BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 9 October 2012

Case Number: T 0344/08 - 3.2.02

Application Number: 02078806.3

Publication Number: 1396274

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Controller for a blood treatment equipment

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 100(b), 54, 56
RPBA Art. 13

Keyword:
"Insufficiency of disclosure (no), novelty (yes), inventive step (yes)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0344/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 9 October 2012

Appellant: (Opponent)
Fresenius Medical Care Deutschland GmbH
Else-Kröner-Straße 1
D-61352 Bad Homburg (DE)

Representative:
Herrmann, Uwe
Lorenz - Seidler - Gossel
Widenmayerstraße 23
D-80538 München (DE)

Respondent: (Patent Proprietor)
Gambro Lundia AB
Magistratsvägen 16
S-22 643 Lund (SE)

Representative:
Thul, Stephan
Manitz, Finsterwald & Partner GbR
Postfach 31 02 20
D-80102 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 13 December 2007 concerning maintenance of the European patent No. 1396274 in amended form.**

Composition of the Board:

Chairman: E. Dufrasne
Members: P. L. P. Weber
M. Stern

Summary of Facts and Submissions

I. The appeal was filed by the opponent against the interlocutory decision of the Opposition Division posted on 13 December 2007 stating that, account being taken of the amendments made by the proprietor during the opposition proceedings, the European patent n°1396274 and the invention to which it relates meet the requirements of the EPC.

The notice of appeal was filed on 13 February 2008 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 22 April 2008.

II. Oral proceedings were held on 9 October 2012.

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

The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed during the oral proceedings or, in the alternative, on the basis of the auxiliary request filed with letter dated 7 September 2012.

III. The following documents are cited in the present decision:

D1: US-A-5744031
D2: US-A-4244787
D3: EP-A-0495412
D4: WO-A-98/55166.

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

1. A controller (12) for a blood treatment equipment (10), said equipment comprising at least a treatment unit (14) including a semipermeable membrane separating the treatment unit in a first compartment (16) for the circulation of blood and in a second compartment (18) for the circulation of a treatment liquid, the controller (12) being adapted to:
- receive one or more entries of measured information measured during the course of a treatment procedure, said measured information being one chosen in the group comprising conductivity of the treatment liquid downstream the treatment unit (14); concentration of a substance in the treatment liquid downstream the treatment unit (14);
- calculate from said measured information at least a significant parameter indicative of the progress of an extracorporeal blood treatment carried out by the equipment (10),
- compare said calculated significant parameter to a prescribed reference value for the same parameter,
- generate at least one output control signal responsive to said comparison,
wherein
said output control signal is generated for automatically controlling a fluid removal rate from said second compartment (18);
the significant parameter indicative of the progress is one chosen in the group comprising:
- the concentration Cb of a substance in the blood of a patient undergoing a treatment
- the dialysis dose KTt after a time Tt.

V. Dependent claims 6, 9, 10 and 11 read as follows:

6. Controller (12) according to claim 1, in which the controller (12) is programmed to compute a hemodialysis treatment procedure time or remaining hemodialysis treatment procedure time by relating a computation of a delivered dialysis dosage reflected by an entry of measured information received by the controller (12) after a determined time increment during a hemodialysis treatment procedure to said prescribed dialysis dosage value.

9. Controller (12) according to claim 6, in which the controller (12) is programmed to compute a remaining treatment procedure time by subtracting said measure of a delivered dialysis dosage from said prescribed dialysis dosage value and dividing the resulting difference by an instantaneous dialysance value measured at the end of said determined time increment, as represented by (KTp — KTt)/DTt.

10. Controller according to claim 1, wherein the equipment includes a variable speed ultrafiltration pump (34), said one or more output control signals responsive to said one or more inter-related values generated by the controller (12) are employed to automatically control the speed of said variable speed ultrafiltration pump (22).

11. Controller (12) according to claim 9, in which said one or more inter-related values comprises a multiplied relationship between said one or more entries of said measured information and a ratio of a difference

between said prescribed dialysis dosage value and a measure of a delivered dialysis dosage to a difference between said prescribed weight loss value and an achieved weight loss, or the inverse of such ratio as respectively represented by ((WLp-WLTt).DTt)/(KTp-KTt), or the inverse of such ratios, wherein the symbols have the meanings identified herein.

