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Datasheet for the decision of 25 May 2011

Case Number: T 0326/08 - 3.2.02

Application Number: 99927067.1

Publication Number: 1083948

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Method for determining waste products in the dialysis liquid in dialysis treatment

Patentee:
AS Ldiamon

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 54(1)(2), 56
RPBA Art. 12(4)

Relevant legal provisions (EPC 1973):
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Keyword:
"Admissibility of auxiliary requests (partially admitted)"
"Novelty: no"
"Inventive step: no"

Decisions cited:
G 0009/91, G 0010/91

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0326/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 25 May 2011

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 13 December 2007 revoking European patent No. 1083948 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
A. Pignatelli

Summary of Facts and Submissions

I. On 13 December 2007 the Opposition Division posted its decision to revoke European patent 1 083 948 for lack of novelty and inventive step, unallowable extension, excluded subject-matter, lack of clarity and amendments not occasioned by grounds of opposition with respect to the subject-matter of the various requests.

II. An appeal was lodged against this decision by the patentee in a notice received on 13 February 2008 with the appeal fees being paid on the same day. The statement setting out the grounds of appeal was received on 22 April 2008.

III. In a communication of 28 February 2011, the Board forwarded its provisional opinion to the parties.

IV. In a letter dated 13 April 2011, the respondent (opponent) withdrew its opposition.

V. Oral proceedings were held on 25 May 2011.

VI. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the sets of claims according to the main request or one of the first to tenth auxiliary requests, all filed on 22 April 2008.

VII. The following documents are of importance for the present decision:

D1: US-A-4 244 787

D2/D2a: N.V. Kornilov et al.: "Monitoring der Zusammensetzung von Dialysierflüssigkeit während der Hämodialysebehandlung", Russische Akademie der Wissenschaften, Wissenschaftlicher Gerätebau, Band 6, Nr. 1-2, Januar-Juni (1996), Sankt Petersburger Verlagsfirma "Nauka", pages 116-117 (German translation)

D4: G. Gál et al.: "Continuous monitoring of the efficiency of haemodialysis by recording the UV transmittance of the dialysis solution", Acta Chirurgica Hungarica 24 (4), pages 231-239 (1983)

D5: G. Gál, J. Gróf: "Continuous UV photometric monitoring of the efficiency of hemodialysis", Int. J. Artif. Organs 3 (6), pages 338-341 (1980)

D6: WO-A-98/19592.

VIII. The independent claims of the requests at issue read as follows:

Main request:

"1. Method for determining the content of waste products in dialysis liquid wherein the measurement of the concentration of a certain substance or a combination of substances included in the waste products is effected directly on the outgoing dialysis

liquid from the dialyzer (14) at dialysis treatment, characterized in that the measurement is effected spectrophotometrically and that the measurement value obtained is multiplied by the flow of dialysis liquid for determining the content of said substance or said combination of substances in the outgoing dialysis liquid from the dialyzer (14), wherein the measurement is effected continuously on the flow of dialysis liquid, and wherein the spectrophotometric measurement is effected by means of UV-light."

"5. Dialysis machine (10) having a device (19) after the dialyzer (14) for determining the concentration of a certain substance or a combination of substances included in the waste products, directly on the outgoing dialysis liquid from the dialyzer at dialysis treatment, characterized in that said device (19) located in or after the dialysis machine comprises a spectrophotometric measuring cell traversed by the outgoing dialysis liquid, wherein the measuring cell (19) is adapted to be continuously traversed by the outgoing dialysis liquid, and wherein the spectrophotometric measurement is effected by means of UV-light."

Claims 2 to 4 are dependent claims.

First auxiliary request:

"1. Method for determining the content of waste products in dialysis liquid wherein the measurement of the concentration of a certain substance or a combination of substances included in the waste products is effected directly on the outgoing dialysis

liquid flow from the dialyzer (14) at dialysis treatment, characterized in that the measurement is effected spectrophotometrically and that the measurement value obtained is multiplied by the flow of dialysis liquid for determining the content of said substance or said combination of substances in the outgoing dialysis liquid from the dialyzer (14), wherein the measurement is effected continuously on the flow of dialysis liquid, and wherein the spectrophotometric measurement is effected by means of UV-light."

"5. Dialysis machine (10) having a device (19) after the dialyzer (14) for determining the concentration of a certain substance or a combination of substances included in the waste products, directly on the outgoing dialysis liquid flow from the dialyzer at dialysis treatment, characterized in that said device (19) located in or after the dialysis machine comprises a spectrophotometric measuring cell traversed by the outgoing dialysis liquid, wherein the measuring cell (19) is adapted to be continuously traversed by the outgoing dialysis liquid flow, and wherein the spectrophotometric measurement is effected by means of UV-light."

Claims 2 to 4 are dependent claims.

Second auxiliary request:

"1. Method for determining the content of waste products in dialysis liquid wherein the measurement of the concentration of a certain substance or a combination of substances included in the waste

products is effected directly on the outgoing dialysis liquid from the dialyzer (14) at dialysis treatment, said dialyzer comprising an outlet conduit (16) through which the outgoing dialysis liquid flow is supplied from the dialyzer to a drain, wherein the measurement is effected spectrophotometrically by means of UV-light and a measuring cell (19), characterized in that said measuring cell (19) is mounted on the outlet conduit (16), such that said measuring cell is traversed by the outgoing dialysis liquid flow, and that the measurement value obtained is multiplied by the flow of dialysis liquid for determining the content of said substance or said combination of substances in the outgoing dialysis liquid from the dialyzer (14)."

"5. Dialysis machine (10) having a device after the dialyzer (14) for determining the concentration of a certain substance or a combination of substances included in the waste products, directly on the outgoing dialysis liquid from the dialyzer at dialysis treatment, said dialyzer comprising an outlet conduit (16) through which the outgoing dialysis liquid flow is supplied from the dialyzer to a drain in use, and said device comprising means (20, 23) to effect the spectrophotometric measurement by UV-light, characterized in that said device located in or after the dialysis machine comprises a spectrophotometric measuring cell traversed by the outgoing dialysis liquid flow, and said spectrophotometric measuring cell is mounted on the outlet conduit (16)."

Claims 2 to 4 are dependent claims.

Third auxiliary request:

"1. Method for determining the content of waste products in dialysis liquid wherein the measurement of the concentration of a certain substance or a combination of substances included in the waste products is effected directly on the outgoing dialysis liquid from a dialyzer (14) with a membrane at dialysis treatment, wherein said dialyzer at one side of the membrane is supplied with dialysis liquid, which is drawn off from the dialyzer at the same side of the membrane in order to be supplied to a drain through an outlet conduit (16), wherein the measurement is effected spectrophotometrically by means of UV-light and a transparent measuring cell (19), characterized in that said measuring cell (19) is mounted on the outlet conduit (16), such that said measuring cell (19) is traversed by the outgoing dialysis liquid flow, and that the measurement value obtained is multiplied by the flow of dialysis liquid for determining the content of said substance or said combination of substances in the outgoing dialysis liquid from the dialyzer (14)."

"5. Dialysis machine (10) having a device after the dialyzer (14) for determining the concentration of a certain substance or a combination of substances included in the waste products, directly on the outgoing dialysis liquid from the dialyzer at dialysis treatment, wherein said device is located in or after the dialysis machine; said dialyzer comprising an outlet conduit (16) through which the outgoing dialysis liquid flow is supplied from the dialyzer to a drain in use, and said device comprising a UV-light source (20) and a photodetector (23) to effect the

spectrophotometric measurement by UV-light, characterized in that said device comprises a spectrophotometric transparent measuring cell (19) mounted on the outlet conduit (16) of the dialyzer, such that the transparent measuring cell (19) is traversed by the outgoing dialysis liquid flow in use."

Claims 2 to 4 are dependent claims.

Fourth auxiliary request:

"1. Method for determining the content of waste products in dialysis liquid wherein the measurement of the concentration of a certain substance or a combination of substances included in the waste products is effected directly on the outgoing dialysis liquid from a dialyzer (14) with a membrane at dialysis treatment, wherein said dialyzer at one side of the membrane is supplied with dialysis liquid, which is drawn off from the dialyzer at the same side of the membrane in order to be supplied to a drain through an outlet conduit (16), wherein the measurement is effected spectrophotometrically by means of UV-light and a transparent measuring cell (19), characterized in that there is mounted somewhere on the outlet conduit (16) of the dialyzer after the dialyzer inside or after the dialysis machine the transparent measuring cell (19) to which the UV-light is supplied from a light source (20) through an optic fibre (21), wherein the light which is supplied to the measuring cell (19) and passes through said cell and dialysis liquid passing therethrough will be absorbed and scattered in a varying degree by the waste products existing in the dialysis liquid so that increased concentration of a

substance in the dialysis liquid reduces the light transmission, and that the measurement value obtained is multiplied by the flow of dialysis liquid for determining the content of said substance or said combination of substances in the outgoing dialysis liquid from the dialyzer (14)."

"5. Dialysis machine (10) having a device (19) after the dialyzer (14) for determining the concentration of a certain substance or a combination of substances included in the waste products, directly on the outgoing dialysis liquid from the dialyzer at dialysis treatment, wherein said device is located in or after the dialysis machine; said dialyzer comprising an outlet conduit (16) through which the outgoing dialysis liquid flow is supplied from the dialyzer to a drain in use, and said device comprising a UV-light source (20), a photodetector (23), and optic fibres (21, 22), supplying light from the UV-light source (20) to a measuring cell (19) and diverting light passing through the measuring cell (19), to effect the spectrophotometric measurement by UV-light, characterized in that said device comprises the spectrophotometric transparent measuring cell (19), mounted somewhere on the outlet conduit (16) of the dialyzer after the dialyzer inside or after the dialysis machine, to which transparent measuring cell (19) the UV-light is supplied from the light source (20) through the optic fibre (21), wherein the light which is supplied to the measuring cell (19) and passes through said cell and dialysis liquid passing therethrough will be absorbed and scattered in a varying degree by the waste products existing in the dialysis liquid so that increased concentration of a

substance in the dialysis liquid reduces the light transmission, such that the transparent measuring cell (19) is traversed by the outgoing dialysis liquid."

Claims 2 to 4 are dependent claims.

Fifth auxiliary request:

The only claim of this request corresponds to device claim 5 of the main request.

Sixth auxiliary request:

The only claim of this request corresponds to device claim 5 of the first auxiliary request.

Seventh auxiliary request:

The only claim of this request corresponds to device claim 5 of the second auxiliary request.

Eighth auxiliary request:

The only claim of this request corresponds to device claim 5 of the third auxiliary request.

Ninth auxiliary request:

The only claim of this request corresponds to device claim 5 of the fourth auxiliary request.

Tenth auxiliary request:

Claims 1 to 4 of this request correspond to method claims 1 to 4 of the main request.

IX. The appellant's arguments are summarised as follows:

In its communication of 12 March 2007 annexed to the summons for oral proceedings, the Opposition Division had not indicated that any of the cited documents could be novelty-destroying. This issue only came up during the oral proceedings, during which a sixth auxiliary request was filed as an attempt to overcome the objection of lack of novelty vis-à-vis documents D4 to D6 by specifying that measurement was performed on the entire outgoing dialysis liquid, i.e. on the main line and not on a branch line. The further requests filed at the appeal stage also represented attempts to resolve this problem. They thus did not constitute a fresh case and should therefore be admitted. The features included in the new sets of claims were clearly derivable from the dependent claims or the description as originally filed.

Essential features common in each independent claim of the newly filed claim sets were that (1) the measuring cell 19 was mounted on an outlet conduit 16 (referred to as "main line" by the Opposition Division) through which the entire flow of outgoing dialysate passed, and (2) to which UV light in use was supplied during the measurement of a substance in the outgoing dialysis liquid. These features were present in the first embodiment in accordance with Figure 1 of the patent in suit. It was important to observe that the outlet

conduit 16 was to be distinguished from the shunt conduit 27 (referred to as "sub-line" or "branch line" by the Opposition Division) as shown in the second embodiment according to Figure 8.

D4 and D5 failed to disclose at least the above-mentioned feature (1) since the cuvette of the photometer disclosed in these documents was arranged in a sub-line in which a fraction of the dialysis solution flowed at 20 ml/min. The last paragraph of page 231 of D4 comprised an explicit reference in this respect. In contrast, the term "traversed by the outgoing dialysis liquid" in claim 5 of the main request comprised the definite article "the", indicating that all outgoing dialysis liquid was meant and that the measuring cell was thus located in the main line. The word "flow" inserted after the expression "outgoing dialysis liquid" in the independent claims of the first auxiliary request had to be given its normal technical meaning, i.e. representing the entire outgoing dialysis liquid flow exiting the dialyzer. This represented an even clearer distinction over D4 and D5 with respect to the location of the measuring cell in the main line.

For analogous reasons D2 also failed to disclose feature (1). Nothing was mentioned in this document to the effect that a measuring cell was mounted on a "main" outlet conduit of the dialyzer. Moreover, it was explicitly stated that **samples** of dialysis liquid were analysed, rather than the measurement being effected continuously as claimed. Furthermore, D2 did not teach the above-mentioned feature (2) since nothing was mentioned regarding supplying UV light through a measuring cell.

When using D2 as a starting point, the skilled person would stay with batch-wise sampling techniques as disclosed in this document and would not consider teachings dealing with continuous measurement such as D4 and D5. Even if he did so, he would not arrive at the claimed subject-matter since these documents did not disclose that the measurement was effected on the main line. This kind of measurement according to the invention would result in a more reliable technique since both the concentration and the flow rate would be determined in the same flow of dialysis liquid. The problem to be solved by the distinguishing features over D2 was hence to achieve a better feedback for reliably monitoring the effectiveness of the dialysis process.

The disclosure of D1 related to a batch-wise sampling technique and the measurement was effected by means of an ammonium ion-sensitive electrode. There was no hint of a continuous spectrophotometric measurement directly on the outgoing flow of dialysis liquid as claimed. D6, on the other hand, did disclose a spectrophotometric measurement, but in the near IR range rather than by means of UV light, and furthermore the concentration of the waste products was also measured on the blood side of the dialyzer.

Accordingly, the claimed method was not rendered obvious by any of the cited documents.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of the various auxiliary requests

The purpose of the inter partes appeal procedure is mainly to give the losing party an opportunity to challenge the decision against it and to obtain a judicial ruling on whether a first-instance decision is correct (see G 9/91 and G 10/91). The appeal proceedings are thus largely determined by the factual and legal scope of the preceding opposition proceedings. Consequently, the parties have only limited scope to amend the subject of the dispute in second-instance proceedings, and the appeal proceedings are not about bringing an entirely fresh case (see "Case Law of the Boards of Appeal of the EPO", 6th ed. 2010, VII.E.16.2.1).

New requests containing further amendments may only exceptionally be admitted in appeal proceedings and should represent serious attempts at overcoming the objections. In particular, they should not contain subject-matter which has not previously been claimed (see "Case Law of the Boards of Appeal of the EPO", 6th ed. 2010, VII.E.16.1.1).

Independent claims 1 and 5 of the second to fourth auxiliary requests comprise various new features (e.g. drain, membrane, optic fibre, transparency of the measuring cell) which were not included in the set of claims as granted and which are mostly taken from the description and drawings. These requests are

furthermore quite different from the numerous auxiliary requests considered in the opposition proceedings (which should have constituted the main subject of the present appeal proceedings). The claimed combinations of features were never examined by the department of first instance. Moreover, the statement of grounds of appeal is devoid of any justification for these requests, i.e. there is no explanation of the objections which the amendments are intended to overcome. During the oral proceedings before the Board, the appellant declared that he had submitted these new requests only at the appeal stage because it was not clear during the opposition proceedings how the Opposition Division interpreted the claims. However, the Board notes that during the opposition procedure the appellant did in fact have the opportunity to present new auxiliary requests after becoming aware of the Opposition Division's interpretation of the claims, at least during the oral proceedings where the meaning of the claimed subject-matter was discussed in depth. This is evident from points 31 to 34 of the minutes of the oral proceedings held on 8 November 2007. Finally, it is to be noted that the third and fourth auxiliary requests gave rise to numerous new objections under Articles 84 and 123(2) EPC.

The seventh to ninth auxiliary requests correspond to the second to fourth auxiliary requests, with the method claims being omitted. The observations presented above therefore apply to these requests as well.

At the appeal stage no new objections were raised which could justify the above-mentioned new requests. Accordingly, the Board does not admit the second to

fourth and seventh to ninth auxiliary requests since they could already have been presented in the first-instance proceedings (Article 12(4) RPBA).

3. Novelty

3.1 Main request

Using the same words as independent claim 5 in suit, document D5 discloses a dialysis machine (Figure 1) having a device after the dialyzer for determining the concentration of a certain substance or a combination of substances included in the waste products, directly on the outgoing dialysis liquid from the dialyzer at dialysis treatment (see paragraph bridging the left and right-hand columns of page 338), wherein said device located in or after the dialysis machine comprises a spectrophotometric measuring cell traversed by the outgoing dialysis liquid, wherein the measuring cell is adapted so as to be continuously traversed by the outgoing dialysis liquid, and wherein the spectrophotometric measurement is effected by means of UV light (see right-hand column of page 338 and page 339). Accordingly, D5 anticipates all the features of claim 5.

The wording of claim 5 merely requires that the measurement be effected "directly on the outgoing dialysis liquid" and that the measuring cell be traversed by "the outgoing dialysis liquid". These features do not rule out the possibility that the cell may be located on a sub-line or branch-line in which only a fraction of the dialysate flows, as is the case in D5. The liquid in the branch-line of D5 can

therefore also be regarded as included in "the outgoing dialysis liquid" as claimed. Contrary to the appellant's view, the definition given in claim 5 does not require that the cell be located in the "main line", i.e. the outlet conduit of the dialyzer. In this respect it is noteworthy that the wording of claim 5 was in fact included in independent claim 13 as granted and intended to cover also the "branch-line" location in a shunt conduit according to dependent claim 15 as granted.

3.2 First auxiliary request

Claim 5 differs from claim 5 of the main request merely in that the word "flow" has been inserted after the term "outgoing dialysis liquid" in both the preamble and the characterizing portion of the claim. In the Board's view, this amendment does not render the claimed subject-matter novel vis-à-vis D5, and the observations presented above under point 3.1 are equally applicable to the slightly amended wording of this claim. Contrary to the appellant's assertion, the amended term "the outgoing dialysis liquid flow" does not represent a limitation to the entire outgoing liquid flow exiting the dialyzer, implying that the cell is located in the "main line".

3.3 Fifth and sixth auxiliary requests

Claim 1 of these requests corresponds to claim 5 of the main request and the first auxiliary request respectively. Consequently, its subject-matter is also anticipated by document D5 as explained above.

3.4 It follows that the main request as well as the first, fifth and sixth auxiliary requests are not allowable for lack of novelty within the meaning of Article 54(1) and (2) EPC.

4. Inventive step - tenth auxiliary request

4.1 Independent method claim 1 comprises in particular the feature that "the measurement value obtained is multiplied by the flow of dialysis liquid for determining the content of said substance or said combination of substances", which was not present in the independent device claims of the previous auxiliary requests. As shown below, document D2/D2a discloses this feature whereas D5 is silent in this respect. Accordingly D2/D2a is considered to represent the closest prior art with respect to this claim. Reference will be made below to the German translation D2a.

Using the same words as claim 1 in suit, D2a discloses a method for determining the content of waste products in dialysis liquid (see title) wherein the measurement of the concentration of a certain substance or a combination of substances included in the waste products is effected directly on the outgoing dialysis liquid from the dialyzer at dialysis treatment, wherein the measurement is effected spectrophotometrically (5th paragraph, lines 1 to 3) and the measurement value obtained is multiplied by the flow of dialysis liquid for determining the content of said substance or said combination of substances in the outgoing dialysis liquid from the dialyzer (5th paragraph, lines 7 to 9; the display of content ("Menge") and concentration ("Konzentration") implies that the value of the content

must have been obtained by multiplication by the flow of dialysis liquid).

The appellant's argument that D2a fails to disclose that the measurement is effected on the main line, i.e. the outlet of the dialyzer, is again not convincing. The wording of the claim does not specify such a limitation, it merely requires that the measurement "is effected directly on the outgoing dialysis liquid from the dialyzer at dialysis treatment", and this feature is clearly disclosed in lines 4 to 7 of the 5th paragraph of D2a ("im Dialysatfluss").

4.2 Consequently, claim 1 is distinguished from the teaching of D2a in that the measurement is effected continuously and by means of UV light, whereas D2a states that measurement and calculation together take up to one minute and is silent about the spectral range.

4.3 The objective technical problem to be solved by these distinguishing features is to allow a more rapid and more specific determination of the content of waste products in the dialysate.

4.4 Continuous measurement with UV light is standard practice in the analysis of waste products in dialysis liquids, as can be seen, for instance, from D4 (page 232, line 1) or D5 (page 338, right-hand column, first sentence of second paragraph). The skilled person would routinely incorporate these features into the method known from D2a, in particular since the waste products of interest (urea, creatinine) are the same in D2a, D4 and D5 as well as in the patent in suit (see paragraph [0018]).

4.5 The appellant's argument that D2a deals with a discontinuous sampling technique and that the skilled person would thus stay in the area of batch-wise sampling and not consider documents dealing with continuous measurement methods is not accepted by the Board. D2a starts from a batch-wise sampling technique and already addresses the problem of the long duration of more than 5 minutes required for each measurement (see 4th paragraph). It in fact aims at a real-time measurement (see end of 2nd paragraph: "Registrierung der Veränderungsdynamik in der tatsächlichen Zeitdimension") and proposes an improved method, taking one minute or less per measurement cycle. D2a therefore gives a clear hint in the direction of continuous measurement. Accordingly, there is no obstacle at all to the skilled person's considering this kind of measurement.

4.6 It follows that the tenth auxiliary request is not allowable for lack of inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Sauter M. Noël