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**Datasheet for the decision  
of 18 December 2024**

**Case Number:** T 1463/22 - 3.2.02

**Application Number:** 16781466.4

**Publication Number:** 3362118

**IPC:** A61M1/16, A61M1/34, A61M1/36

**Language of the proceedings:** EN

**Title of invention:**

RENAL FAILURE THERAPY SYSTEM AND METHOD FOR ELECTRICALLY SAFE  
TREATMENT

**Patent Proprietor:**

Gambro Lundia AB

**Opponents:**

B. Braun Avitum AG  
Fresenius Medical Care AG

**Relevant legal provisions:**

EPC Art. 54(2), 56  
RPBA 2020 Art. 12(4)

**Keyword:**

Amendment to case - admitted (yes)  
Novelty - (yes)  
Inventive step - (yes)

**Decisions cited:**

G 0003/14



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 1463/22 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 18 December 2024**

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**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
12 April 2022 concerning maintenance of the  
European Patent No. 3362118 in amended form.**

**Composition of the Board:**

**Chairman**            M. Alvazzi Delfrate  
**Members:**            A. Martinez Möller  
                              N. Obrovski

## **Summary of Facts and Submissions**

I. Appeals were filed by the patent proprietor and by the opponents against the interlocutory decision of the Opposition Division finding that auxiliary request 1 filed during the oral proceedings before the Opposition Division met the requirements of the EPC.

II. Oral proceedings before the Board took place on 18 December 2024. At the end of the oral proceedings, the requests of the parties were as follows.

The highest ranked request of the patent proprietor ("proprietor") was that the decision under appeal be set aside and that the patent be maintained on the basis of the claim request filed as the second auxiliary request with the proprietor's statement of grounds of appeal.

Opponent 1 and opponent 2 requested that the decision under appeal be set aside and that the patent be revoked.

III. Claim 1 of the second auxiliary request reads as follows:

"A renal failure therapy system (10) including a renal failure therapy machine (12) for providing treatment to a patient using an external electrical device (200), the machine (12) comprising:

a dialyzer (102);

a blood circuit (100) in fluid communication with the dialyzer (102);

a dialysis fluid circuit (30) in fluid communication with the dialyzer (102); and  
a housing supporting the dialyzer (102), the blood circuit (100) and the dialysis fluid circuit (30); characterized in that the renal failure therapy machine comprises  
at least one electrical socket (170) held by the housing, the electrical socket (170) providing a voltage output dedicated to a particular voltage type of external electrical device (200) for powering or charging the external electrical device (200), the at least one electrical socket (170) including electrical insulation for protecting the patient while powering the external electrical device (200),  
wherein the electrical insulation provides an extra galvanic separation between the patient and the renal failure therapy machine to minimize leakage or fault currents."

IV. The following documents are relevant to the present decision:

D2 US 2010/0168653 A1  
D9 Analog Devices, Technical Article MS-2569 -  
Power Management for Healthcare Applications

V. The opponents' arguments relevant to the present decision can be summarised as follows.

*Second auxiliary request - admittance*

The second auxiliary request should not be admitted under Article 12(4) RPBA. The proprietor did not provide reasons for submitting it in the appeal proceedings, nor did the proprietor indicate why it overcame the objections raised. The request was not

convergent in view of the first auxiliary request and included features from the description which might require an additional search. The request was also contrary to procedural economy since the scope of protection of claim 1 lay between that of claim 1 as granted and that of claim 1 as maintained in the decision under appeal.

The proprietor could not have been surprised by the Opposition Division's interpretation of claim 1 as granted since the underlying issues had already been addressed in the written proceedings, and it was to be expected that an Opposition Division could deviate from its preliminary opinion. Moreover, the Opposition Division had already admitted new claim requests filed by the proprietor at the oral proceedings.

*Second auxiliary request - clarity*

Claim 1 was not clear because it defined two external electrical devices.

*Second auxiliary request - added subject-matter*

In claim 1, the feature that the electrical insulation provides an extra galvanic separation only defined the purpose of the insulation and was an unallowable intermediate generalisation from the disclosure of paragraphs [0007] and [0008] as filed. These paragraphs disclosed providing a galvanic separation in combination with other features not included in claim 1, such as a transformer. Paragraph [0064] as filed did not provide a basis for the amendment either because only specific implementations enabled the electrical socket to power an external electrical device, and they could not be generalised. For some examples of

insulation in paragraph [0064], the person skilled in the art would not know how an electrical socket with such insulation could power an external electrical device.

*Second auxiliary request - novelty*

The subject-matter of claim 1 was not novel over D2.