VI. There is no need for the present decision to consider the subject-matter of the auxiliary request.

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

Main request

Sufficiency of disclosure

The invention according to claim 1 cannot be carried out over the whole scope of the claim because the feature "*said output control signal is generated for automatically controlling a fluid removal rate from the second compartment (18)*" covers too many embodiments. It covers control of the removal rate of the ultrafiltrate UF alone or of the removal rate of the dialysis fluid Qd together with the ultrafiltrate UF, or even of the removal rate of the dialysis fluid alone, but the patent only discloses an embodiment in which the UF removal rate alone is changed. Accordingly, the person skilled in the art has to become inventive in order to carry out the invention over the whole scope of the claim.

Claims 10 and 11 refer to "*said one or more inter-related values*" and are respectively dependent on claim 1 and claim 9 in which no such inter-related values are mentioned, so that the person skilled in the art cannot carry out the invention according to these claims because he does not know what these values should be related to.

Novelty

D1 discloses a controller for a blood treatment equipment having all the features of the subject-matter of claim 1. In particular, the last feature of claim 1, whose disclosure is disputed by the respondent, is also disclosed by D1. From claim 11 of D1 it is implicit that the controller regulates the ultrafiltration pump on the basis of the dialysis dose and not on the basis of the clearance. Claim 11 namely specifically requires control means for controlling extraction means as a function of a desired quantity of blood filtrate to be extracted, and as a function of the calculated duration of the treatment time according to a comparison between a predetermined clearance and the calculated clearance. It seems self-evident that in order to be able to determine the remaining treatment time the dose already received must be determined. This can mathematically only mean that a time element is combined with a clearance element, which is nothing else than a dialysis dose. It follows that also in D1 the ultrafiltration pump 21 is controlled on the basis of the dialysis dose, which is what is claimed in claim 1 of the patent in suit. The disclosure of the other features of claim 1 in D1 was not disputed, so that the subject-matter of claim 1 is not new over D1.

Inventive step

New objections under inventive step, starting from D3 or D4 as closest prior art, were being submitted at a late stage because when studying the case for the oral proceedings these new attacks were found to be relevant. They are based on the documents already on file, so the respondent should not have any difficulty replying to them. Further, it is also the duty of the European Patent Office not to maintain a patent if it is invalid. These new objections should therefore be admitted into the proceedings.

The subject-matter of claim 1 is not inventive for several reasons.

Starting from D1 the only difference with the subject-matter of claim 1 is that the dialysis dose is calculated instead of the clearance. However, the person skilled in the art will automatically be led to a calculation of the dialysis dose when he has to estimate the duration of the treatment session.
It is the aim of each treatment session to reach a certain dialysis dose, and from D1 the person skilled in the art already learns that when the clearance is below that expected he should lengthen the duration of the treatment session, which is done for no other reason than to reach a specific dialysis dose. It is therefore a natural step for the person skilled in the art to use the dialysis dose as a control parameter, instead of the clearance in the device according to D1, in order to be able to calculate the duration of the treatment session, and by doing so he would inevitably

arrive at the subject-matter of claim 1. In addition, the use of the dialysis dose instead of the clearance as a treatment regulation parameter is suggested by D4 or D3. D4 proposes to integrate the clearance in order to know the dialysis dose and to use this value for adjusting the dialysis treatment (page 3, line 16), so from D4 the person skilled in the art gets the clear teaching that the dialysis dose is an alternative to the clearance for controlling a dialysis treatment. But also in D3 it is explained that the dialysis dose is typically selected by the physician and used to terminate a treatment session. Hence, from D3 or D4 the person skilled in the art learns that the dialysis dose can be used alternatively to the clearance for the control of a dialysis treatment.

Therefore, the subject-matter of claim 1 is not inventive when starting from D1, in combination with the general knowledge of the person skilled in the art or in combination with D3 or D4.

The subject-matter of claim 1 is also not inventive when starting from D3 or D4. These documents teach to calculate the dialysis dose and to use the dialysis dose as a parameter to terminate the treatment when the desired value is reached. In other words, the treatment duration is a function of the dialysis dose reached. The person skilled in the art knows from D1 that when the duration of a treatment session is changed the delivery of the pump for extraction of the blood filtrate should be changed to achieve the same prescribed weight loss during the treatment. Also in this way the person skilled in the art is directly guided to the subject-matter of claim 1.

Finally, when starting from D4, as already explained above, the person skilled in the art is taught to terminate the treatment session when the desired dialysis dose is reached. While it is not explicitly mentioned in D4 how the treatment session is terminated, it cannot be considered inventive to terminate the treatment session by automatically sending a control signal to stop fluid removal from the second compartment. By doing so, however, nothing else is done than what is claimed to be done by the controller in claim 1. The subject-matter of claim 1 is therefore also not inventive for this reason.

