than the methods disclosed in D2 (different approach to dissolution and concentration control)or D7 (recirculation mixing of predetermined amounts of solids and water), and hence disadvantageous, is not relevant for the assessment of the inventive step underlying the apparatus of claim 1. An apparatus comprising a container in combination with separate, solids containing vessels, which are to be connected to a recirculation loop one by one, requires different manipulations in terms of the steps to be taken before the start of the solution preparation, and allows for different modes of solution preparation (e.g. multiple components), which may be preferable under certain conditions of use, depending e.g. on the type of solid substances, their solubility, their dissolution speed, their formulation and/or packaging and commercial availability, and/or the qualifications of the operator.

4.8 As acknowledged in D2 (see page 3, line 48 to page 4, line 4, the preparation of medical solutions from

solids rather than liquid concentrates has advantages under certain circumstances. However, although document D1 relates to the preparation of hemodialysis solutions with compositions depending on the individual patient's needs (see column 5, lines 34 to 55), it does not deal with the dissolution of **solid** components at all. Rather, the desired solution is obtained by injecting liquid concentrates through venturi means into a main stream of water (see figures 1 and 2, claims 1 and 4). Moreover, D1 requires the two components to be added to the solution sequentially, but in two entirely **separated** recycle loops. Recycling through the two loops is not provided for dissolving solids, but for sucking and mixing the liquid concentrates into the main water stream. Therefore, the board takes the view that the skilled person confronted with the above mentioned technical problem would not even consider this document. Assuming in the appellant's favour that he/she would consider D1, a combination of it's disclosure with the teachings of any of D2 or D7 would still not lead to the claimed apparatus in an obvious manner, since none of the documents discloses valve means for sequentially connecting solids containing vessels to a recirculation flowpath comprising a solution container.

4.9 Summarising, none of the combinations of documents D1, D2 and/or D7 leads - without ex post facto reconstruction - to an apparatus having valve means for connecting different solids containing vessels to a recirculation flowpath comprising a container. The board is not aware of any evidence concerning common general knowledge which would render these features obvious.

4.10 The board is convinced, and it was not disputed, that the other documents cited by the appellant do not come closer to the invention and do not contain any more relevant information. They merely concern theoretical aspects of the dissolution of solids and of conductivity measurements in salt solutions.

4.11 Therefore, since the apparatus of claim 1 cannot be derived in an obvious manner from the disclosures of any of the cited prior art documents taken alone or in combination, it is considered to be based on an inventive step as required by Articles 52(1) and 56 EPC.

5. Dependent claims 2 to 19 concern preferred embodiments of the apparatus according to claim 1 and are thus equally novel and inventive (Article 52(1) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Rauh R. Spangenberg