The feature "the at least one electrical socket including electrical insulation" did not require the electrical insulation to be located in the electrical socket; it only imposed a functional limitation that an electrical insulation for the electrical socket had to be present, irrespective of where this electrical insulation was located. Moreover, claim 1 did not define where the socket started and ended.

The device of D2 had to convert the voltage from the wall outlet (220 V) to the USB power supply voltage of 5 V. Paragraph [0051] of D2 also disclosed that a transformer was provided to isolate the device from voltage surges and leakage current from the wall outlet. The USB port of D2 thus included electrical isolation via a transformer, which is a specific type of galvanic separation, and anticipated an electrical socket including electrical insulation that provides an extra galvanic separation between the patient and the renal failure therapy machine.

*Second auxiliary request - inventive step starting from D2*

Even if the location of the galvanic separation within the socket were considered to distinguish the subject-matter of claim 1 from D2, it had no technical effect



and did not involve an inventive step. The transformer in D2 could only be provided in the electrical socket or elsewhere in the device, so its inclusion in the socket was an obvious choice using common general knowledge.

Moreover, the person skilled in the art starting from D2 and looking for an alternative positioning of the transformer would have consulted D9, which discussed power management for dialysis machines and disclosed a USB with electrical isolation including a transformer.

*Second auxiliary request - inventive step starting from D9*

The subject-matter of claim 1 was not inventive in view of D9 combined with common general knowledge. It would have been obvious to start from the dialysis machine disclosed in the section "Instrumentation" of D9 and to implement in it the USB with a transformer disclosed in the section "Patient Monitoring".

VI. The proprietor's arguments relevant to the present decision can be summarised as follows.

*Second auxiliary request - admittance*

The second auxiliary request should be admitted under Article 12(4) RPBA. The request was identified as an amendment, and reasons were given for its submission in the appeal proceedings. The Opposition Division presented for the first time at the oral proceedings three new aspects on the interpretation of a feature of claim 1, deviating from its preliminary opinion. The second auxiliary request addressed two of these aspects and was neither detrimental to procedural economy nor

complex since the galvanic separation included in claim 1 related to the level of protection of the electrical insulation and went in the same direction as the transformer present in claim 1 as maintained.

*Second auxiliary request - added subject-matter*

The second auxiliary request complied with Article 123(2) EPC. The basis for providing a galvanic separation without restricting it to a transformer was found in paragraphs [0007] and [0008] of the application as filed. The argument that the person skilled in the art would not know how to implement some examples in paragraph [0064] did not relate to added subject-matter but to sufficiency of disclosure.

*Second auxiliary request - novelty*

Claim 1 required that the electrical insulation be included in the electrical socket. The transformer mentioned in D2 was not included in the USB port. The subject-matter of claim 1 was thus novel over D2.

*Second auxiliary request - inventive step starting from D2*

The subject-matter of claim 1 was inventive when starting from D2. The socket with an electrical insulation, which provided an extra galvanic separation between the patient and the machine, had the technical effect of minimising leakage currents which could be harmful for the patient whose blood circulated through the machine during treatment. The problem solved was how to safely power and use an external electrical device during dialysis. Neither D2 nor D9 taught the claimed solution. D9 emphasised that power management

requirements were different for different application areas, including patient monitoring and instrumentation. Therefore, the teaching of D9 for patient monitoring devices would not be consulted when starting from an instrumentation device such as a dialysis machine.

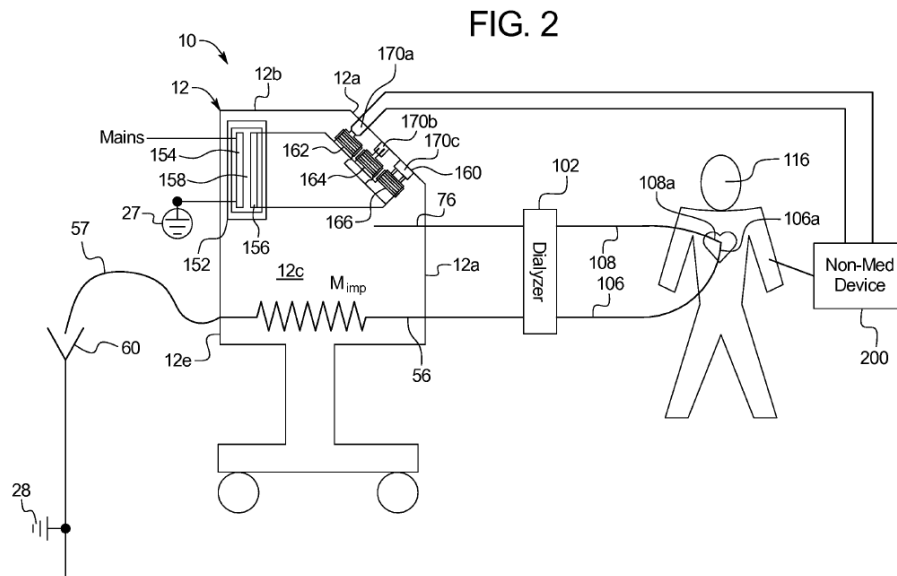
*Second auxiliary request - inventive step starting from D9*

D9 was not a good starting point for the subject-matter of claim 1 because it only mentioned a dialysis machine as an example of instrumentation equipment, without giving any details about the machine or the type of dialysis. D9 only disclosed USB and a transformer for a different application area, and the person skilled in the art would not combine what was disclosed for a different application area without applying inventive skill.

## **Reasons for the Decision**

1. Patent
  - 1.1 Patients connected to dialysis machines may be poorly protected against leakage current from an external electrical device such as a laptop or smartphone. Leakage current can occur, for example, if a poor quality charger is used.
  - 1.2 It is therefore advisable for dialysis clinics to ask patients not to plug their electronic devices into an external power source during treatment. This is inconvenient for patients, who may have to undergo treatment for three to four hours several times a week.

- 1.3 The contested patent aims at providing a renal failure therapy system that allows a patient to safely power an external electrical device during treatment.
- 1.4 The system of claim 1 as granted comprises a dialyser, a blood circuit, a dialysis fluid circuit, a housing and at least one electrical socket. The housing supports the dialyser, the blood circuit and the dialysis fluid circuit. The housing also holds at least one electrical socket providing a voltage output dedicated to a particular voltage type of an external electrical device for powering or charging the external electrical device. The at least one electrical socket includes electrical insulation for protecting a patient while powering the external electrical device.
- 1.5 An embodiment of the claimed system is shown in Figure 2 of the patent specification, reproduced below, in which the electrical sockets are identified with reference signs 170a, 170b and 170c.



2. Second auxiliary request - admittance
- 2.1 The second auxiliary request was filed for the first time with the proprietor's statement of grounds of appeal. It therefore constitutes an amendment within the meaning of Article 12(4) RPBA.
- 2.2 In its statement of grounds of appeal, the proprietor identified this amendment and stated that it was filed in response to the Opposition Division's new interpretation of the feature "the at least one electrical socket including electrical insulation for protecting a patient while powering the external electrical device" of claim 1 as granted. The proprietor indicated that the amendment addressed two aspects of the feature's new interpretation: that the term "a patient" did not necessarily refer to a patient being dialysed by the claimed system and that "electrical insulation for protecting a patient" did not specify the level of protection provided and was anticipated by the basic electrical insulation provided in any electrical socket (see point 2.2.1.6.3 of the appealed decision).
- 2.3 This interpretation, presented by the Opposition Division at the oral proceedings before it, had not been mentioned in the preliminary opinion of the Opposition Division. The Opposition Division's new interpretation had ultimately led to the conclusion that the subject-matter of claim 1 was not novel over D2, contrary to what had been indicated in the Opposition Division's preliminary opinion.
- 2.4 Opponent 2 submitted that a deviation from a preliminary opinion could not be considered a surprise,

especially since opponent 2 had discussed the interpretation of these two aspects of the feature on page 4, third paragraph of its letter to the Opposition Division of 26 November 2020. The Board notes that the paragraph cited by opponent 2 concerns the same feature but states something (essentially that claim 1 does not restrict the electrical insulation to a mechanical electrical insulation and that an electrical insulation protects the patient by definition) which does not even suggest, let alone correspond to, the claim interpretation which the Opposition Division presented at the oral proceedings before it.

- 2.5 In summary, the Opposition Division presented a new interpretation of a claim feature for the first time at the oral proceedings before it. This interpretation had not previously been put forward by any of the parties and changed the outcome of the question whether claim 1 as granted was novel.
- 2.6 As noted by opponent 2, a new auxiliary request had been admitted at the oral proceedings before the Opposition Division. However, the admittance of a late-filed request in the first-instance proceedings does not, as such, preclude the admittance of a new auxiliary request in appeal proceedings.
- 2.7 As noted by opponent 1, the second auxiliary request is not convergent with the (now withdrawn) first auxiliary request. As indicated in the proprietor's submissions, the first auxiliary request addressed a third - and different - issue of claim interpretation. The Board considers the filing of these auxiliary requests to be a reasonable response to the three new aspects of claim interpretation raised by the Opposition Division.

