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**Datasheet for the decision
of 24 January 2023**

Case Number: T 1722/18 - 3.2.02

Application Number: 08871077.7

Publication Number: 2219705

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

Language of the proceedings: EN

Title of invention:
A MEDICAL APPARATUS FOR EXTRACORPOREAL TREATMENT

Patent Proprietor:
Gambro Lundia AB

Opponent:
B. Braun Avitum AG

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(4), 13(2)

Keyword:
Inventive step - (yes)
Late-filed objection - admitted (no)

Decisions cited:

Catchword:



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
Fax +49 (0)89 2399-4465

Case Number: T 1722/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 January 2023

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)

Respondent:

(Patent Proprietor)

Gambro Lundia AB
P.O. Box 10101
220 10 Lund (SE)

Representative:

PGA S.p.A., Milano, Succursale di Lugano
Via Castagnola, 21c
6900 Lugano (CH)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
4 May 2018 concerning maintenance of the
European Patent No. 2219705 in amended form.**

Composition of the Board:

Chairman

M. Alvazzi Delfrate

Members:

A. Martinez Möller

N. Obrovski

Summary of Facts and Submissions

- I. The opponent filed an appeal against the interlocutory decision of the Opposition Division finding that, account being taken of the amendments made by the patent proprietor according to the then main request filed during the oral proceedings before the Opposition Division, European patent No. 2219705 and the invention to which it related met the requirements of the EPC.
- II. Oral proceedings before the Board took place by videoconference on 24 January 2023.

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

The respondent (proprietor) requested that the appeal be dismissed (main request) or, as an auxiliary measure, that the patent be maintained on the basis of the first auxiliary request filed with the submission dated 28 January 2019 or the second auxiliary request filed with the submission dated 3 January 2023.

- III. Claim 1 of the **main request** (i.e. claim 1 of the version found to meet the requirements of the EPC in the appealed decision) reads as follows:

"A medical apparatus (100) for extracorporeal blood treatment, comprising:

- a support structure (101) internally exhibiting a housing chamber (102), the housing chamber exhibiting at least one liquid collection zone (103),

- a hydraulic circuit (1) having at least one supply channel (2), destined to transport a treatment liquid from at least one source (3) towards a treatment station (4), and at least one discharge channel (6), destined to transport a used liquid from the treatment station (4) towards an evacuation zone (7), the hydraulic circuit being located in the housing chamber (102) above the liquid collection zone (103) such that liquid leakage from the hydraulic circuit system can at least partially accumulate in the liquid collection zone,
- a liquid sensor (108) destined at least to detect presence of a liquid in the liquid collection zone, characterized in that the medical apparatus comprises at least one measuring chamber (111) arranged externally of the housing chamber and a channel (112) which sets the at least one liquid collection zone (103) in contact with the measuring chamber, the liquid sensor (108) operating in a distanced position with respect to the liquid collection zone (103)."

IV. The following documents are relevant to this decision:

E1 WO 2004/096322 A1

E2 US 5,674,390

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

Inventive step starting from E2

E2 disclosed all features of claim 1, so that the subject-matter of claim 1 was not inventive over E2 alone.

The drain in the base of the module 28 served to accumulate liquid leakage from the dialysate circuit

provided within the module 28. This drain thus anticipated the liquid collection zone. The liquid leakage was then drained to the catchment basin 284 at the bottom of the machine, where it was detected by the fluid sensor 286.

By detecting liquid in the catchment basin 284, the fluid sensor 286 detected the presence of liquid in the drain of the module 28, even if no liquid was present in the drain anymore. This corresponded to the indirect detection taught in the contested patent. Claim 1 of the contested patent did not specify the vertical position of the measuring chamber relative to the liquid collection zone. The apparatus shown in Figures 5-9 of the contested patent showed that the measuring chamber could be in a lower location, so that when liquid was detected by the sensor, there might not be any liquid in the liquid collection zone.

Inventive step starting from E1 in view of E2

The subject-matter of claim 1 was rendered obvious starting from E1 in view of E2. E1 disclosed all features of claim 1 except the channel and the measuring chamber. These features did not solve any technical problem because claim 1 encompassed the sensor being provided in the housing.

Also, if the feature "the liquid sensor operating in a distanced position with respect to the liquid collection zone" was regarded as a further distinguishing feature, E2 disclosed all three features. Hence, the person skilled in the art starting from E1 in view of E2 would have arrived at the subject-matter of claim 1.

Admittance of the objections of added subject-matter

Since the description had not been properly adapted to the amended claims, claim 1 when read in view of the description encompassed hybrid embodiments with the liquid sensor being provided within the housing despite the presence of the external measuring chamber. The application as filed did not disclose such hybrid embodiments, resulting in added subject-matter. This objection should be admitted because it had been raised with the notice of opposition and never withdrawn, as was apparent from points 2 and 8 of the minutes of the oral proceedings before the Opposition Division.

Claim 5 also comprised added subject-matter because it included the wording "in particular" which was not present in claim 9 as originally filed. The appellant only discovered it now because the applicant/respondent had not properly identified this amendment during the examination proceedings. This represented exceptional circumstances within the meaning of Article 13(2) RPBA 2020 justifying admittance of a late-filed objection.

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

Inventive step starting from E2

Any liquid leakage in E2 would be drained to the catchment basin 284. The fluid sensor 286 detected liquid in the basin 284 but not in the drain of the module 28. Even if the drain were to be regarded as a liquid collection zone, the sensor of E2 did not detect the presence of a liquid in the liquid collection zone. The distinguishing features allowed easier maintenance and inspection of the measuring chamber and the sensor.

Hence, E2 alone did not render obvious the subject-matter of claim 1.

Inventive step starting from E1 in view of E2

E1 did not disclose the features related to a measuring chamber, a channel and a liquid sensor operating at a distanced position. These features facilitated maintenance and inspection of the measuring chamber and the sensor. Even if when starting from E1 and faced with this problem the structure of the dialysis machine taught by E2 was considered, the person skilled in the art would not have arrived at a machine with all features of claim 1.

Admittance of the objections of added subject-matter

The objection of added subject-matter of claim 1 encompassing undisclosed embodiments should not be admitted. The notice of opposition was directed against the claims as granted. At the oral proceedings before the Opposition Division, the respondent/proprietor filed a new main request, and the appellant/opponent explicitly stated that it had no objection under Article 123(2) EPC to it. Moreover, claim 1 corresponded to the combination of claims 1 and 8 as originally filed so that the objection was *prima facie* not relevant.

The objection of added subject-matter against claim 5 should not be admitted. There were no exceptional circumstances under Article 13(2) RPBA 2020 because claim 5 had been there since the first-instance proceedings.

Reasons for the Decision

1. The invention

The invention is a medical apparatus for extracorporeal blood treatment, such as haemodialysis or haemofiltration.

Such apparatuses typically include a hydraulic circuit for transporting treatment liquid (usually dialysis liquid) towards the treatment zone and from the treatment zone towards an evacuation zone. The hydraulic circuit comprises numerous components such as pumps, valves, tubes, etc. A liquid leak from the hydraulic circuit can occur over the lifespan of the machine, which could damage the machine and be dangerous for the patient undergoing treatment.

The invention addresses this problem by providing a machine which is able to detect liquid leakage by means of a liquid sensor for which maintenance and inspection of the liquid sensor are easy.

This is done in claim 1 by providing an apparatus with a support structure (101) which internally exhibits a housing chamber (102) in which there is a hydraulic circuit (1) located above at least one liquid collection zone (103) such that liquid leakage from the hydraulic circuit can accumulate in the liquid collection zone. The apparatus also comprises at least one measuring chamber (111) arranged externally of the housing chamber and a channel (112) which sets the at least one liquid collection zone in contact with the measuring chamber. The apparatus further comprises a liquid sensor (108) for detecting the presence of a liquid in the liquid collection zone, the sensor

operating in a distanced position with respect to the liquid collection zone.

An apparatus as claimed is shown in Figure 3 of the contested patent, reproduced below, with the hydraulic circuit represented by a rectangular frame in a broken line.

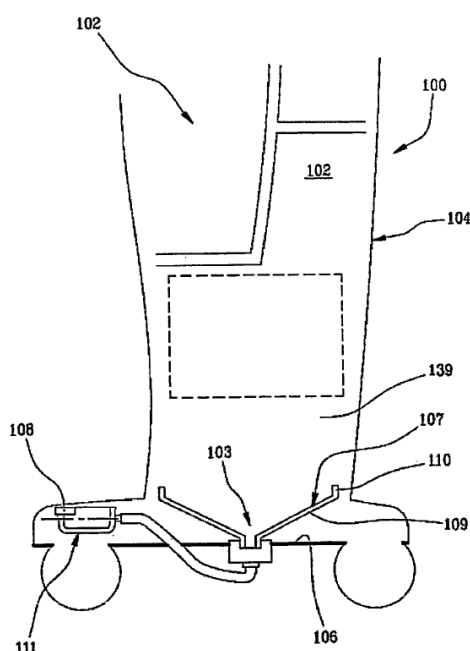
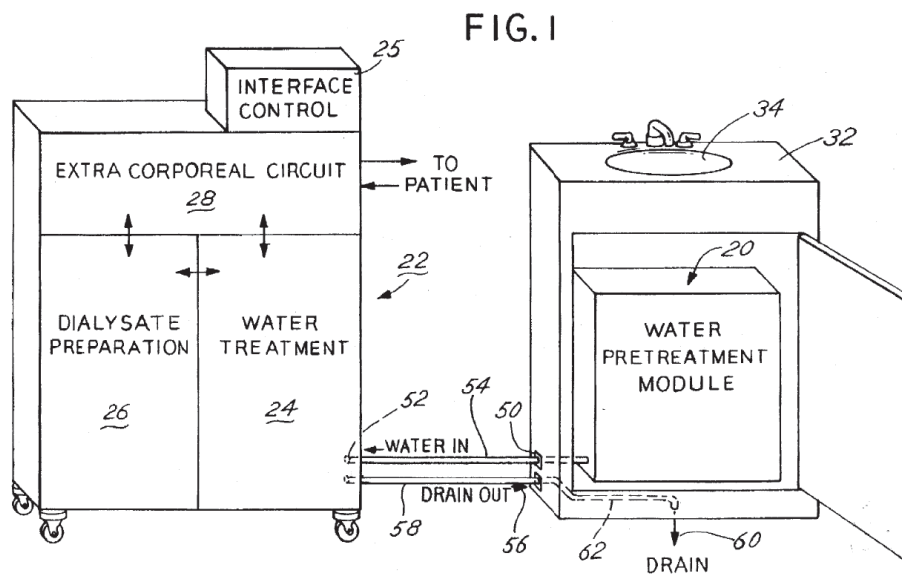


FIG 3

2. Main request - inventive step starting from E2

2.1 In the dialysis machine disclosed in E2, a drain and drain tube conduct any liquid leaked within the blood circuit module 28 towards the catchment basin 284 located at the floor of the machine (see column 33, line 65 to column 34, line 2). A fluid sensor 286 determines the presence of liquid in the catchment basin 284, liquid which may have leaked from any of the modules 24, 26 or 28 (see column 18, lines 33-46). A schematic block diagram of the dialysis machine of E2 is shown in Figure 1 reproduced below.



E2 discloses an embodiment in which the dialysate circuit 402 can be part of the blood circuit module 28 (column 51, lines 59-61), which is placed above the other modules (see Figure 1 above and column 33, lines 64-65). In this embodiment, the drain of the module 28 collects the liquid leaked from the dialysate circuit 402 and thus can be regarded as anticipating the liquid collection zone of claim 1. The catchment basin 284 can be regarded as anticipating the measuring chamber of claim 1.

2.2 It is disputed whether E2 discloses the feature "a liquid sensor (108) destined at least to detect presence of a liquid in the liquid collection zone".

The fluid sensor 286 of E2 detects the presence of a liquid in the catchment basin 284. Detection of liquid in the catchment basin 284 does not imply that there is liquid present in the drain of the module 28. Even if the liquid in the catchment basin 284 had come from the module 28 and not from any other module of the dialysis machine of E2, it is uncertain whether there would

still be any liquid present in the drain of the module 28 when liquid is detected in the catchment basin 284. In view of the purpose of a drain, it is instead likely that there would be no liquid present in the drain anymore.

The disputed feature of claim 1 relates explicitly to detecting the presence of a liquid in the liquid collection zone. An apparatus which does not achieve this cannot be seen as anticipating this feature.

2.3 The appellant submitted that this detection can be direct or indirect. The contested patent taught that the liquid sensor could be located in the measuring chamber, in this case thus only indirectly detecting the presence of a liquid in the liquid collection zone.

The appellant further submitted that the liquid sensor (108) of claim 1 did not need to detect that liquid was currently present in the liquid collection zone (103). This was apparent from several figures of the contested patent which showed that the bottom of the measuring chamber 111 was located lower than the liquid collection zone 103 so that liquid would be detected in the measuring chamber 111 when there would possibly be no liquid present in the liquid collection zone 103.

This line of argument disregards the role played by channel 112 connecting the liquid collection zone 103 and the measuring chamber 111. In Figures 5, 9 and 10 of the contested patent, any liquid accumulating in the liquid collection zone 103 and filling the channel 112 only starts entering the measuring chamber 111 once the liquid level reaches the channel's end 113b, connected at a lateral wall 114 of the measuring chamber 111 (see also the third sentence of paragraph [0047] of the

patent specification; note that the end 113b is incorrectly indicated with reference sign 113a in Figure 9).

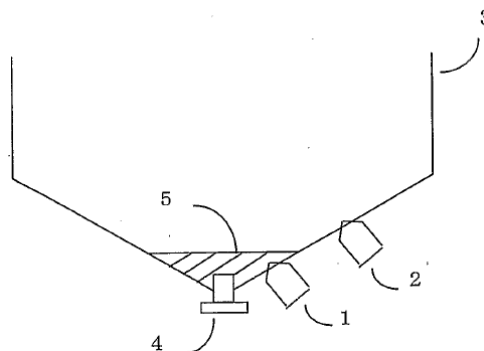
The channel's end 113b is located at the same height as the lower part of the liquid collection zone 103. Hence, liquid will be present in the liquid collection zone 103 whenever liquid enters the measuring chamber 111. Thus, despite the bottom of the measuring chamber 111 being lower than the liquid collection zone 103 in the apparatus shown in those figures, the detection of liquid in the measuring chamber 111 is still an (indirect) detection of the (current) presence of a liquid in the liquid collection zone 103. Hence, the description does not support the interpretation of the disputed feature of claim 1 brought forward by the appellant.

- 2.4 In view of the above and in the absence of any reasoning why the person skilled in the art would have modified the apparatus of E2 by providing this feature, the Board concludes that the subject-matter of claim 1 is not obvious in view of E2 alone.

3. Main request - inventive step starting from E1

- 3.1 E1 discloses a blood dialyser with a casing part for storing liquid leakage and two liquid detection means for detecting the stored liquid leakage at two different liquid heights (see Figure 1 reproduced below).

Fig. 1



It is common ground that E1 does not disclose a measuring chamber arranged externally of the housing chamber and a channel which sets the liquid collection zone in contact with the measuring chamber.

3.2 The appellant argued that the liquid detection means of E1 shown with reference sign 2 in Figure 1 anticipated the last feature of claim 1. However, this liquid detection means is placed directly at the inclined floor of the casing where the liquid accumulates. Hence, it does not operate "in a distanced position with respect to the liquid collection zone" as required by the last feature of claim 1.

3.3 In its written submissions, the appellant did not address this additional distinguishing feature. At the oral proceedings, the appellant stated that E2 disclosed all three distinguishing features, so that the subject-matter of claim 1 was rendered obvious by the combination of E1 and E2. However, the appellant did not explain how the person skilled in the art would have modified the apparatus of E1 in view of E2.

3.4 Even if the person skilled in the art in view of E2 had added a drain to the casing of E1 and a lower catchment basin towards which the liquid is drained, a liquid sensor operating in this catchment basin would not have

anticipated the feature of detecting "presence of a liquid in the liquid collection zone" for the same reasons explained for E2 above.

3.5 It follows that the subject-matter of claim 1 is not obvious in view of E1 in combination with E2.

4. Main request - admittance of the objections of added subject-matter

4.1 Claim 1 and not properly adapted description

The minutes of the oral proceedings before the Opposition Division were uncontested.

The main request on appeal corresponds to the main request filed during the oral proceedings before the Opposition Division. According to the minutes, the objection of added subject-matter raised in the notice of opposition against the claims of the patent as granted was not repeated for the main request. To the contrary, the appellant/opponent stated that it had no objections under Article 123(2) to the claims of the main request (last sentences in section 2 of the minutes).

The appellant/opponent further stated that the description should be adapted to the new claims (see penultimate sentence of the penultimate paragraph in section 2 of the minutes and second sentence in section 8 of the minutes, relating to Article 84 EPC; see also point 2.2.1 of the appealed decision). After an adapted description had been filed, the appellant/opponent, while requesting in the context of Article 84 EPC (see the heading of section 8 of the minutes) that a statement on an embodiment be added to the minutes,

stated that it had no further objection to the adapted description (sixth to eighth paragraph in section 8 of the minutes).

In summary, the minutes do not support the appellant's assertion that it raised and maintained in the opposition proceedings an objection that the claims of the main request when read in view of the description resulted in added subject-matter.

Moreover, the objection of added subject-matter raised on appeal is not *prima facie* relevant for the following reasons. Claim 1 of the main request is the combination of claims 1 and 8 as originally filed. The disclosure of claim 1 is thus identical to the disclosure of claim 8 as originally filed, including any embodiments encompassed by it. In these circumstances, whether the description properly identifies all embodiments which allegedly contradict claim 1 is an issue to be considered under Article 84 EPC, not Article 123(2) EPC.

Hence, the Board decided under Article 12(4) RPBA 2007 not to take this objection of added subject-matter into account.

4.2 Claim 5

At the end of the oral proceedings before the Board, the appellant amended its appeal case by raising an objection of added subject-matter against claim 5. The admittance of this objection is subject to the conditions set out in Article 13(2) RPBA 2020.

The amendment to claim 5 disputed by the appellant had been carried out in examination proceedings.

Irrespective of whether this amendment had been properly identified by the applicant/respondent in examination proceedings, the appellant could and should have verified all changes between the application as filed and the patent as granted when preparing the notice of opposition. Failure to do so cannot justify raising an objection at such a late stage of the proceedings. Hence, there are no exceptional circumstances within the meaning of Article 13(2) RPBA 2020. Accordingly, the Board decided not to take this objection into account.

5. Since none of the appellant's objections prejudices the maintenance of the patent on the basis of the main request, the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated