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Datasheet for the decision of 6 February 2025

Case Number: T 0605/23 - 3.2.02

Application Number: 10837602.1

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Title of invention:
BLOOD PURIFICATION DEVICE

Patent Proprietor:
Nikkiso Company Limited

Opponent:
B. Braun Avitum AG

Relevant legal provisions:
EPC Art. 54(3), 84

Keyword:
Novelty - main request (no) - auxiliary request (yes)
Claims - clarity - auxiliary request (yes)

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Case Number: T 0605/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 February 2025

Appellant: (Patent Proprietor)	Nikkiso Company Limited 43-2, Ebisu 3-chome Shibuya-ku Tokyo 150-8677 (JP)
Representative:	von Hirschhausen, Helge Grosse - Schumacher - Knauer - von Hirschhausen Patent- und Rechtsanwälte Nymphenburger Straße 14 80335 München (DE)
Appellant: (Opponent)	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen (DE)
Representative:	Winter, Brandl - Partnerschaft mbB Alois-Steinecker-Straße 22 85354 Freising (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 January 2023 concerning maintenance of the European Patent No. 2514447 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent appealed against the interlocutory decision of the opposition division to maintain the contested patent as amended on the basis of auxiliary request 1.

II. In its decision, the opposition division found, *inter alia*, that document EP 2 218 472 A1 (**D1**), as prior art under Article 54(3) EPC, was novelty-destroying for the subject-matter of claim 1 as granted but not for the subject-matter of claim 1 of auxiliary request 1.

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

The **appellant-patent proprietor** requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, that it be maintained as amended on the basis of the claims of one of auxiliary requests 1 and 2 as filed on 28 September 2021 (auxiliary request 1 being the one found allowable by the opposition division) or on the basis of one of auxiliary requests 3 and 4 as filed on 12 July 2022.

IV. Oral proceedings were held before the Board on 6 February 2025, during which the patent proprietor filed amended paragraphs of the description of the patent.

V. Claim 1 of the **main request** (patent as granted) reads as follows (with the feature numbering used in the decision under appeal):

M1.0 "*A blood purification apparatus comprising*

M1.1 *a blood purification instrument (2) for extra corporeally circulating blood of a patient and*

M1.2 *a concentration detecting means (5) adapted to detect a concentration of liquid flowing during blood purification*

M1.3 *wherein the concentration detecting means (5) comprises:*

M1.3.1 *a light emitting means (11) for irradiating light onto said liquid,*

M1.3.2 *a light receiving means (12) for receiving light from the light emitting means (11) transmitted through said liquid,*
characterized in that

M1.4 *the concentration detecting means (5) further comprises:*

M1.4.1 *a reference light receiving means (15) for receiving reference light branched from the light emitting means (11) without being transmitted through said liquid, and*

M1.4.2 *a detecting means (13) for detecting the light intensity respectively of the transmitted light received by the light receiving means (12) and of the reference light received by the reference light receiving means (15), and in that*

M1.5 *the blood purification apparatus further comprises an error absorbing means*

M1.5.1 *for detecting the concentration of the liquid based on the received light intensity of the transmitted light received by the light receiving means (12) and detected by the detecting means (13) and*

M1.5.2 *for absorbing a detected error of the concentration detecting means (5) based on the received light intensity of the reference light received by the reference light receiving means (15),*

M1.5.3 *wherein the error absorbing means comprises a correcting means (16) for correcting a current supplied to the light emitting means (11) so that a light amount irradiated by the light emitting means (11) is constant with the passage of time based on the received light intensity of the reference light received by the reference light receiving means (15),*

M1.6 *wherein the concentration detecting means (5) is a discharged liquid concentration sensor that can monitor the blood purification efficiency by detecting the concentration of the liquid discharged from the blood purification instrument (2).*"

VI. Claim 1 of **auxiliary request 1** differs from claim 1 of the main request by the following additional features, M1.7 and M1.8, being appended to the claim:

"*[...] and*

M1.7 *wherein the blood purification apparatus is configured such that a calibration of the discharged liquid concentration sensor is performed prior to the blood purification, and that*

M1.8 *the correction of the current supplied to the light emitting means (11) is performed at a predetermined time during the blood purification.*"

VII. Claim 1 of **auxiliary request 2** differs from claim 1 of the main request by feature M1.5.3 being amended as follows:

M1.5.3 *[...] a correcting means (16) ~~for~~ configured to correct~~ing~~ a current [...]"*

and by the following additional features, M1.7, M.10 and M1.11, being appended to the claim:

M1.7 "*wherein the blood purification apparatus is configured such that a calibration of the discharged liquid concentration sensor is performed prior to the blood purification,*

M1.10 *wherein both the light receiving means (12) and the reference light receiving means (15) comprise a light receiving element(s) generating a voltage corresponding to the received light intensity,*

M1.11 *wherein the correction of the current supplied to the light emitting means (11) is based on a ratio between the voltage generated by the reference light receiving means (15) at a time of calibration and the voltage generated by the reference light receiving means (15) during the blood purification.*"

VIII. The **opponent's arguments**, where relevant to this decision, can be summarised as follows.

Main request - novelty in view of D1

The subject-matter of claim 1 as granted was not novel in view of D1. In D1, the intensity of the reference light was proportional to the intensity of the light emitted by the light emitting means (paragraph [0030]).

Thus, the correction of the current disclosed in D1 to keep the former intensity constant resulted in keeping the latter intensity constant as well. This was also explicitly disclosed in paragraph [0005]. Therefore, D1 disclosed feature M1.5.3.

Auxiliary request 1 - novelty in view of D1

D1 also disclosed features M1.7 and M1.8. Thus, the subject-matter of claim 1 of auxiliary request 1 was not novel in view of D1 either. D1 disclosed (in paragraphs [0041]-[0045]) that the correction of the current was carried out during the entire duration of the blood treatment ("während der Nierenersatz-behandlung"), i.e. in particular immediately after the patient had been connected to the apparatus and the blood treatment had started, which was "a predetermined time during the blood purification" as defined by feature M1.8.

Auxiliary request 2

Clarity

Claim 1 of auxiliary request 2 was unclear. The term "based on" in feature M1.11 did not clearly indicate how the ratio between the voltage generated by the reference light receiving means at a time of calibration and the voltage generated by the reference light receiving means during the blood purification was integrated into the correction process, and in particular whether this ratio was directly used in a calculated correction or whether another correlating variable was obtained from a calculated ratio which was then directly included in the correction.

Novelty in view of D1

D1 also disclosed, at least implicitly, features M1.10 and M1.11. Thus, the subject-matter of claim 1 of auxiliary request 2 was not novel in view of D1 either. The correction of the current in D1 aimed at keeping the voltage U_{45_t} at its target value U_{45} as measured at the time of calibration (paragraph [0045]). This necessarily required that these two voltages be measured and used to determine the correction. Hence, this correction was inevitably based on the ratio between these voltages, as required by feature M1.11. Paragraph [0033] actually disclosed how to compensate for variations in the light intensity of the light source based on the ratio U_{45_t}/U_{45}, and paragraph [0034] disclosed that the correction of the current was in fact intended to keep this ratio equal to 1. In any event, a feedback control loop to maintain a parameter at a target value was necessarily based on either the difference or a ratio between the actual value of the parameter and the target value.

IX. The **patent proprietor's arguments**, where relevant to this decision, can be summarised as follows.

Main request - novelty in view of D1

The subject-matter of claim 1 as granted was novel in view of D1. D1 did not disclose feature M1.5.3, which required the light intensity of the emitted light to be kept constant. In D1, however, it was the intensity of the reference light detected by reference detector 45, i.e. the output voltage U_{45}, which was controlled and kept at its target value (column 8, lines 52-56; column 9, lines 16-18). The authors of D1 only assumed that this should automatically also keep the intensity

of the light emitted by the light emitting means constant. However, this did not directly and unambiguously anticipate feature M1.5.3.

Auxiliary request 1 - novelty in view of D1

D1 did not disclose feature M1.8 and therefore the subject-matter of claim 1 of auxiliary request 1 was also novel in view of D1. The person skilled in the art would understand that the expression "at a predetermined time during the blood purification" excluded the possibility that the current correction can take place immediately after - i.e. at an infinitesimal time after - the start of the blood purification, as disclosed for the apparatus of D1. This understanding was also supported by the description of the patent, which disclosed that the correction could be performed "at a commencement of [the] dialysis treatment" (paragraphs [0041]-[0042]).

Auxiliary request 2 - novelty in view of D1

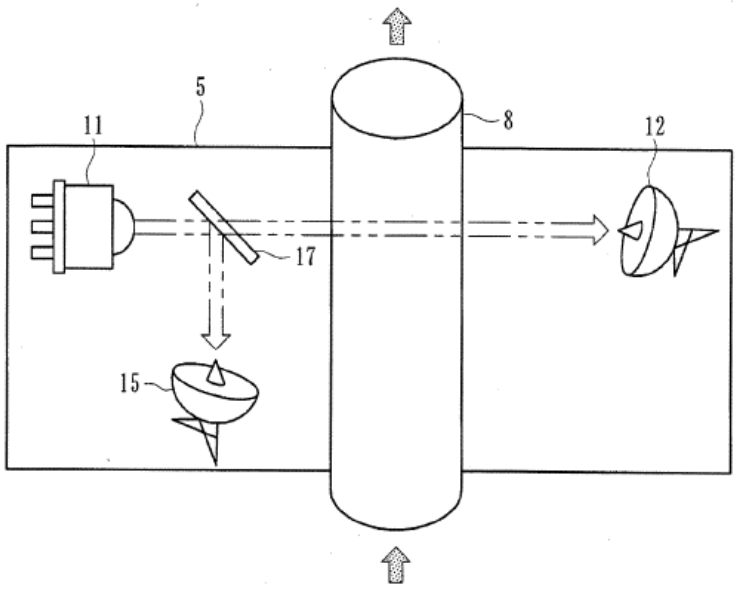
D1 did not directly and unambiguously disclose feature M1.11 and therefore the subject-matter of claim 1 of auxiliary request 2 was also novel in view of D1. D1 did not disclose how the current was controlled to be maintained at a target value. There were many different ways of doing that, which were not necessarily based on a ratio as claimed in feature M1.11. Paragraphs [0033] and [0034] merely disclosed that the two voltages U_{45} and U_{45_t} were substantially equal as a result of the correction made, resulting in a simpler formula for calculating the absorption. However, this did not mean that the correction of the current was based on the ratio between these two voltages.

Reasons for the Decision

1. The subject-matter of the contested patent

1.1 The contested patent relates to a blood purification apparatus as defined in claim 1. In addition to a blood purification instrument, such as a dialyser, this apparatus comprises a concentration detecting means adapted to optically detect the variations of a concentration of interest in a liquid flowing in a line of the apparatus during the blood purification, such as a urea concentration in the dialysate flowing in the dialysate discharging line, for the purpose of monitoring the blood purification efficiency (paragraph [0042]).

1.2 As shown in Figure 2 reproduced below, the concentration detecting means (5) comprises a light emitting means (11), such as an LED, for irradiating light onto the liquid flowing in a line (8) of the apparatus, and a first light receiving means (12) for detecting the intensity of the light transmitted through the liquid ("transmitted light").



1.3 Temperature variations in the apparatus can cause a drift in the light emission and detection ("thermal drift"), which adversely affects the accuracy of the concentration measurements (paragraph [0006]). In order to minimise this effect and improve accuracy, the patent proposes including in the apparatus an "error absorbing means" comprising a correcting means for correcting the current supplied to the light emitting means, so that the amount of light emitted by the light emitting means is constant (feature M1.5.3; paragraphs [0012] and [0034]).

For this purpose, the concentration detecting means comprises a second (reference) light receiving means (15) for measuring the intensity of a part of the light emitted by the light emitting means (11) which is not transmitted through the liquid ("reference light"), for example derived from the main light beam by a semitransparent mirror (17).

The principles of the correction of the current are explained in paragraphs [0034]-[0040] with reference to Figure 4.

2. Main request - novelty over D1

2.1 Contrary to the proprietor's view, the subject-matter of claim 1 of the main request is not novel in view of D1. The Board already took this view in its communication under Article 15(1) RPBA (point 3). At the oral proceedings before the Board, the proprietor did not provide any further comments on this issue; it merely referred to its written submissions.

2.2 It is common ground that D1 is prior art within the meaning of Article 54(3) EPC.

2.3 The proprietor did not dispute, and the Board agrees, that D1 discloses a blood purification apparatus comprising features M1.0-M1.5.2 and M1.6 of claim 1 as granted, as set out in point II.7.2 of the decision under appeal (see, in particular, in Figure 2 the following parts of the concentration detecting means 40: light emitting means 41, 43; transmitted light receiving means 44; reference light receiving means 45).

2.4 However, the proprietor argued that D1 did not directly and unambiguously disclose the remaining feature of claim 1, i.e. feature M1.5.3. The Board disagrees for the following reasons, which were already set out in the Board's communication under Article 15(1) RPBA.

As argued by the opponent and accepted by the opposition division in the decision under appeal (see point II.7.2.1 of the Reasons), keeping constant in D1 the reference light intensity signal detected by the reference light detector 45 (i.e. the voltage U_{45_t} produced by this detector during the treatment) by correcting the current supplied to the light emitting means 41, 43 results in keeping constant not only the amount of reference light, but also the amount of light emitted by the light emitting means itself, since the two are directly proportional due to the absence of any absorption of the reference light (see, in particular, paragraphs [0030] and [0043]-[0045]; see also the last paragraph of claim 15). This is explicitly recognised in particular in paragraph [0045]: "eine stabile und konstante emittierte elektromagnetische Strahlung ermöglicht".

This correction is no different from the correction of the supply current carried out in the example embodiment described in the contested patent, where, as described in paragraphs [0038]-[0040], the supply current is corrected by being adjusted to a corrected value A_1 specifically calculated to bring the reference light voltage output by the reference light sensor 15 from the value IR_1 measured with thermal drift, before the current correction, back to the value IR_0 that would have been measured without thermal drift with the uncorrected current A0 (for example at the time of calibration). The thermal drift correction in the apparatus according to claim 1 as granted is therefore also implicitly based on keeping the voltage output by the reference light sensor 15 constant.

Therefore, contrary to the proprietor's argument, the system of D1 anticipates an "error absorbing means" comprising a "correcting means for correcting a current supplied to the light emitting means so that a light amount irradiated by the light emitting means is constant with the passage of time based on the received light intensity of the reference light received by the reference light receiving means" as defined by feature M1.5.3.

3. Auxiliary request 1 - novelty over D1

3.1 Claim 1 of auxiliary request 1 differs from claim 1 of the main request by the two additional features M1.7 and M1.8.

3.2 D1 also discloses these two features, and therefore the subject-matter of claim 1 of auxiliary request 1 is

not novel in view of D1 either, contrary to the proprietor's view.

3.3 *Feature M1.7*

D1 discloses, for example in paragraph [0041], that before the patient is connected to the apparatus ("vor Anschluss des Patienten"), i.e. before the blood purification, the apparatus measures and stores initial values of the light intensities detected by the light detecting means to subsequently serve as target values ("Sollwert") in the feedback control loop running during the blood purification. This is the case, in particular, for the initial light intensity I_{45_Soll} detected by the reference light detecting means 45, i.e. for the initial voltage U_{45} output by the latter (see paragraph [0043]). As argued by the opponent, this amounts to a calibration of the concentration sensor as defined by feature M1.7. This was not disputed by the proprietor.

3.4 *Feature M1.8*

As further argued by the opponent, the correction of the current supplied to the light emitting means in D1 is carried out, after the patient has been connected to the apparatus, throughout the dialysis treatment and in particular from the very beginning thereof (see, for example, paragraph [0010]: "somit zu Beginn jeder Behandlung [...] Sobald Abweichungen [...] auftreten [...] Abweichung kompensiert"; paragraph [0041]: "während der folgenden Nierenersatzbehandlung"; paragraph [0045]: "während der Nierenerstzbehandlung").

The proprietor did not dispute this, but objected that the person skilled in the art would understand that the

expression "at a predetermined time during the blood purification" excludes the possibility that the correction can take place immediately after - i.e. at an infinitesimal time after - the start of the blood purification, as disclosed in D1. Thus, according to the proprietor, D1 did not disclose feature M1.8.

The proprietor's argument is not convincing, however. The Board agrees that the expression "at a predetermined time during the blood purification" requires that the time at which the correction is made be predetermined with respect to the blood purification. However, when reading claim 1 both on its own and in the context of the contested patent, the person skilled in the art would not derive from this expression the exclusion asserted by the proprietor. Rather, they would consider the time at which the blood purification begins to be a "a predetermined time during the blood purification".

Contrary to the proprietor's view, the description of the contested patent does not lead to a different understanding. In particular, paragraph [0041], relied on by the proprietor, discloses that the correction may be "performed only one time at a commencement of dialysis treatment". While the use of the expression "at a commencement" may indeed suggest, as the proprietor argued, that the correction may be made after a certain time has elapsed from the start of the treatment, it does not exclude, and in fact includes, the possibility that the correction is made immediately at the start of the treatment. Moreover, the fact that the terms "commencement" and "completion" are put on the same footing in paragraph [0042] ("the urea nitrogen concentration at times of both commencement and completion of the hemodialysis treatment") in fact

rather suggests that "commencement", like "completion", refers to a discrete point in time, namely the time at which the blood treatment starts.

The Board therefore concludes, in agreement with the opponent, that D1 also discloses feature M1.8.

4. Auxiliary request 2

4.1 Claim 1 of auxiliary request 2 differs from claim 1 of the main request by the additional features M1.7 (also referred as feature M1.9 by the parties), M1.10 and M1.11.

4.2 Clarity

Contrary to the opponent's argument, claim 1 of auxiliary request 2 is clear.

The opponent objected in its written submissions that the term "based on" in feature M1.11 did not clearly indicate how the ratio between the voltage generated by the reference light receiving means at a time of calibration and the voltage generated by the reference light receiving means during the blood purification was integrated into the correction process. At the oral proceedings before the Board, the opponent did not comment further on this issue; it merely referred to its written submissions.

As stated in the Board's communication under Article 15(1) RPBA (point 5.2), this objection is not convincing. The person skilled in the art would understand from reading feature M1.11 on its own that a mathematical ratio between the two voltages is calculated and then used to determine the correction to

be applied to the current supplied to the light emitting means.

The same understanding is supported by the description of the contested patent, which states (see the last sentence of paragraph [0040]) that the correction of the current is based on the ratio IR_0/IR_1, where IR_0 is the voltage produced by the reference light receiving means without thermal drift, i.e. at a time of calibration, and IR_0 is the voltage produced by the reference light receiving means with thermal drift, before the correction of the current is applied.

Contrary to the opponent's argument, the fact that this ratio could be used either directly or indirectly to determine the correction does not render feature M1.11 unclear.

4.3 Novelty in view of D1

Contrary to the opponent's view, D1 does not directly and unambiguously disclose, even implicitly, feature M1.11, with the consequence that the subject-matter of claim 1 of auxiliary request 2 is novel in view of D1.

It is true, as argued by the opponent, that the correction implemented in the apparatus in D1 (see point 2.4 above) in order to keep the voltage U_{45_t} (produced by the reference light detecting means 45 during the blood purification) at its target value U_{45} (initially measured at the time of calibration; see paragraph [0045]) requires that these two voltages be measured and taken into account in order to calculate the correction to be applied.

However, the Board does not accept the opponent's argument that this inevitably implies that a ratio between the two voltages is calculated and used to determine the correction, as required by feature M1.11.

D1 does not disclose in detail how the correction is determined. It only refers in general terms in paragraph [0042] to an adaptive controller ("Die Regelung erfolgt mit einem adaptive Regler") or some other unspecified form of control ("Die Regelung kann ebenfalls mit jeder anderen Art von Regelung erfolgen") and, although D1 refers to a transfer function ("Übertragungsfunktion"), its specific form is not described either.

As submitted by the proprietor (see point 3.2 on pages 5-7 of its reply), there are different ways of controlling a parameter in order to keep it at a target value, and these are not necessarily based on a ratio as claimed in feature M1.11. Moreover, the opponent itself acknowledged that another possible option could be based on the difference, and not the ratio, between the actual value and the target value of the parameter.

The opponent's reference to paragraphs [0033] and [0034] is also unconvincing. While the formula in paragraph [0033] does indeed compensate the absorption for fluctuations in intensity of the light source by multiplying and dividing by U_{45} and U_{45_t}, this formula is expressly not used in the apparatus of D1, as indicated by the term "Gewöhnlich" ("Usually"). Instead, paragraph [0034] describes that as a result of the correction of the current, U_{45} and U_{45_t} can be considered substantially equal, so that the formula of paragraph [0033] can indeed be simplified to the

formula of paragraph [0034], where U_{45} and U_{45_t} do not appear. However, this does not disclose that a ratio between U_{45} and U_{45_t} is used to determine the correction of the current.

4.4 Other objections

Neither the opponent nor the Board had any further objections to auxiliary request 2 or objections to the description as amended by the proprietor during the oral proceedings before the Board.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

   - claims 1 and 2 of auxiliary request 2 as filed on 28 September 2021

   - description: paragraphs [0001]-[0008], [0010]-[0014], [0016]-[0036] and [0038]-[0053] of the patent specification and paragraphs [0009], [0015] and [0037] as filed during the oral proceedings before the Board

   - drawings of the patent specification

The Registrar: The Chairman:

G. Magouliotis M. Alvazzi Delfrate

Decision electronically authenticated