2.8 A transformer (present in claim 1 as maintained by the Opposition Division) is a specific way of providing galvanic separation (present in claim 1 of the second auxiliary request). Hence, although the features added to the second auxiliary request come from the description, the amendment addresses the type of electrical insulation, which was a central issue of discussion both for claim 1 as granted and for claim 1 as maintained by the Opposition Division. This means that the second auxiliary request does not shift the focus of the case, in particular the discussion of patentability, to completely new aspects. It is thus neither complex nor detrimental to procedural economy.

2.9 In conclusion, taking into account that the patentability of claim 1 as granted was assessed in the first-instance proceedings on the basis of a new interpretation presented by the Opposition Division for the first time at the oral proceedings before it and that the Board does not consider the second auxiliary request to be complex or detrimental to procedural economy, the Board decided to exercise its discretion under Article 12(4) RPBA to admit the second auxiliary request.

3. Second auxiliary request - clarity

3.1.1 Opponent 2 submitted that claim 1 was not clear because it defined two external electrical devices.

3.1.2 In the phrase "voltage output dedicated to a particular voltage type of external electrical device for powering or charging the external electrical device", neither a definite nor an indefinite article is used before the first mention of "external electrical device". However, any possible lack of clarity in this respect was

already present in claim 1 as granted and is excluded from examination in accordance with G 3/14.

3.1.3 Moreover, with the addition of "an external electrical device" in the preamble of claim 1, the person skilled in the art would understand that the subsequent "external electrical device" (without any article) refers to the one from the preamble. The amendment does not cause any doubt as to the scope of protection. Therefore, the objection of lack of clarity is not convincing.

4. Second auxiliary request - added subject-matter

4.1 The opponents submitted that the application as filed did not disclose providing an extra galvanic isolation without further related features such as a transformer.

4.2 Paragraphs [0007] and [0008] of the application as filed disclose that in the electrical socket allowing a patient undergoing treatment to power an external device, the electrical insulation provides an extra galvanic separation. It is clear from the second and third sentences of paragraph [0007] and from the whole of paragraph [0008] that there are various ways in which the electrical insulation can provide a galvanic separation and that the use of a transformer for AC sockets is only one possible way. Paragraph [0064] confirms that there are different ways to provide a galvanic separation. Therefore, the amendment in claim 1 specifying that the electrical insulation provides an extra galvanic separation without the additional restriction that the electrical insulations includes a transformer does not result in added subject-matter.



- 4.3 The question raised by opponent 2 as to whether or not the person skilled in the art would know how to implement some of the options mentioned in the last sentence of paragraph [0064] does not change what is disclosed by paragraphs [0007] and [0008] and is not the relevant question for assessing whether claim 1 comprises added subject-matter.
- 4.4 The Board is thus not convinced by the objection of added subject-matter.
5. Second auxiliary request - novelty over D2
- 5.1 Opponent 1 put forward that the feature "the at least one electrical socket including electrical insulation ..." was a functional limitation which did not require the electrical insulation to be located in the electrical socket but could be located anywhere in the claimed system or even outside the system, as long as electrical insulation of the electrical socket was achieved.
- 5.2 The Board construes the feature differently. The word "including" in the above feature indicates that the electrical insulation is included in (i.e. is part of) the electrical socket. This is the usual meaning of the word "including", and there is nothing to suggest that anything else is meant in claim 1. The contested patent also shows the electrical insulation, which provides galvanic separation, as being part of the electrical socket (see Figures 2 to 4 and paragraphs [0054] to [0058]).
- 5.3 D2 discloses a dialysis device including a universal serial bus (USB) host device with one or more USB ports for connecting peripheral devices (see Figure 1B and

paragraphs [0076] to [0078])). A USB port can be considered to anticipate an electrical socket within the meaning of claim 1.

- 5.4 As submitted by the opponents, in D2 the alternating current (AC) at the voltage supplied by, for example, a wall outlet needs to be converted to direct current (DC) at the voltage(s) required by the internal components of the dialysis machine and by the USB port(s). This is usually done using a power supply including one (or more) transformers. A transformer also isolates a device from a surge on the electrical outlet, as disclosed in paragraph [0051] of D2. However, even assuming that a transformer is present in the device of D2, e.g. located in an internal power supply close to the point where the power cord reaches the device, D2 would still not disclose that the transformer is included in any of the USB ports.
- 5.5 Opponent 1 argued that claim 1 left open where an electrical socket started and where it ended, meaning that it could encompass a transformer provided in a different part of the device. However, the person skilled in the art would not construe an electrical socket as extending from the USB socket to a different part of the device (e.g. the power supply) where a transformer may be located.
- 5.6 It follows that D2 does not disclose the features "the at least one electrical socket including electrical insulation for protecting the patient while powering the external electrical device, wherein the electrical insulation provides an extra galvanic separation between the patient and the renal failure therapy machine to minimize leakage or fault currents".

Therefore, the subject-matter of claim 1 is novel over D2.

6. Second auxiliary request - inventive step starting from D2

6.1 According to the opponents, the only difference between the subject-matter of claim 1 and the device of D2 was the location of the galvanic separation/transformer, and this did not result in any technical effect.

6.2 However, as noted by the proprietor, the requirement that the electrical socket includes electrical insulation that provides an extra galvanic separation between the patient and the renal failure therapy machine prevents leakage currents originating from the external electrical device from passing through the electrical socket and through components of the dialysis machine (e.g. the blood circuit) into the patient's blood and potentially harming the patient. If a transformer is instead provided e.g. at the power supply of the dialysis machine, there is no additional galvanic separation between the patient and the dialysis machine. Leakage currents from an external electrical device plugged into the electrical socket held by the housing of the dialysis machine could potentially reach other components of the dialysis machine, such as the blood circuit, and thus reach the patient's blood. The Board thus concludes that the distinguishing features have a technical effect and that the problem to be solved when starting from D2 may be regarded as how to allow a patient to use and power an external electronic device during treatment safely.

6.3 Moreover, even if the problem submitted by the opponents of providing an alternative arrangement of

the electrical insulation were to be accepted, the Board considers that the person skilled in the art starting from D2, and in view of common general knowledge or D9, would not arrive at a system anticipating the subject-matter of claim 1.

- 6.4 The opponents' argument that the electrical insulation including a transformer can only be provided at the USB port (i.e. at the electrical socket) or elsewhere (i.e. anywhere else), meaning that either option would be obvious, is incorrect. Using this type of argument, it could also be said that any device may or may not have any given feature, leading to the absurd conclusion that it is obvious to have or not have any feature in a device. Even assuming that a transformer is present in the dialysis machine of D2, D2 does not indicate the transformer's location, and including it in the USB port is a very precise location from many possible locations within the machine. The claimed location is thus not one of only two equally possible locations.
- 6.5 A transformer that isolates a device from a surge on the electrical outlet (i.e. as disclosed in paragraph [0051] of D2, albeit not stating that it is present in the dialysis machine) is typically located within the power supply that converts the external AC voltage to the DC voltage(s) used by the components of the device. Assuming this to be the case in D2, the person skilled in the art would not be prompted by common general knowledge to move this transformer to a point remote from the power supply of the dialysis machine, let alone to include it within the USB port for peripheral devices of D2.
- 6.6 The combination with D9 is also not convincing. D9 deals with power management for healthcare

applications. D9 distinguishes in the first paragraph of page 1 between four healthcare application areas (home healthcare, instrumentation, patient monitoring and imaging). D9 concludes on page 3 that "[p]ower management requirements in healthcare applications are quite different depending on the application area".

6.7 D9 mentions dialysis machines as an example application in instrumentation (page 2, left column, second paragraph). For instrumentation, D9 discloses that an AC-DC power supply can be used to generate one or more intermediate DC voltages (12 V/5 V), and that a micro power management with switching regulators is used to generate lower DC voltages out of the intermediate voltage(s). However, this section does not mention any USB port, let alone placing these electronic elements within a USB port. Opponent 2 referred to a different section of D9, namely the section dealing with patient monitoring applications with systems used e.g. to measure blood pressure. However, this section would not be consulted when starting from the dialysis machine of D2 in view of the teaching of D9 that each application area has different power management requirements.

6.8 It follows that the subject-matter of claim 1 is inventive over D2 in combination with either common general knowledge or D9.

7. Second auxiliary request - inventive step starting from D9

7.1 D9 discloses dialysis machines as an example in the "Instrumentation" section, without giving any details of the dialysis machines. Starting from the generic dialysis machine mentioned in D9, D9 lacks at least all features of claim 1 starting with "at least one

electrical socket". Nothing in D9 suggests that the dialysis machine could be provided with a USB port or any other electrical socket providing a voltage output for powering or charging an external electrical device. Since D9 teaches that each application area has different requirements, the section on patient monitoring would not be consulted when starting from a dialysis machine. Even if it were consulted, the section on patient monitoring does not teach that it is advantageous for a dialysis machine to include a USB port for powering or charging an external electrical device.

7.2 It follows that the subject-matter of claim 1 is inventive over D9 in combination with common general knowledge.

## **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 to 13 of the second auxiliary request filed with the patent proprietor's statement of grounds of appeal
  - description and drawings of the patent specification

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated