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Datasheet for the decision of 5 February 2010

Case Number: T 0172/08 - 3.2.02

Application Number: 01915621.5

Publication Number: 1200141

IPC: A61M 1/34

Language of the proceedings: EN

Title of invention:
Dialysis machine

Patentee:
GAMBRO HOSPAL (Schweiz) AG

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 139

Relevant legal provisions (EPC 1973):
-

Keyword:
"Extended subject-matter (no, main request)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0172/08 **-** 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 5 February 2010

Appellant: (Patent Proprietor)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 29 November 2007 concerning maintenance of European patent No. 1200141 in amended form.

Composition of the Board:

Chairman: M. Noël
Members: P. L. P. Weber
A. Pignatelli

Summary of Facts and Submissions

I. The appeal of the patentee is against the decision of the Opposition Division posted on 29 November 2007 to maintain the patent in amended form according to the auxiliary request. The patent as granted was considered to infringe Article 123(2) EPC.

II. The opposition was based on the grounds of insufficiency of disclosure (Article 100(b) EPC) and inadmissible extension (Article 100(c) EPC).

III. The notice of appeal of the patentee (appellant) was filed on 21 January 2008 and the appeal fee was paid on the same day.
The statement setting out the grounds of appeal was filed on 31 March 2008.

IV. The opponent filed a notice of appeal on 29 January 2008 and a statement setting out the grounds of appeal on 28 March 2008. It withdrew its appeal on 7 May 2008.

V. By letter of 17 December 2009 the opponent (respondent) informed the Board that it would not make any further submissions and would not attend the oral proceedings.

VI. Oral proceedings took place on 5 February 2010.

The appellant requested that the impugned decision be set aside and the patent be maintained on the basis of the main request or on the basis of one of the auxiliary requests 1 to 3 filed with letter of 23 December 2009.

The respondent as a party as of right did not file any explicit request.

VII. Claim 1 according to the main request reads as follows:

"Dialysis machine comprising:

a filter (4) having a blood compartment (5) and a dialysis liquid compartment (6) separated by a semi-permeable membrane (7);

an extracorporeal blood circuit having an arterial pipe (12) connected to an inlet of the blood compartment (5) and a venous pipe (15) connected to an outlet of the blood compartment (5);

a dialysis liquid circuit having a supply pipe (17) connected to an inlet of the dialysis liquid compartment (6) and a drain pipe (18) connected to an outlet of the dialysis liquid compartment (6), the drain pipe (18) being fitted with a pump (20) supplying a used liquid flow;

an infusion circuit having a pre-dilution pipe (25) connected to the arterial pipe (12) and a post-dilution pipe (26) connected to the venous pipe (15);

means (23,24) for varying the flow of an infusion liquid in the pre-dilution pipe (25) and in the post-dilution pipe (26); and

control means (31) for controlling the flow varying means (23,24) so that the flow of the infusion liquid in the pre-dilution pipe (25) and the post-dilution (26)

pipe matches a determined distribution of the infusion flow in the pre-dilution and post-dilution pipes;

characterized

in that the control means (31) comprises means for determining the infusion flow distribution in the pre-dilution and post-dilution pipes from at least one characteristic value which is **a** function of the concentration of the blood and/or the filtration efficiency of the filter (4), and

in that an ultrafiltration pipe (8) is connected to the drain pipe (18) between the filter (4) and the pump (20) and is fitted with an ultrafiltration pump (21) supplying a flow."

VIII. The arguments of the appellant can be summarized as follows:

The incorporation of the Article "a" before the word "function" in the last paragraph of claim 1 as granted was the result of an obvious correction of a grammatical error.

The object of the invention was to overcome the problems of the prior art with regard to the pre-dilution and the post-dilution techniques, and the general solution to this problem was indicated on page 10, where it was made clear that the infusion of liquid was regulated by adjusting the delivery of a physiological liquid upstream and downstream of the filter. It was thus clear that what was inherent to the solution of the problem was the use of the pre-dilution

and the post-dilution techniques and the balancing of both of these dilution types on the basis of the measured characteristic values. The rest of the application taught how this could be implemented in one particular case.

Claim 1 as filed did not define precisely what kind of sequence was meant, any sequence was covered by the wording of the claim so that it could be said that the word "sequence" as originally used was within the meaning of "distribution".

The person skilled in the art would read the patent and the prior art bearing in mind its general knowledge and would unambiguously understand that the invention was focused primarily on the distribution of the infusion flow between the pre-dilution and the post-dilution pipes.

A further indication that the word "sequence" was to be construed generally could be found in the originally filed claim 12, where it was indicated that the infusion solution was infused in either one or both of the arterial and venous pipes.
It was further to be noted that it was not because the specific embodiment described was narrow that a more general concept could not be claimed.

Finally even if one supposed that the word "distribution" was broader in meaning than the word "sequence", the application of the three points test would lead to the same conclusion that "distribution" was nevertheless allowable since the use of a determined sequence was never presented as essential in

the originally filed description, it was clear for the person skilled in the art that a sequence was not indispensable for the solution to the problem set out in the application, and no modification of other features of the claim would become necessary as a consequence of a change from "sequence" to "distribution".

IX. No objections were raised by the respondent against claim 1 as granted.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Claim 1 according to present main request differs from granted claim 1 only by the addition in the characterising portion of the indefinite Article "a" before the word "function" so that the relevant passage reads "… which is **a** function of the concentration…".

This is no more than a linguistic correction falling under Rule 139 EPC (former Rule 88 EPC 1973). It is immediately evident that said indefinite Article "a" was missing in the granted wording of claim 1, so that this obvious linguistic correction of the wording of granted claim 1 fulfils the requirements of Rule 139 EPC.

3. *Extension of subject-matter (Article 100(c) EPC)*

In claim 1 the following features were considered objectionable by the Opposition Division:

"...control means (31) for controlling the flow varying means (23,24) so that the flow of the infusion liquid in the pre-dilution pipe (25) and the post-dilution (26) pipe matches a determined distribution of the infusion flow in the pre-dilution and post-dilution pipes;

characterized in that the control means (31) comprises means for determining the infusion flow distribution in the pre-dilution and post-dilution pipes from at least one characteristic value ..." (emphasis added).

The corresponding passage in originally filed claim 1 reads as follows:

"...and control means (31) for controlling the flow varying means (23,24) so that the flow of the infusion liquid in the pre-dilution pipe (25) and the post-dilution (26) pipe matches a determined sequence."

The Opposition Division considered that the word "distribution" was broader than the word "sequence", therefore a new concept, and thus new subject-matter was introduced into claim 1 which was not disclosed in the originally filed application documents.

The Board agrees with the first instance in that the word "distribution" is more general than the word "sequence" as it encompasses all kinds of ways of

distributing the infusion flow including non sequential ones.

The question is thus whether for the person skilled in the art this more general concept of distributing the infusion flow is directly and unambiguously derivable from the originally filed application documents.

In the originally filed introductory part of the description it is explained that in order to increase the efficiency of dialysis treatment, it is known to cause the ultrafiltration of large amounts of plasma water so as to enhance the effects of transport of the undesirable waste by convection. The quantity of plasma water removed in excess of the desired final weight-loss is compensated for by a substitution liquid which is infused into the extracorporeal blood circuit. This substitution liquid is infused either upstream of the filter (pre-dilution technique) or downstream of the filter (post-dilution technique).
As explained on page 2 of the application as filed, both pre-dilution and post-dilution techniques have their respective advantages and disadvantages:
In the post-dilution technique, the plasma water removed through the membrane is more concentrated than in the pre-dilution technique and, at equal flowrates, the treatment is more efficient. On the other hand, the blood becomes more easily concentrated, which can give rise to the phenomenon called filter "caking".
With the pre-dilution technique the critical conditions leading to caking are avoided but this technique is less efficient than the post-dilution technique.

Therefore the aim of the invention is to avoid the drawbacks of both the post-dilution technique and the pre-dilution technique.

While the specific embodiment described operates with a sequential and alternate opening and closing of the pre-dilution pipe or post-dilution pipe, it is clear for the person skilled in the art that the teaching of the patent as a whole is primarily to use a suitable combination of pre-dilution and post-dilution techniques in order to avoid caking of the filter and thus optimise the overall efficiency of the dialysis treatment.
The general concept of distribution of the flows of liquid between the pre-dilution pipe and the post-dilution pipe emerges clearly from page 14, line 21 of the originally filed description, where it is mentioned: "*It is emphasized, in particular, that the present method permits accurate regulation and distribution of the infusion flow rate IR. Moreover, ..., for the purpose of improving the filtration efficiency and avoiding critical situations.*" (emphasis added), thus confirming that the most important criterion for avoiding critical situations arising in the devices according to the prior art is an accurate regulation and distribution of the infusion flow.

Further indications that this general distribution concept is most important and has precedence over the alternate opening and closing of the pre-dilution and post-dilution pipes can be found, for example, in the following passage on page 10, lines 3-6:
"*In use, the infusion of liquid is regulated by adjusting the delivery ... of a liquid ... upstream and*

downstream from the filter 4." or still in other passages such as page 11, lines 15-21; page 12, lines 12-16, where the distribution is presented as the principal solution, before any sequential operation.

The Board is thus satisfied that claim 1 according to the main request fulfils the requirements of Article 123(2) EPC.

4. The Opposition Division considered that the requirement of sufficiency of disclosure (Article 100(b) EPC) was satisfied and the Board does not see any reason to deviate from the opinion of the Opposition Division on this question.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance department with the order to maintain the patent in the following version :

   – claim 1 according to the main request as filed with the letter dated 23 December 2009
   – claims 2 to 10 as granted
   – description as granted
   – figures as granted

The Registrar: The Chairman:

D. Sauter M. Noël