Late objection with regard to the adaptation of the description

When preparing the oral proceedings it appeared to the appellant that the description had not been properly adapted during the first-instance proceedings. Paragraphs [0051] to [0053] should have been deleted because they concerned the fourth option in claim 2 as granted, which is, however, no longer claimed in the claims according to the main request on file. This objection should therefore be introduced into the appeal proceedings and examined.

VIII. The arguments of the respondent can be summarised as follows:

Main request

Sufficiency of disclosure

In particular in paragraph [0027] of the patent it is explicitly mentioned that the flow rates into and out of the dialysate compartment are controlled by conventional means. These conventional means are known by the person skilled in the art, so he would not have any difficulties in carrying out the invention according to claim 1. The one way of carrying out the invention described in detail in the patent specification does not hinder the person skilled in the art from using obvious constructional alternatives to come to the same result.

Concerning the subject-matter of claims 10 and 11 and the reference to inter-related values, the person skilled in the art will be able to find out from the whole patent specification what the inter-related values refer to. He will already find indications e.g. in claims 2 and 3 and so have no difficulties in carrying out the invention according to claims 10 and 11.

Novelty

In D1, column 7, lines 19 to 21, it is mentioned that the unit 26 calculates by extrapolation on the basis of the dialysance for sodium, and according to known rules of correspondence, the clearance of the urea. This means that a calculation as meant in D1, and thus also in claim 11 of D1, has nothing to do with an integration of clearance over time as in the present invention according to claim 1 (according to the definitions given in paragraph [0025] of the patent). In actual fact what is done in the device according to D1 is to increase the treatment time e.g. by a fixed

amount of time depending on the value of the clearance. This has nothing to do with a regulation on the basis of the dialysis dose as required by claim 1 of the patent in suit.

Inventive step

The late-filed objections under inventive step should not be admitted into the proceedings. The appellant had ample time during the opposition and appeal proceedings to file these objections much earlier.

When starting from D1 the appellant failed to explain what would be the motivation of the person skilled in the art to change anything. The submitted problem of finding an alternative for regulation on the basis of the clearance cannot be the objective problem to be considered when applying the problem-solution approach. Regulation on the basis of the dialysis dose, as in the present invention, has the advantage of taking better account of the history of the treatment, which in the end will lead to the actual treatment being aligned more closely with the desired treatment.

Hence, the objective problem to be solved is to provide a controller for blood treatment equipment which assures precise control of the blood purification achieved during the dialysis, so that it assures a predetermined amount of metabolic waste, such as urea, to be removed during the treatment and also allows a predetermined weight to be removed during the treatment.

The solution to this problem proposed in claim 1 is not suggested by the cited documents.

D4 discloses a method of measuring and/or calculating a dialysis dose in order to replace blood sampling, but gives no hint as to a better regulation of a treatment session on the basis of the dialysis dose. An indication that the use of the clearance to regulate the treatment session, as in D1, has disadvantages cannot be found in D4 either. In fact D4 discloses nothing more than a computerised monitoring system to replace monitoring on the basis of blood samples. The same is true for D3, which in fact principally aims at reducing the costs of a dialysis centre by a better estimate of the treatment duration for individual patients. Information that regulation on the basis of the clearance might have disadvantages cannot be found in this document either.

In both documents the regulation of the treatment session is not an issue. Both documents consider the termination of the treatment session, but this is apparently done by a technician as can be read for instance in D3, column 8, lines 22-23.

For the other objections raised by the appellant in respect of inventive step, the respondent considers that according to the case law on the problem-solution approach D3 or D4 cannot be starting points for an inventive step reasoning as they do not disclose any controller at all (which is what is claimed in claim 1). They only disclose monitoring systems.

The decision on the late objection in relation to the adaptation of the description is left to the Board, but the cited passage is not clearly inappropriate as alleged by the appellant.

Reasons for the Decision

1. The appeal is admissible.

2. Sufficiency of disclosure

2.1 The appellant argues that the feature "*said output control signal is generated for automatically controlling a fluid removal rate from the second compartment (18)*" is not sufficiently described for it to be carried out, because it encompasses more embodiments than the only one disclosed in the patent in which only the UF removal rate is controlled and changed.

Means (e.g. pumps) which allow control of the circulation rate of the dialysis fluid or the removal rate of the ultrafiltrate are well known in the art, so the Board cannot see any difficulty in carrying out what is claimed. While it is true that in the only embodiment described in the description the ultrafiltration pump is controlled, the person skilled in the art knows that the same effect could be obtained, for example, by controlling the dialysate pump in the outlet line of the dialysate compartment. Of course the person skilled in the art might have to make simple tests to adjust the removal rates so as to obtain the expected result, but this does not mean that

the invention according to claim 1 cannot be carried out without undue burden.

2.2 Concerning the objection against dependent claims 10 and 11 because the "*inter-related values*" appearing in these claims are not present in the claims on which they depend, the Board notes that the same "*inter-related values*" are present in a number of other claims not objected to by the appellant.
This shows that the objection of the appellant is a clarity objection under Article 84 EPC rather than an objection of insufficiency of disclosure under Article 100(b) EPC. Such an objection is however not to be admitted in opposition proceedings or opposition appeal proceedings when it concerns the granted version of the claims, as is presently the case. Article 84 EPC is not listed in Article 100 EPC which exhaustively defines the available grounds of opposition.

For the sake of completeness the Board would like to emphasise that if, after having read claims 10 and 11, the person skilled in the art were to have any doubts as to how he has to understand and carry out these "*inter-related values*", he would already find in claim 2, for example, a clear indication as to how these "*inter-related values*" can be obtained.

2.3 Therefore in the Board's opinion the ground of opposition of insufficiency of disclosure pursuant to Article 100(b) EPC cannot hold.

3. Novelty

3.1 D1 discloses a dialysis machine with a controller for adjusting the therapeutical process in order to achieve a therapeutic objective set by the physician (column 2, lines 62 to 67). The data which are supplied to the system prior to the treatment session are mentioned in column 6, lines 5 to 25 and include the duration T of the session, the flow rates of the blood QB and of the dialysis liquid QD, the desired loss of weight WL, the desired concentration [A], [B], [C] of electrolytes A, B, C in the blood, and in particular, the desired clearance of urea KUR.

Measurements are taken in the dialysis liquid throughout the treatment session by means of sensors. In D1 the example of the concentration of sodium is given. The concentration of sodium is measured and the controller 26 compares the measured concentration with the desired concentration stored in its memory and, if required, actuates pumps for increasing or decreasing the concentration of sodium in the dialysis liquid. Additionally, the controller 26 calculates by extrapolation, on the basis of the dialysance for sodium, the clearance of urea. Here again, if the clearance of urea does not correspond to the desired clearance of urea KUR, the controller either changes the delivery of the circulating pump 15 for the dialysis liquid or the delivery of the circulating pump 6 for the blood circulation, or changes the duration of the initially programmed treatment session. In the latter case, the controller 26 modifies the delivery of the pump 21 for extraction of the blood filtrate to

take into account the prolongation or shortening of the dialysis session (column 7, lines 11 to 36).

From the above, it follows that with the controller according to D1 only in one single situation is an action taken on the ultrafiltration pump, namely when the duration of the treatment time is changed due to discrepancy between the desired clearance for urea KUR and the actual clearance for urea. As mentioned above, the actual clearance for urea was extrapolated from the dialysance for sodium, and it is well known that both these values are instantaneous values. The controller according to D1, hence, does not actuate the ultrafiltration pump on the basis of the dialysis dose KTt after a time Tt, as required by the last feature of claim 1. Still less does it actuate the ultrafiltration pump on the basis of a concentration of a substance in the blood, which is the other alternative mentioned in the last feature of claim 1, since, when the concentration of sodium is not in accordance with the prescription or objective, it is the composition of the dialysate which is changed.

3.2 The appellant considered that the mention in independent claim 11 of D1 that control means are present for controlling the extraction means as a function of a desired quantity of blood filtrate to be extracted, and as a function of the calculated duration of the treatment session according to a comparison between a predetermined clearance and the calculated clearance, would unequivocally imply that the dialysis dose must be calculated.

In the Board's opinion there is no basis in D1 for such a conclusion. In the last feature of independent claim 11, the word "*calculated*" is actually used in the term "*calculated duration*". However, nowhere in D1 is there a mention of the calculation of the dialysis dose as required according to claim 1 of the patent in suit. Such calculation as mentioned in D1 could for instance rely on empirical curves stored in the control unit, or on specific values taken from tables of correspondences stored in the control unit, or on any other basis. D1 is silent about the way the calculation of the duration of the treatment session is made. In addition, when the verb "calculate" is used in relation to the clearance of urea in column 7, lines 19 to 22, it is specified that the unit 26 calculates the clearance of urea "*by extrapolation*" and "*according to known rules of correspondence*". This indicates rather that in the context of D1 the verb "calculate" is not used in its precise mathematical meaning, and confirms that only the clearance is considered and no calculation of the dialysis dose after a certain time is made.

3.3 Hence, the subject-matter of claim 1 is novel within the meaning of Article 54 EPC.

4. Inventive step

4.1 Late-filed arguments

With letter of 7 September 2012 the appellant introduced new combinations of documents against inventive step, namely D3 combined with D1, and D4 combined with D1. At the oral proceedings the appellant

further wished to develop a line of argumention against inventive step on the basis of D4 alone.

Against the objection of the respondent, the Board decides to admit these new lines of argumentation into the proceedings pursuant to Article 13 RPBA. The three documents used for these new lines of argumentation are the same as the documents used for the lines of argumentation presented in the statement setting out the grounds of appeal, which the respondent necessarily had to examine in order to reply to the objections already on file. In addition, two of the three new lines of argumentation were presented one month before the oral proceedings and the last line of argumentation starts with the same document (D4) as one of the other two lines mentioned, so that the Board considers that the new lines do not introduce new complex matter and that the respondent is able, even at this stage of the proceedings, to reply to these late-filed objections. In this specific context the prima facie relevance of the new lines did not need to be considered.

4.2 Closest prior art

The subject-matter of claim 1 is "*A controller for a blood treatment equipment*", which in the opinion of the Board implies that a computing unit (the controller) is permanently connected to, i.e. interacts throughout the treatment session, with the equipment used for treatment of the blood. This is the nature of a controller. Its functionalities are stated more precisely further on in the claim, when it is specified that measurements are made during the course of a treatment procedure, and on the basis of a comparison

between an actual value of a significant parameter indicative of the progress of the extracorporeal blood treatment carried out by the equipment and its prescribed reference value at least one output control signal is generated for automatically controlling a fluid removal rate from a second compartment for the circulation of a treatment liquid. This means that there is an interaction between the controller and the means for removing fluid from the second compartment so as to regularly adjust the fluid removal rate as a function of the deviation from the prescribed reference value of the value of the significant parameter indicative of the progress of the extracorporeal blood treatment.
In other words, this is a regulation of the fluid removal rate from the second compartment as a function of the deviation of the parameter value during the blood treatment session.

Of the cited documents, only D1 describes a controller which regulates a fluid removal rate or more generally a blood treatment process on the basis of the deviation from a prescribed value of a parameter indicative of the treatment progress. In other words, only D1 discloses a controller for a blood treatment equipment. In D4, instead of cumbersome and not unproblematic blood sampling for estimating dialysis efficiency, it is proposed to calculate or estimate the dialysis dose on the basis of the measurement of the urea concentration in the used dialysis liquid. However, the value thus found is not used to control the blood treatment. When the dialysis dose is achieved the treatment is simply terminated (page 11, lines 24 to 28, or page 18, lines 13 to 16). The same is true

for D3, in which in order to improve the cost efficiency of a dialysis centre in which all the dialysis machines are running for the same length of time, the dialysis dose for each individual patient is estimated in order to be able to stop the machines earlier once patients have received the prescribed dose. The treatment is, however, stopped by a technician (column 8, lines 22 to 24) when it is signalled to him to do so (column 9, lines 7 to 9). D2 is even further away because it is about measuring concentrations in the used dialysate instead of withdrawing blood from a patient in order to calculate or estimate body levels of metabolites (column 1, lines 10 to 20 and column 1, line 67 to column 2 line 17), and no action on the treatment is described.

From the above it appears that D1 is the only document disclosing a controller for a blood treatment equipment, so that according to the established case law of the boards of appeal holding that the closest prior art should be an apparatus of the same type as that claimed, D1 is the closest prior art for the assessment of inventive step in the present case.

For the reasons above, and contrary to the opinion of the appellant, the Board considers that D3 and D4 are further away from the invention according to claim 1 than D1 and can therefore not be considered to be the closest prior art for the assessment of inventive step.

4.3 Differentiating feature

As mentioned above, in one of the described modes of operation of the apparatus according to D1 the fluid

removal rate from the second compartment is changed depending on the duration of the treatment which itself was changed depending on the value of the clearance.

Instead the controller according to claim 1 regulates the fluid removal rate from the second compartment on the basis of the value of the dialysis dose KTt.

4.4 Effects of the differentiating feature on the state of the art

If in the device according to D1 the adaptation of the fluid removal rate were made on the basis of the value of the dialysis dose instead of on the basis of the value of the clearance, the control of the treatment would be better. The clearance being an instantaneous value, any control on its basis will be more sensitive to momentary variations in its value, and, of its essence, it does not take account of the history of the treatment, or in other words of the part already completed, whereas the dialysis dose, which is meant to be the integral over time of the clearance (according in particular to the definitions given in paragraph [0025] of the patent), is a much more reliable parameter.

4.5 Objective technical problem

In view of the effects obtained, the objective technical problem can be seen as being to improve the control of the dialysis equipment in such a way as to allow a better guarantee of reaching a prescribed dialysis dose and a prescribed weight loss for a given patient in a specific treatment session.

4.6 Inventive step

In the Board's opinion the subject-matter of claim 1 is inventive.

In the cited documents there is no teaching whatsoever to use the dialysis dose as a parameter for automatically controlling the fluid removal rate from the second compartment. Both documents D3 and D4, which teach to use the dialysis dose to terminate a blood treatment when the desired dose is achieved, not only do not teach to use the dialysis dose as a control parameter to automatically control any of the treatment parameters, but even less do they teach to use the dialysis dose as a control parameter for specifically controlling automatically the fluid removal rate from the second compartment.

Using the dialysis dose as control parameter allows more certainty as to the dose obtained by the patient, and by controlling the fluid removal rate from the second compartment with this same parameter it is possible, for a particular patient, to finish a treatment and achieve at the same time a predetermined dialysis dose and a predetermined weight loss. None of the cited documents suggests such a control.

The appellant considered that the person skilled in the art would readily arrive at the invention by carrying out the invention mentioned in claim 11 of D1, because one obvious way to calculate the duration of the treatment session is to calculate first the dialysis

dose achieved over a certain time, which moreover was what was done in D3 or D4.

In the Board's opinion, the reasoning proposed by the appellant is based on hindsight. The appellant has failed to convincingly demonstrate that the person skilled in the art, faced with the objective problem, would seek a solution in relation to the duration of the treatment session when in D1 several ways of controlling the treatment are indicated. If the prescribed treatment data are not achieved, D1 suggests changing the composition of the dialysate (pumps 19 or 20), or changing the delivery of the circulating pump (15) for the dialysis liquid, or changing the delivery of the circulation pump (6) for blood circulation, or changing the duration of the treatment session. It is only in this last case that D1 tells the person skilled in the art to change the delivery of the pump (21) for extraction of blood filtrate. No reason has been provided as to why the person skilled in the art would specifically wish to improve the calculation of the duration of the treatment session, when D1 does not place any specific importance on that parameter and there are many other parameters which might be improved.

Moreover, the question whether the person skilled in the art, faced with the objective problem, would consult documents D3 or D4 and find a solution to the objective problem therein, must also be answered in the negative.

In the Board's opinion, it is already questionable whether the person skilled in the art would consider D3

or D4 because, as already discussed above, these documents do not disclose any means for controlling a blood treatment, so that there is no hint for the person skilled in the art, starting from D1, to find a solution for an improved control system, when no such control system is disclosed in the other documents. If anything, these documents would teach the person skilled in the art to abandon the control means of D1 and to replace it with a calculation of the dialysis dose and, when the dialysis dose is reached, to stop the machine manually. This, however, is not the subject-matter of claim 1.

4.7 Therefore, the subject-matter of claim 1 involves an inventive step within the meaning of article 56 EPC.

5. Late-filed objection concerning the adaptation of the description

During the oral proceedings, the appellant raised an objection in relation to the adaptation of the description. The appellant considered that paragraphs [0051] to [0053] described an embodiment of the invention that no longer fell under the present claims and that, therefore, they should have been deleted.

The Board declines to admit this objection into the proceedings pursuant to Article 13 RPBA because it has not been shown to be prima facie relevant. The mentioned paragraphs are introduced by the sentence "*An alternative approach to the invention...*", and the Board considers that such a term can be read as meaning that what follows is normally not part of the invention, so that the assessment of the appellant is

not prima facie established and there is no reason to admit this objection into the proceedings at this late stage.

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 with the order to maintain the patent on the basis of:

   - claims 1 to 31 of the main request filed during the oral proceedings on 9 October 2012,
   - columns 1 to 6 and 11 to 13 of the description of the patent as granted and columns 7 to 10 of the description filed on 23 November 2007, and
   - Figures 1 to 7 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne