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Datasheet for the decision of 9 January 2025

Case Number: T 0352/22 - 3.2.02

Application Number: 15793590.9

Publication Number: 3144022

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Language of the proceedings: EN

Title of invention:
BLOOD PURIFICATION DEVICE

Patent Proprietor:
Nikkiso Company Limited

Opponents:
B. Braun Avitum AG
Fresenius Medical Care AG

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 84
RPBA 2020 Art. 12(2)

Keyword:
Novelty - main request (no) - auxiliary request 3 (no) - auxiliary request 5 (yes)
Inventive step - auxiliary requests 1 and 2 (no) - auxiliary request 5 (yes)
Claims - clarity - auxiliary request 4 (no)
Auxiliary requests 1 to 5 - appeal case directed to requests on which decision was based (yes)

Decisions cited:
T 1685/07, T 0649/14

Catchword:

Europäisches Patentamt
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Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0352/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 9 January 2025

Appellant: (Patent Proprietor)	Nikkiso Company Limited 20-3, Ebisu 4-chome Shibuya-ku Tokyo 150-6022 (JP)
Representative:	von Hirschhausen, Helge Grosse - Schumacher - Knauer - von Hirschhausen Patent- und Rechtsanwälte Nymphenburger Straße 14 80335 München (DE)
Appellant: (Opponent 1)	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen (DE)
Representative:	Winter, Brandl - Partnerschaft mbB Alois-Steinecker-Straße 22 85354 Freising (DE)
Party as of right: (Opponent 2)	Fresenius Medical Care AG Else-Kröner-Str. 1 61352 Bad Homburg (DE)
Representative:	Bobbert & Partner Patentanwälte PartmbB Postfach 1252 85422 Erding (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 November 2021 concerning maintenance of the European Patent No. 3144022 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	Y. Podbielski

Summary of Facts and Submissions

I. Both opponent 1 and the patent proprietor filed an appeal against the interlocutory decision of the opposition division that the patent could be maintained on the basis of auxiliary request 5.

II. Oral proceedings before the Board took place on 9 January 2025.

III. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted, or that the patent be maintained on the basis of one of auxiliary requests 1 to 14, whereby:
- auxiliary requests 1 to 5 were filed with letter dated 16 November 2020,
- auxiliary request 6 was filed with letter dated 23 July 2021,
- auxiliary requests 7 to 11 were filed with letter dated 13 September 2021,
- auxiliary requests 12 to 14 were filed with the statement setting out the grounds of appeal dated 21 March 2022, and
- auxiliary request 5 corresponded to the request held by the opposition division to comply with the requirements of the EPC.

The appellant-opponent 1 requested that the decision under appeal be set aside and that the patent be revoked. They furthermore requested that none of auxiliary requests 1 to 14 be admitted into the appeal proceedings.

The party as of right-opponent 2 had filed no request

in writing.

IV. Claim 1 of the main request (patent as granted) reads as follows.

"A blood purification apparatus comprising:

a circuit for blood purification (1) having an arterial blood circuit (1a) and a venous blood circuit (1b) that constitute a blood circuit (1) for extracorporeally circulating at least blood of a patient;
a blood purifier (2) for purifying the blood extracorporeally circulated by the blood circuit (1);
a device main body (8) provided with various treatment means (16) for performing blood purification treatment in the blood circuit (1) and the blood purifier (2),
wherein the blood purification apparatus includes an identification means (α, β) that allows specific information to be identified, the specific information including an operating condition of the circuit for blood purification (1) or the blood purifier (2) at the time of blood purification treatment or preparation for the treatment,
a reading means (13) by which the specific information of the identification means (α, β) is readable, and
a control unit (17) configured to perform blood purification treatment or preparation for the treatment based on the operating condition in the specific information read by the reading means (13),
characterized in that,
the operating condition as the specific information in the identification means (α, β) includes a parameter indicating a restriction or an acceptable range related to blood purification treatment or preparation for the treatment, and that the control unit (17) of the device main body (8) allows a treatment condition to be

restricted based on the information identified by the identification means (α, β)."

V. Claim 1 of auxiliary request 1 is based on claim 1 of the main request and includes the additional feature "and that the device main body (8) includes a display means (9) and is configured such that the specific information read by the reading means (13) can be displayed by the display means (9).".

VI. Claim 1 of auxiliary request 2 is based on claim 1 of auxiliary request 1 and further includes the features "the specific information including ... additional information such as an expiration date of the circuit for blood purification (1) or the blood purifier (2)" and "that the device main body (8) further includes a storage unit (14) that is configured to store the specific information including the operating condition out of the information read by the reading means (13)".

VII. Claim 1 of auxiliary request 3 is based on claim 1 of the main request and further includes the features that "the device main body (8) further includes an input means (15) provided for inputting an initial setting for performing blood purification treatment or preparation for the treatment,
the device main body (8) is configured such that the initial setting inputted by the input means (15) is transmitted to the control unit (17), and that
the control unit (17) is configured to determine whether or not the initial setting is in line with the operating conditions in the specific information, and, when it is determined that the initial setting is in line with the operating conditions, to perform blood purification treatment or preparation for the treatment

based on the operating conditions".

VIII. Claim 1 of auxiliary request 4 reads as follows.

"A blood purification apparatus comprising:
a circuit for blood purification (1) having an arterial blood circuit (1a) and a venous blood circuit (1b) that constitute a blood circuit (1) for extracorporeally circulating at least blood of a patient;
a blood purifier (2) for purifying the blood extracorporeally circulated by the blood circuit (1);
a device main body (8) provided with various treatment means (16) for performing blood purification treatment in the blood circuit (1) and the blood purifier (2),
wherein the blood purification apparatus includes an identification means (α, β) that allows specific information to be identified, the specific information including an operating condition of the circuit for blood purification (1) or the blood purifier (2) at the time of blood purification treatment or preparation for the treatment and additional information including an expiration date of the circuit for blood purification (1) or the blood purifier (2),
a reading means (13) by which the specific information of the identification means (α, β) is readable, and
a control unit (17) configured to perform blood purification treatment or preparation for the treatment based on the operating condition in the specific information read by the reading means (13),
characterized in that,
the operating condition as the specific information in the identification means (α, β) includes a parameter indicating a restriction or an acceptable range related to blood purification treatment or preparation for the treatment,
the control unit (17) of the device main body (8)

allows a treatment condition to be restricted based on the information identified by the identification means (α, β),
the device main body (8) includes a display means (9) and is configured such that the specific information read by the reading means (13) can be displayed by the display means (9),
the device main body (8) further includes a storage unit (14) that is configured to store the specific information including the operating condition out of the information read by the reading means (13),
the device main body (8) further includes an input means (15) provided for inputting an initial setting for performing blood purification treatment or preparation for the treatment, wherein the device main body (8) is configured such that the initial setting inputted by the input means (15) is transmitted to the control unit (17),
the control unit (17) is configured to determine whether or not the initial setting is in line with the operating condition in the specific information,
wherein, when it is determined that the initial setting is not in line with the operating condition, the control unit (17) is configured such that a respective notification is displayed by the display means (9),
and, when it is determined that the initial setting is in line with the operating condition, the control unit (17) is configured to determine whether or not the circuit for blood purification (1) or the blood purifier (2) is within the expiration date in consideration of the expiration date out of the additional information read by the reading means (13),
wherein, when it is determined that the circuit for blood purification (1) or the blood purifier (2) is out of the expiration date, the control unit (17) is configured such that a respective notification is

displayed by the display means (9), and, when it is determined that the circuit for blood purification (1) or the blood purifier (2) is within the expiration date, the control unit (17) is configured to perform the preparation for the blood purification treatment based on the operating condition in the specific information stored in the storage unit (14), and that the control unit (17) is configured, after the preparation for the blood purification treatment is completed, to allow a setting of treatment conditions related to blood purification treatment using the input means (15), and subsequently to perform blood purification treatment based on the operating conditions in the specific information stored in the storage unit (14) by controlling the treatment means 16."

IX. Claim 1 of auxiliary request 5 reads as follows.

"A blood purification apparatus comprising:
a circuit for blood purification (1) having an arterial blood circuit (1a) and a venous blood circuit (1b) that constitute a blood circuit (1) for extracorporeally circulating at least blood of a patient;
a blood purifier (2) for purifying the blood extracorporeally circulated by the blood circuit (1);
a device main body (8) provided with various treatment means (16) for performing blood purification treatment in the blood circuit (1) and the blood purifier (2),
wherein the blood purification apparatus includes an identification means (α, β) that allows specific information to be identified, the specific information including an operating condition of the circuit for blood purification (1) or the blood purifier (2) at the time of blood purification treatment or preparation for the treatment,

a reading means (13) by which the specific information of the identification means (α, β) is readable, and a control unit (17) configured to perform blood purification treatment or preparation for the treatment based on the operating condition in the specific information read by the reading means (13), wherein the operating condition as the specific information in the identification means (α, β) includes a parameter indicating a restriction or an acceptable range related to blood purification treatment or preparation for the treatment, and that the control unit (17) of the device main body (8) allows a treatment condition to be restricted based on the information identified by the identification means (α, β) characterized in that
the blood purifier (2) has a plurality of connecting portions connectable to the circuit for blood purification (1), respective connection flow paths are extended from the connecting portions of the blood purifier (2), and the blood purifier (2) and the circuit for blood purification (1) are configured to be connectable via the connection flow paths, the blood purification apparatus comprises a first connector (3) formed by bundling leading ends of the circuit for blood purification (1), and a second connector (4) formed by bundling leading ends of the connection flow paths, and connection of the first connector (3) and the second connector (4) allows the circuit for blood purification (1) corresponding to the connecting portions of the blood purifier (2) to communicate with each other, and the identification means (α, β) is formed in the first connector (3) or the second connector (4)."

X. The following documents are referred to in this decision.

D2 US 2002/147423 A1
D4 US 2012/123322 A1
D6 DE 201 13 789 U1
D7 EP 1 576 972 A2
D8 EP 1 235 614 B1
D9 US 6,695,806 B2
D10 EP 0 027 470 B1
D11 EP 1 936 524 A1
D12 WO 2004/064886 A2
D13 WO 2012/110251 A1
D30 WO 2009/081241 A1
D31 WO 2012/097971 A1
D32 DE 10 2009 024 606 A1
D33 US 2010/0282834 A1
D34 US 2003/0088203 A1
D36 WO 2009/006491 A2
D37 WO 2010/087764 A1
D38 EP 2 075 724 A2
D39 WO 2012/162515 A2
D40 US 4,707,335

D34 is the publication of the application of the patent D9. Since their content in the relevant passages is identical, it will only be referred to the text passages of D34 in the following.

XI. The appellant-patent proprietor's arguments may be summarised as follows.

Main request - claim 1 - novelty in view of D34/D9

Claim 1 required that the identification means allowed specific information to be identified, the specific information including an operating condition at the time of blood purification treatment or preparation for

the treatment. The operating condition had to include a parameter indicating a restriction or an acceptable range related to the blood purification treatment or preparation for the treatment. On the basis of this information, the operating condition had to be restricted.

A model number on an electronic key as disclosed in paragraph [0022] of D34/D9 could not be regarded as the specific information specified in claim 1.

According to the definition of the term "parameter" in the claim, a concrete restriction or range with respect to the treatment or its preparation had to be present in the parameter itself. On the contrary, the model number was merely a name which itself did not allow a treatment condition to be restricted. A further source of information would have to be consulted to retrieve the specific restriction of the treatment condition indicated by this model number. The model number itself could therefore not be regarded as the specific information according to claim 1.

Hence, D34/D9 did not disclose an identifying means allowing specific information to be identified, the specific information including an operating condition of the circuit for blood purification or the blood purifier at the time of blood purification treatment or preparation for the treatment, the operating condition including a parameter indicating a restriction or an acceptable range related to blood purification treatment or preparation for the treatment, and that a treatment condition was restricted based on the information identified by the identification means . The subject-matter of claim 1 as granted was novel in view of D34/D9.

Admittance of auxiliary requests 1 to 5

Auxiliary requests 1 to 5 were filed in response to the notices of opposition. The Opposition Division took a decision on them. Hence, pursuant to Article 12(2) RPBA, they formed part of the appeal proceedings and there was no legal basis for a discussion about the convergence requirement.

The decisions cited by opponent 1 concerned auxiliary requests which were filed in the appeal stage of an opposition case. They were therefore not relevant for the present case.

Auxiliary request 1 - Inventive step starting from D34/ D9

D34/D9 did not disclose a display of information read by the reading means.

According to claim 1, the information displayed on the display had to be the operating condition and the parameter. Due to this configuration of the display means the user was given the opportunity to review the read information and the safety for the patient was increased.

None of the cited documents disclosed or suggested the the required displaying of the information read by the reading means. Therefore, the subject-matter of claim 1 of auxiliary request 1 was based on an inventive step.

Auxiliary request 2 - Inventive step starting from D34/ D9

Claim 1 of auxiliary request 2 explicitly excluded that an expiration date, a model number or mere physical properties were considered representing an operating condition. Rather these data represented additional information which was included in the specific information of the identification means in addition to the operating condition.

Thus, claim 1 of auxiliary request was sufficiently delimited from those prior art documents, in which additional information within the meaning of the present invention was included in identification means.

Thus, the subject-matter of claim 1 of auxiliary request 2 involved an inventive step.

Auxiliary request 3 - Novelty in view of D34/D9

A mere information about the kind of therapy for which the relevant disposable was suitable as mentioned in paragraph [0107] of D34 was not an operating condition that specifically restricted a corresponding treatment condition, but rather generally prevented the treatment as a whole, if applicable.

Hence, D34/D9 did not disclose that the control unit was configured to determine whether or not the initial setting was in line with the operating conditions in the specific information. The subject-matter of claim 1 of auxiliary request 3 was therefore novel.

Auxiliary request 4 - Clarity

Claim 1 did not require that both the treatment and the preparation for the treatment were actually performed on the basis of the respective operating conditions.

According to the configuration of the control unit defined in the final feature of the claim, the treatment was performed on the basis of the corresponding operating condition, in case such an operating condition was present in the specific information, and the preparation for the treatment was performed on the basis of a corresponding operating condition, if present. In case one of the relevant operating conditions was not contained in the identification means, or if the contained operating condition only related to either the treatment or to its preparation, then only one of the two processes would be performed on the basis of the contained operating condition.

Hence, claim 1 did not lack clarity.

Auxiliary request 5 - Novelty in view of D9/D34

Claim 1 defined two connectors which were each formed by bundling leading ends of the circuit for blood purification and of the connection flow paths, respectively. Hence, the two connectors had to be physically distinct components which were connectable to each other.

The housing 129 shown in Figure 2 of D34/D9 could not be regarded as representing both connectors at the same time. Hence, D34/D9 did not disclose a first connector formed by bundling leading ends of the circuit for blood purification, and a separate second connector formed by bundling leading ends of the connection flow paths. D34/D9 did not disclose either that the identification means was formed in the first connector or the second connector.

Hence, the subject-matter of claim 1 was novel in view of D34/D9.

Auxiliary request 5 - inventive step starting from D34/ D9 in combination with D36, D4, D37, D38, D39 and D40

D36 disclosed that the ends 56 of the fluid lines 352 could be bundled together in an organiser 356 (Figure 6). However, such a bundling was not suggested for the ends 200 of the lines 38. Likewise, none of D4 and D37 to D40 disclosed two connectors formed by bundling leading ends of fluid lines, wherein one connector was provided with an identification means.

Therefore, with the additional teaching of any one of D36, D4, D37, D38, D39 and D40 the person skilled in the art would not arrive at the subject-matter of claim 1 of auxiliary request 5.

Hence, the subject-matter of claim 1 involved an inventive step when starting from D34/D9.

Auxiliary request 5 - inventive step starting from D6 in combination with D34/D9, D36, D4, or any of D37 to D40

D6 failed to disclose two separate and separable connectors and the identification means applied thereon as defined in the last features of claim 1. The element identified by opponent 1 in Figure 1 at the transition from the thicker tubes to the thinner tubes could be some kind of adapter piece. However, no further details about the construction of this component could be derived from the drawing. In particular, the apparently segmented illustration of this transition element did not allow the conclusion that there were two separate

components, or even connectors, which were connectable to each other and which were shown here in a connected state. Moreover, D6 did not disclose identification means applied on bundled connectors.

Since these features were not disclosed in any of the cited documents, the combination of D6 with any of these documents would not result in an apparatus according to claim 1 of auxiliary request 5.

Hence, the subject-matter of claim 1 involved an inventive step when starting from D6.

XII. The appellant-opponent 1's arguments may be summarised as follows.

Main request - claim 1 - novelty in view of D34/D9

D34/D9 disclosed a blood purification apparatus comprising an integrated disposable set with an electronic key for storing information concerning the set (paragraph [0015] of D34). The key could be regarded as the identification means mentioned in claim 1. The stored information could be (among others) an expiration date (paragraph [0022] of D34), a model number (paragraph [0019]) or a software (paragraph [0108]), i.e. information about the use of the disposable set (paragraph [0018]).

Claim 1 merely required that the specific information could be identified. Hence, it was not required that the specific information, which had to include the parameter, was read from the key. According to paragraph [0107] of D34/D9, the model number was read from the key and used by the controller to set up the correct mode of treatment or to establish correct

treatment settings. Hence, although the model number was further processed in the system, it could be considered to represent a parameter indicating a restriction of the treatment or the preparation of the treatment.

Thus, the subject-matter of claim 1 lacked novelty in view of D34/D9.

Admittance of auxiliary requests 1 to 5

Auxiliary requests 1 to 5 should not be admitted into the appeal proceedings since they represented a batch of divergent requests (see T 1685/07 and T 649/14). This created a confusing and unacceptable procedural situation for the opponent.

Auxiliary request 1 - Inventive step starting from D34/D9

The subject-matter of claim 1 lacked an inventive step starting from D34/D9 in combination with any of D2, D6, D7, D8, D10, D11, D12, D13, D30, D31, D32, D33 or the common general knowledge.

D34/D9 disclosed that the user was informed if he tried to initiate an incorrect treatment mode (paragraph [0107] of D34). Since a correct or an incorrect treatment mode could be regarded as a parameter indicating a restriction, D34/D9 disclosed that an operating condition and a parameter including a restriction or an acceptable range were communicated to the user somehow. It was obvious for the person skilled in the art to use a display for providing the user with this information, in particular since a display was rendered obvious by any of D2, D6, D7, D8, D10, D11,

D12, D13, D30, D31, D32 or D33, or by the common general knowledge.

Auxiliary request 2 - Inventive step starting from D34/D9

D34/D9 disclosed in paragraph [0022] that the expiration date was included in the specific information of the key in addition to the various operating conditions. A storage unit was implicitly disclosed in D34/D9.

Hence, the subject-matter of claim 1 differed from the system of D34/D9 only in that it included a display means for displaying the information read by the reading means, and lacked an inventive step for the same reasons as claim 1 of auxiliary request 1.

Auxiliary request 3 - Novelty in view of D34/D9

The additional features of claim 1 were disclosed in D34/D9 (paragraph [0107]), the initial setting being the initializing of the treatment mode (CVVHD or CVVH). The treatment mode was mentioned in the patent in suit (paragraph [0039]) as an operating condition indicating a restriction or an acceptable range.

Hence, the subject-matter of claim 1 of auxiliary request 3 was not novel in view of D34/D9.

Auxiliary request 4 - clarity

Claim 1 of auxiliary request 4 required that both the preparation for the treatment and the treatment were performed based on the (same) operating condition in the specific information. It was unclear how this was

possible in case the operating condition related either to the preparation or to the treatment.

Hence, the requirements of Article 84 EPC were not met.

Auxiliary request 5 - Novelty in view of D34

The upper part of the cartridge 129 shown in Figure 2 of D34/D9 represented the second connector bundling leading ends of the connecting flow paths and the lower part of the cartridge 129 represented the first connector bundling leading ends of the circuit for blood purification. Thus, D34/D9 disclosed a first and a second connector which were integrally connected. As mentioned in paragraph [0061] of D34, a key code, i.e. an identification means, could be integrated into the housing 129.

Hence, the subject-matter of claim 1 of auxiliary request 5 lacked novelty.

Auxiliary request 5 - inventive step starting from D34/ D9 in combination with D36, D4, D37, D38, D39 and D40

D36 disclosed in Figure 6 an organizer 356 representing a first connector according to claim 1. This organizer bundled the cassette tubes 352 (paragraph [0063]). D36 further mentioned in paragraph [0063] that tubes 38 with housings 200 could also be bundled in an organizer 356. This organizer could be regarded as the second connector. Since the housings 200 (bundled in organizer 356) had RFID tags 210 (paragraph [0061]), D36 also disclosed the feature that an identification means was provided on one of the connectors.

In view of the teaching of D36, it would thus be

obvious for the person skilled in the art to modify the system of D34/D9 such that the fluid lines were bundled in two organizers at the housing 129 and that the identification means 130 was provided on one of the organizers.

The bundling of fluid lines in connectors and the provision of an identification means on one of the connectors was also rendered obvious by the teaching of any of D4 (paragraphs [0297] to [0300], Figures 10 to 11-4), D37 (claim 1), D38 (paragraph [0060]), D39 (page 68, Figures 25 to 27) or D40 (Figure 1).

The subject-matter of claim 1 of auxiliary request 5 therefore did not involve an inventive step when starting from D34/D9.

Auxiliary request 5 - inventive step starting from D6 in combination with D34/D9, D36, D4 or any of D37 to D40

D6 disclosed a blood purification apparatus comprising all the features of claim 1 except that the identification means was formed in the first or the second connector. The first connector and the second connector were represented as two sections of a connector housing shown in Figure 1. This connector housing bundled fluid lines from the dialyzer and the blood purifying circuit. D6 also disclosed that identification means could be provided on various components of the apparatus (page 6, second to fourth paragraph, claim 1).

The person skilled in the art was prompted to provide the identification means on the connector housing by the common general knowledge or the teaching of any of

D34/D9 (paragraph [0061]), D36 (paragraphs [0061] and [0063], Figure 6), D4 (paragraphs [0297] to [0300], Figures 10 to 11-4), D37 (claim 1), D38 (paragraph [0060]), D39 (page 68, Figures 25 to 27) or D40 (Figure 1).

Thus, the subject-matter of claim 1 also lacked an inventive step when starting from D6.

XIII. The party as of right-opponent 2's arguments may be summarised as follows.

Main request - claim 1 - novelty in view of D34/D9

The appellant-opponent 1's submissions were concurred with.

Moreover, D34/D9 referred in paragraph [0036] to the treatment modality as a piece of information stored on the key.

Furthermore, claims 4, 12 and 24 referred to information relating to the operation of the blood filtration system.

Hence, the subject-matter of claim 1 lacked novelty in view of D34/D9.

The party as of right-opponent 2 did not make any further submissions relevant to this decision.

Reasons for the Decision

1. Subject-matter of the patent

1.1 The patent relates to a blood purification apparatus for performing haemodialysis treatment. The apparatus comprises a tubing circuit for blood purification (1), a blood purifier (dialyzer, 2) and a device main body (8), to which the tubing circuit and the dialyzer are mounted during the treatment (Figures 4, 3 and 2). The apparatus further comprises an identification means (α,β, Figure 6) that allows specific information - including an operating condition of the tubing circuit (1) or the dialyzer (2) - to be identified, a reading means (13, Figure 11) by which the specific information is readable and a control unit (17, Figure 11) configured to perform the treatment or preparation for the treatment based on the operating condition. According to dependent claim 4 of the patent as granted, the identification means is formed on one of the first connector (3) or the second connector (4) shown in Figure 4.

1.2 According to the characterizing portion of claim 1 as granted the operating condition of the tubing circuit (1) or the dialyzer (2) includes a parameter indicating a restriction or an acceptable range related to the treatment or the preparation for the treatment. Based on this information, the control unit allows a treatment condition to be restricted.

1.3 According to paragraph [0013] of the patent, the advantage of having an identification means including a parameter indicating a restriction or an acceptable range is that this parameter does not need to be pre-stored in the device main body. The restriction of the treatment condition is said to improve the safety of

the treatment (paragraph [0014]).

2. Main request - novelty in view of D34/D9

2.1 D34/D9 discloses a blood purification apparatus comprising an integrated disposable set with an electronic key for storing information concerning the set (paragraph [0015] of D34). This information can be (among others) a model number (paragraph [0019]).

2.2 In paragraph [0107] of D34 it is mentioned that the model number that is read from the key is used by the console to set up the correct mode of treatment or the correct treatment settings. If a user attempts to initiate a treatment mode for which the set is not designed or if the user tries to set the treatment settings to a value that does not match with the set, the controller will prevent it. It is mentioned in paragraph [0039] of the patent in suit that the operating condition included in the specific information can include a feasible treatment mode. Hence, the model number includes an operating condition including a parameter indicating a restriction or an acceptable range related to the blood purification treatment.

2.3 The patent proprietor argued that the model number was merely a name and that a further source of information had to be used to retrieve the specific restriction of the treatment involved in this model number. The Board does not agree that, therefore, the model number could not be regarded as the specific information according to claim 1. According to paragraph [0107] of D34, the model number allows the specific information (relating to the treatment mode and thus an operating condition) to be identified, as required by claim 1. It is

mentioned in paragraph [0037] of the patent in suit that the identification means can be comprised of a bar code or QR code with encoded information. It is evident that this information after having been read by the reading means has to be decoded and that for such decoding a further source of information has to be used. This is, however, not excluded by granted claim 1 of the patent in suit. Hence, contrary to the patent proprietor's view, the claim does not exclude that a further source of information is consulted to retrieve the operating condition from the specific information.

2.4 Consequently, the electronic key comprising the model number as disclosed in D34/D9 can be considered a specific information including an operating condition of the blood purifier at the time of blood purification treatment including a parameter indicating a restriction or an acceptable range. Hence the subject-matter of claim 1 of the main request lacks novelty in view of D34/D9.

3. Admittance of auxiliary requests 1 to 5

3.1 Auxiliary requests 1 to 5 correspond to auxiliary requests 1-5 underlying the appealed decision. They were filed with the response to the notices of opposition. In opponent 1's view, they should not be admitted into the appeal proceedings since they represented a batch of divergent requests.

3.2 Under Article 12(1) RPBA appeal proceedings are based on, *inter alia*, the decision under appeal. Article 12(2) RPBA requires parties to the appeal proceedings to direct their case to the requests, facts, objections, arguments and evidence on which the decision under appeal was based. The Board's discretion

under Article 12(4) RPBA not to admit an amendment to a party's appeal case is limited to those parts of a party's case which are not covered by Article 12(2) RPBA. This is clear from the wording of Article 12(4) RPBA which defines an amendment as "any part of a party's appeal case which does not meet the requirements in paragraph 2" (i.e. Article 12(2) RPBA).

3.3 The Board has thus no discretion regarding the admittance of auxiliary requests 1-5. Instead, these requests form part of the appeal proceedings pursuant to Article 12(1) and (2) RPBA. The fact that these requests might not be convergent cannot change this result.

4. Auxiliary request 1 - Inventive step starting from D34/D9

4.1 It cannot be derived directly and unambiguously from D34/D9 that the information read by the reading means is displayed by a display means.

4.2 The patent proprietor argues that, due to the configuration of the display means to display the operating condition and the parameter, the user was given the opportunity to review the read information, and the safety for the patient was increased.

4.3 However, D34/D9 discloses that the user is informed if the user tries to initiate an incorrect treatment mode (paragraph [0107] of D34). Hence, no increase in safety is provided by the claimed display of information and the claimed technical effect is not associated with it.

4.4 In any event, it was obvious for the person skilled in the art to use a display for providing the user with

the information described in paragraph [0107] and with the information read from the key that is used to determine it, in particular since a blood purification apparatus having a display is disclosed in any of D2, D6, D7, D8, D10, D11, D12, D13, D30, D31, D32 or D33.

Hence, the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step.

5. Auxiliary request 2 - Inventive step starting from D34/D9

Contrary to the proprietor's view claim 1, which merely stipulates that additional information such as an expiration date of the circuit or the blood purifier is also included in the specific information, does not exclude that the model number represents the operating condition. D34/D9 discloses that information in addition to the model number is stored in the key (paragraphs [0020] to [0026]) and that the additional data can be the expiration date (paragraph [0022]). Furthermore, a memory into which data from the key is read is disclosed in paragraph [0082]. Thus, D34/D9 discloses at least implicitly that the device body includes a storage unit that is configured to store the specific information according to claim 1.

Hence, the subject-matter of claim 1 of auxiliary request 2 differs from the system of D34/D9 only in that it includes a display means for displaying the information read by the reading means. It does therefore not involve an inventive step for the same reasons as claim 1 of auxiliary request 1.

6. Auxiliary request 3 - Novelty in view of D34/D9

The features that

- the device main body further includes an input means provided for inputting an initial setting for performing blood purification treatment or preparation for the treatment,

- the device main body is configured such that the initial setting input by the input means is transmitted to the control unit, and that

the control unit is configured to determine whether or not the initial setting is in line with the operating conditions in the specific information, and, when it is determined that the initial setting is in line with the operating conditions, to perform blood purification treatment or preparation for the treatment based on the operating conditions of claim 1 of auxiliary request 3 are disclosed in D34/D9 (paragraph [0107]), the initial setting being the setting of the treatment mode or the ultrafiltrate rate.

The proprietor argues that the treatment modes mentioned in paragraph [0107] of D34 would not represent an operating condition in the sense of the claim. However, the claim merely stipulates that the initial setting must be "in line" with the operating condition. This requirement is satisfied by the device of D34/D9 since the model number can be regarded as the specific information which involves information about the treatment mode and the correct treatment settings, i.e. operating conditions.

Hence, the subject-matter of claim 1 of auxiliary request 3 is not novel.

7. Auxiliary request 4 - clarity

7.1 According to claim 1, the specific information may include only one operating condition relating to either the treatment or the preparation of the treatment ("an operating condition" in feature M1.4), and the control unit is configured to perform the preparation for treatment based on this operating condition. It is not clear how this is done if the operating condition relates to the treatment and not to the preparation. The control unit is further configured to perform subsequently the treatment based on the "operating conditions". Hence, the performance of the treatment is based on more than one operating condition. It is also unclear how this is done if the specific information includes only one operating condition.

7.2 Actually, it is not clear how the preparation and the treatment can be performed at all with the specific information including only one operating condition. It is noted that, according to the description of the patent (paragraphs [0038], [0043], [0049], [0052] and [0053]), the specific information includes "operating conditions", i.e. more than one operating condition, and these operating conditions are used for the preparation and for the treatment.

7.3 Hence, auxiliary request 4 is not allowable as claim 1 does not meet the requirements of Article 84 EPC.

8. Auxiliary request 5 - novelty in view of D34/D9

8.1 The objection of opponent 1 is based on the assumption that the cartridge 129 shown in Figure 2 represented both the first and the second connectors which were

"integrally connected".

8.2 However, claim 1 requires that the two connectors are structurally individual components each bundling leading ends of fluid flow paths.

8.3 Hence, D34/D9 does not disclose the features "the blood purification apparatus comprises a first connector formed by bundling leading ends of the circuit for blood purification, and a second connector formed by bundling leading ends of the connection flow paths, and connection of the first connector and the second connector allows the circuit for blood purification corresponding to the connecting portions of the blood purifier (2) to communicate with each other" and "the identification means is formed in the first connector or the second connector".

8.4 Hence, the subject-matter of claim 1 is novel in view of D34/D9.

9. Auxiliary request 5 - inventive step starting from D34/D9 in combination with D36, D4, D37, D38, D39 and D40

9.1 D36 discloses an organiser 356 bundling the ends 56 of the fluid lines 352 together (Figure 6). However, such a bundling is not suggested for the ends 200 of the lines 38. Hence, D36 does not disclose two connectors each bundling a number of fluid lines.

9.2 Likewise, none of D4 and D37 to D40 discloses two connectors formed by bundling leading ends of fluid lines, wherein one connector is provided with an identification means. Hence, the combination of D34/D9 with any of these documents would not result in an

apparatus according to claim 1 of auxiliary request 5.

9.3 Therefore, the subject-matter of claim 1 involves an inventive step when starting from D34/D9.

10. Auxiliary request 5 - inventive step starting from D6 in combination with D34/D9, D36, D4, or any of D37 to D40

10.1 The objection of opponent 1 is also based on the assumption that the first and the second connectors were represented by two sections of a one-piece "connector housing" shown in Figure 1.

10.2 However, D6 does not mention anything at all concerning the element identified by the opponent as the connector housing. From Figure 1 it can be derived that the relevant element maybe some kind of adapter piece. No further details about the construction of this component can be derived from the drawing. In particular, the apparently segmented illustration of this transition element does not allow the conclusion that there are two separate components, or even connectors, which are connectable to each other and which are shown here in a connected state.

Hence, D6 fails to disclose two separate and separable connectors and the identification means thereon.

10.3 Since these features are not disclosed in any of the cited documents, the combination of D6 with any of these documents would not result in an apparatus according to claim 1 of auxiliary request 5.

10.4 Hence, the subject-matter of claim 1 also involves an inventive step when starting from D6.

11. It follows from the above that none of the objections of opponent 1 prejudice the maintenance of the patent on the basis of auxiliary request 5, i.e. in the version found allowable by the opposition division.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated