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Datasheet for the decision of 25 June 2026

Case Number: T 0182/24 - 3.2.02

Application Number: 19192317.6

Publication Number: 3782671

IPC: A61M1/36

Language of the proceedings: EN

Title of invention:
METHOD FOR PRIMING AN EXTRACORPOREAL BLOOD CIRCUIT OF AN APPARATUS FOR EXTRACORPOREAL TREATMENT OF BLOOD AND APPARATUS FOR EXTRACORPOREAL TREATMENT OF BLOOD

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care AG

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54, 56, 111(1), 101(3)(b)
RPBA 2020 Art. 11, 12(2), 12(4)

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It can be changed at any time and without notice

Keyword:
Grounds for opposition - lack of patentability (yes)
Novelty - (no)
Inventive step - (no) - obvious alternative - problem invention (no) - obvious modification
Appeal decision - remittal to the department of first instance (no)

Decisions cited:
G 0001/24

Catchword:

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Case Number: T 0182/24 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 June 2026

Appellant: (Patent Proprietor)	Gambro Lundia AB Magistratsvägen 16 226 43 Lund (SE)
Representative:	PGA S.p.A., Milano, Succursale di Lugano Via Castagnola, 21c 6900 Lugano (CH)
Appellant: (Opponent)	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/ electronically transmitted on 6 December 2023 concerning maintenance of the European Patent No. 3782671 in amended fo rm.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	T. Rosenblatt
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor and the opponent (appellants) each filed an appeal against the interlocutory decision of the opposition division, in which the opposition division found that European patent No. 3 782 671 in amended form met the requirements of the EPC.

II. The parties were summoned to oral proceedings before the Board. With a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the parties were informed of the Board's provisional opinion.

In reply to this opinion, the appellant-proprietor submitted further comments with its letter dated 22 June 2026.

III. The appellant-proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, in the alternative, that the patent be maintained on the basis of any of the first to third auxiliary requests, submitted with the appellant-proprietor's statement of grounds of appeal dated 8 April 2024, the fourth auxiliary request, found allowable by the opposition division, or any of the fifth to twelfth auxiliary requests, submitted with the appellant-proprietor's reply to the appellant-opponents statement of grounds of appeal dated 12 August 2024. The appellant-proprietor further requested the remittal of the case for further consideration if any of the fifth to twelfth auxiliary requests became relevant.

IV. The appellant-opponent requested that the decision under appeal be set aside and that European patent No. 3 782 671 be revoked.

V. Claim 1 of the patent as granted reads as follows (bold feature numbering in square brackets according to page 5 of the statement of grounds of appeal of the appellant-proprietor, in the following also "appeal grounds"):

> "[**1**] *A method for priming an extracorporeal blood circuit of an apparatus for extracorporeal treatment of blood, wherein the apparatus for extracorporeal treatment of blood comprises:*
> [**1.2**] *optionally a blood treatment unit (2);*
> [**1.3**] *an extracorporeal blood circuit, optionally coupled to the blood treatment unit (2);*
> [**1.4**] *a blood pump (11) configured to be coupled to a pump section of the extracorporeal blood circuit;*
> [**1.5**] *a membrane gas exchanger (18) operatively coupled to the extracorporeal blood circuit to exchange gas with blood flowing in the extracorporeal blood circuit, wherein the membrane gas exchanger (18) comprises a blood side in fluid communication with the blood circuit and a gas side;*
> *wherein the method comprises:*
> [**2**] *- feeding a priming fluid in the extracorporeal blood circuit and into the blood side of the membrane gas exchanger (18);*
> [**2.1**] *- generating a transitory pressurization step in the priming fluid flowing in the blood circuit and in the blood side of the membrane gas exchanger (18) to prevent release of air bubbles at a blood outlet (18d) of the membrane gas exchanger (18).*"

In claim 1 of the **first auxiliary request**, the following feature has been added to the end of granted claim 1:

", *whereby the apparatus for extracorporeal treatment of blood is configured to prevent formation of bubbles in the extracorporeal blood circuit due to the presence of the membrane gas exchanger*"

In claim 1 of the **second auxiliary request**, the following feature has been inserted before the feature added in claim 1 of the first auxiliary request:

", *wherein the transitory pressurization step results:*
o in the forcing of some priming fluid into hydrophobic pores of a membrane of the membrane gas exchanger (18) leading to a reduction of gas transfer, and
o in a removal of micro-air bubbles, accumulated at a wall of the membrane, through the membrane and before their aggregation into macro-bubbles"

In claim 1 of the **third auxiliary request**, the feature added to granted claim 1 according to the first auxiliary request is omitted, while the feature added in the second auxiliary request is kept.

Claim 1 of the **fourth auxiliary request** is based again on granted claim 1 to which the following feature has been added at the end (feature numbering in square brackets added by the Board):

"*; wherein generating the transitory pressurization step comprises:*

[**3**] *restricting or occluding transiently a portion of the extracorporeal blood circuit placed downstream of the membrane gas exchanger (18) with respect to a flow direction of the priming fluid*"

Claim 1 of the **fifth, sixth and seventh auxiliary requests** is based on claim 1 of the corresponding first, second and third auxiliary requests, respectively, and further comprises the feature added in the fourth auxiliary request.

Claim 1 of the **eighth auxiliary request** is again based on granted claim 1, to which the following feature has been added at the end (feature numbering in square brackets added by the Board):

"*;* [**4**] *wherein, at the end of the priming and before patient connection, a pressure in the blood circuit and in the blood side of the membrane gas exchanger (18) is kept between 20mmHg and 400mmHg*"

Claim 1 of the **ninth auxiliary request** is based on claim 1 of the fourth auxiliary request to which the following features have been added at the end (feature numbering in square brackets added by the Board):

"[**5**] *wherein the transitory pressurization step in the priming fluid is generated once the priming fluid fills the blood side of the membrane gas exchanger (18), and*
[**4'**] *wherein, at the end of the priming and before patient connection:*
[**4''**] *the blood pump is stopped while a return clamp or valve placed on a blood return line and downstream of the membrane gas exchanger is kept closed; and*

[**4'''**] *a pressure in the blood circuit and in the blood side of the membrane gas exchanger (18) is kept between 20mmHg and 400mmHg*"

Claim 1 of the **tenth, eleventh and twelfth auxiliary** requests is based on claim 1 of the corresponding first, second and third auxiliary requests, respectively, and further comprises the features added in the ninth auxiliary request.

The opposed patent and all auxiliary requests also comprise a corresponding independent apparatus claim. The wording of these claims is, however, not relevant for the current decision and is therefore not reproduced here.

VI. The following documents from the impugned decision are relevant to this decision:

D1: WO 2017/190718 A1
D24: WO 2016/020061 A2

VII. The arguments of the appellant-proprietor may be summarised as follows.

Main request - novelty

The subject-matter of claim 1 was novel over, *inter alia,* D1. The transient pulsatile nature of the blood pump according to the method disclosed in D1 did not prevent the release of air bubbles; rather, it only separated, released or dislodged as many trapped residual bubbles as possible. Dislodged air bubbles were transported by the normal flow rate of the blood pump, i.e. not by the pulsatile pressure variation, to the oxygenator where they were removed by the

oxygenator.

First auxiliary request

When the claim was interpreted in the light of the description (see in particular paragraphs 11, 12 and 13 of the patent specification), as required by G 1/24, the added feature could not be reduced to mean "*move bubbles... due to the presence of the membrane gas exchanger*". The description referred to prior-art systems in which air was removed or vented from an oxygenator or blood lines by dislodging and transporting bubbles in the blood circuit to the oxygenator for their removal. In light of the objects of the invention disclosed in the description (see paragraphs 12 and 13), the added feature clarified that the effect of the transient pressurisation step was, however, to prevent the formation of new bubbles at the membrane gas exchanger itself, i.e. bubble formation due to the presence of the membrane gas exchanger. This implied that the transient pressure increase was such that the gas permeability properties of the membrane were temporarily altered such that no bubbles could form on the membrane. This effect was further supported by the experimental data presented in the patent.

D1 used the oxygenator to remove air bubbles. Thus, the corresponding membrane had to remain permeable to allow the air bubbles to be removed. The purpose of the pulsatile mode in D1 was to release and convey residual air to the oxygenator for evacuation. In a pulsatile mode, pressure increases were followed by phases in which the pressure decreased. A temporary small pressure increase occurring when a blood pump like in D1 was accelerated was not sufficient to produce the claimed effect (prevention of bubble formation caused

by the membrane gas exchanger). The fact that claim 1 did not exclude loosening air bubbles by the transitory pressurisation step before their removal or removal of the bubbles by the oxygenator did not establish lack of novelty of the first auxiliary request since the amended claim defined a positive requirement that the apparatus be configured to achieve the claimed effect. It could also not be seen to be implicitly (inherently) disclosed in D1 since an inherent feature could only be considered disclosed if it was the inevitable result of carrying out the teaching. This was not the case since D1 required the oxygenator to be maintained as the venting path, thus the membrane had to remain gas permeable.

Second and third auxiliary requests - novelty

The added features according to the second auxiliary request gave technical substance to the feature "*prevention of bubble formation*" discussed throughout the description and identified the physical mechanism by which the invention achieved what the prior art did not. The claimed pressurisation step thus had to produce a membrane-level effect, rather than merely generating a temporary pressure increase while bubbles were being transported or vented.

D1 did not directly and unambiguously disclose that the membrane was affected by the transitory pressurisation step. D1 did not disclose the magnitude, duration or pressure profile of the pressure increase at the membrane which was necessary to force priming fluid into hydrophobic membrane pores to reduce gas transfer. Nor did it disclose the membrane properties, pore geometry, capillary entry pressure, gas-side pressure conditions or any other parameter from which the

claimed effects could be inevitably derived. A mere pressure variation occurring in D1 was insufficient to conclude on the claimed effects. Membrane gas exchangers were designed so that their hydrophobic membranes allowed gas transfer while resisting liquid penetration. It could not be assumed that every pulsatile operation of a pump during priming necessarily caused priming fluid to enter the membrane pores in a manner leading to a reduction of gas transfer. Notably, D1 did not disclose that after the pulsatile operation had ceased or between pressure peaks, the membrane gas exchanger was conditioned to prevent further bubble formation caused by gas passage from the gas side to the blood side. D1 relied on the oxygenator remaining able to vent gas. If the pressure variations in D1 were inherently sufficient to force priming fluid into the hydrophobic pores and reduce gas transfer in the claimed sense, this would run counter to that function. While D1 disclosed loosening and conveying residual air bubbles to the oxygenator, it did not disclose the removal of micro air bubbles accumulated at a wall of the membrane through the membrane before aggregation into macro bubbles. A mere possibility or a general assumption that some pressure increase according to the method of D1 might produce some degree of pore wetting or some reduction of gas transfer was insufficient to establish an implicit disclosure of the claimed effect. For a feature to be implicitly disclosed, it had to be the inevitable consequence of what was directly and unambiguously disclosed in the prior art.

Arguments similar to those made regarding the second auxiliary request also applied to the third auxiliary request.

Fourth auxiliary request - inventive step

The distinguishing feature defined a specific spatial and functional arrangement in which a restriction or occlusion was located downstream of the membrane gas exchanger with respect to the flow direction of the priming fluid. Consequently, the priming fluid displaced by the pump accumulated upstream of the restriction. A local pressure build-up was produced specifically on the blood side of the membrane gas exchanger and not merely as a global flow pulsation distributed along the extracorporeal circuit (see paragraphs 42 and 43 of the patent specification). The pressure build-up achieved by the operation of the blood pump in the pulsatile method according to D1 only served to dislodge and move air bubbles, without there being any intention to use this pressure build-up precisely on the blood side of the oxygenator's membrane.

Moreover, the downstream restriction according to the distinguishing feature of amended claim 1 did not merely represent an arbitrary alternative to generating pressure variations by varying the operation of a pump. Instead and according to the description of the opposed patent, the pressure input was converted into the relevant pressure build-up by closing or restricting the downstream portion of the circuit. Modification of the operation of any pump (i.e. the blood pump, the infusion pump or the air pump, see paragraphs 42 to 47 of the specification) was never used in isolation but constituted the common technical measure used in all embodiments for localising the pressurisation on the blood side of the membrane gas exchanger.

The objective technical problem was thus "*how to*

generate, during priming and using existing circuit components, a localised pressure build-up, i.e. acting locally at the blood side of the membrane gas exchanger, rather than merely a global flow pulsation in the extracorporeal circuit".

Neither D1 itself nor D24 led the skilled person to the claimed restriction or occlusion of the blood circuit downstream of the oxygenator's membrane.

D1 contained no teaching of restricting or occluding the circuit downstream of the oxygenator to build up pressure on the blood side.

D24, dealing with a dialysis machine and concerned with washing out bubbles which adhered to the inner surfaces of the tubing and components from target regions of the blood circuit, would not be considered by the skilled person faced with a problem in a heart-lung machine or oxygenator. D24 did not deal with conditioning the membrane of a membrane gas exchanger and contained no detail on how such a method could be implemented in D1.

D24 taught that the preferred embodiment was to release bubbles by using speed variations of the blood pump. D1 already implemented this preferred solution. Priming a heart-lung machine including a centrifugal pump taught against the use of a clamp located downstream of the blood pump since this could create backflow in the pump which might damage it. D24 at most disclosed a list of generic actuators for producing flow or pressure variations in a rinsing method which did not constitute a teaching to create a pressure build-up on the blood side of a membrane gas exchanger by restricting the circuit downstream of that gas exchanger. In D24, both the pump variation and the

clamp actuation served the same purpose of dislodging bubbles from the tubing surfaces, whereas the distinguishing feature of claim 1 used the downstream restriction to pressurise a specific component that D24 did not even contain. Even the mention of a venous clamp in D24 did not point to the claimed solution since venous clamps were conventional circuit components used in D24 for washing bubbles out of the circuit, without any connection to, or prompt for, creating a downstream restriction that produced a pressure build-up or back pressure on the blood side of gas exchanger's membrane to act upon that membrane. Moreover, the clamp position was technically not relevant in D24 since other positions were also mentioned. D24 thus provides no reason to position the clamp by reference to a membrane gas exchanger and does not recognise the effect of doing so.

Fifth to twelfth auxiliary requests - remittal

Since the subject-matter of these auxiliary requests had not been discussed before the opposition division, the case should be remitted to the opposition division. The amendments in these requests were directed to technical features which had not been addressed before. Continuation of the appeal proceedings would mean that the Board would have to perform a substantial first-instance examination.

Fifth to seventh auxiliary requests - inventive step

The arguments submitted with regard to novelty and inventive step in respect of the first, second and third auxiliary requests and with respect to the fourth auxiliary request applied to the respective fifth to

seventh auxiliary requests.

Eighth auxiliary request - inventive step

The added feature prevented that if the gas exchanger was left open to the atmosphere after completed priming and the circuit was not used immediately, air could enter the blood circuit once the temporary pressurisation effects had ceased. None of the prior-art documents on file disclosed closing the blood circuit after priming and maintaining an overpressure inside it.

Ninth auxiliary request - inventive step

The added features of amended claim 1 defined a specific operational state in which a particular pressure range is tied to a temporal and structural configuration of the priming circuit, i.e. after priming is complete and before the patient is connected, when the pump is stopped and the downstream return clamp or valve is kept closed. While the transitory pressurisation steps generated during priming were intended to prevent the release of air bubbles at the blood outlet of the membrane gas exchanger, these steps were, by their nature, temporary. Once priming had been completed, and once the transitory pressurisation steps had ceased, the membrane gas exchanger could again become a source of air intake if the blood side was not kept at a pressure above the gas side, notably between completion of priming and patient connection. The technical effect was thus that, after completion of priming and before patient connection, the blood side of the membrane gas exchanger was kept under positive pressure in a closed circuit condition, thereby preventing the

reintroduction of air through the membrane during the waiting period before the patient is connected.

The objective technical problem solved by claim 1 of the ninth auxiliary request was:

"*how to provide an extracorporeal blood circuit comprising a membrane gas exchanger that is reliably ready for safe patient connection following an interval after completion of the priming*"

According to the patent, a number of different solutions existed, for example, keeping the oxygenator at the lowest level in the circuit.

An objection of lack of inventive step required a pointer in the prior art towards the claimed measure; here there was none. Since the problem was not recognised in any prior art document, no solution to it could be obvious. The claimed end-of-priming condition was not rendered obvious by any of the prior art on file. Neither D1 nor D24 addressed the objective technical problem. The teaching of D1 gave the skilled person no reason to address this problem, let alone to incorporate a further operational state, since D1 did not indicate that, after completion of priming, the membrane gas exchanger itself could again allow air intake if the blood side was not maintained under positive pressure. D1 did not even disclose where the needles were arranged. D24 taught pressure or flow variations during rinsing to wash out bubbles but not how to preserve a primed membrane gas exchanger after priming.

The considerations by the appellant-opponent on what the skilled person would have done after priming were

based on hindsight.

Tenth to twelfth auxiliary requests - inventive step

Arguments with regard to novelty and inventive step already brought forward with respect to the first, second and third auxiliary requests and with respect to the ninth auxiliary request applied to the respective tenth to twelfth auxiliary requests.

VIII. The arguments of the appellant-opponent may be summarised as follows.

Main request - novelty

The conclusion reached by the opposition division on lack of novelty of granted claim 1 over D1 should be upheld. The pulsatile operation of the priming pump or blood pump used in D1 had the same effect as defined by feature 2.1. Air bubbles were evacuated by the oxygenator. Consequently, they were no longer present at the oxygenator's outlet and were therefore not released from it.

First auxiliary request - novelty

The reasoning given by the opposition division, considering also the added feature to be inherently obtained by the pressure increases according to D1, should be endorsed. The transient pressurisation step was not further defined and was thus arbitrary. Such a transient pressurisation could not achieve any effect which would not also be achieved by an arbitrary pressurisation increase disclosed in the prior art.

Second and third auxiliary requests - novelty

The reasoning given in the impugned decision should be accepted. Moreover, amended claim 1 did not require the entire membrane, i.e. all its pores, to be filled with priming liquid, either entirely or partly. Wetting of the membrane's blood side with priming liquid was not incompatible with the claimed method. Amended claim 1 did also not define features leading to a modification of membrane properties. Since the purpose of the priming method according to D1 was to remove all air bubbles via the oxygenator by pulsatile pressure increases, both air bubbles and priming liquid had to be forced into the membrane. As an inevitable consequence of the removal of all air bubbles, including micro air bubbles, such micro air bubbles could no longer aggregate to form macro bubbles on the blood side of the oxygenator membrane.

The reasoning in the impugned decision for the third auxiliary request should be endorsed.

Fourth auxiliary request

The objective technical problem solved by the feature added to amended claim 1 was to provide an alternative way of generating a pressurisation step. The patent itself disclosed several alternative ways without indicating any particular advantage for any of them. Although D24 related to methods for priming a dialysis machine, it was mentioned that these methods could also be used for priming heart-lung machines (see page 3). The skilled person would consider, without any prompt, priming any filter in such machines that comprised a membrane, including an oxygenator, in the manner disclosed in D24. Faced with the question of which

clamps referred to in D24 to use for occluding or restricting the blood circuit, the skilled person would have had no difficulty selecting from among the clamps already present in the blood circuit and which allowed pressurisation at the membrane. In view of the purpose of using a clamp to create pressure pulses in the blood circuit to be primed, it appears questionable that the skilled person would have considered an arterial clamp helpful. However, since during priming the blood circuit in D1 is operated in a closed loop, every clamp in this circuit could equally be seen as being upstream or downstream of the membrane to be primed, so that the question concerning the selection of an arterial or venous clamp would not have presented the skilled person with any particular difficulty. Moreover, if several equivalent alternative solutions were known, none of these could be inventive (see T 357/02).

Fifth to twelfth auxiliary requests - remittal

A remittal of the case for consideration of these auxiliary requests would be inefficient. Moreover, their discussion would not involve any new technical considerations.

Fifth to seventh auxiliary requests - inventive step

Since none of first, second, third and fourth auxiliary requests was allowable, the same applied to the resulting combinations in which the features added according to the first, second and third auxiliary requests were combined with those added in the fourth auxiliary request.

Eighth auxiliary request - inventive step

The added feature did not contribute to an inventive step. During priming, the pressure on the membrane's blood side had to be higher than on its gas side, something commonly achieved by positioning a priming liquid container sufficiently high above the gas exchanger. A height difference of approximately 27 cm resulted in a pressure difference of approximately 20 mm Hg. The lower limit of the claimed range was thus a common value used during such priming procedures. The upper limit was rather arbitrary and had no link to any technical advantage.

Ninth auxiliary request

The added features 5 and 4'-4''' defined two unrelated aspects which could not involve inventive activity. Feature 5 defined a necessary condition for the transitory pressurisation step to be started. Priming fluid necessarily had to fill the blood side of the oxygenator's membrane for pressure to build up. Feature 4' only defined a temporary relationship without constituting any technical feature itself. Feature 4'' defined the common practice of connecting a patient to a primed extracorporeal blood circuit. Feature 4''' defined a broad pressure range which encompassed pressure values commonly applied for maintaining an overpressure to avoid air entry through the membrane once priming was complete. The skilled person who had completed the priming method according to D1 was commonly faced with the task of connecting the primed circuit to the patient. Care would have to be taken not to lose the primed state and not to reintroduce air. The skilled person was aware that if, after priming, pressure in the extracorporeal blood circuit, i.e. on the blood side of the oxygenator, was just reduced, the risk of new air intake through the membrane increased.

So the skilled person would have to, in any case, maintain a higher pressure on the blood side of the oxygenator's membrane after priming, otherwise priming would have been meaningless. If pressure had to be maintained in the extracorporeal blood circuit, the venous clamp downstream of the oxygenator had to be kept closed after priming. The broad pressure interval according to feature 4''' covered the entire practical range. The lower and upper pressure limits were rather arbitrary, with no link to any technical advantage. For example, the lower limit corresponded to a common height (approximately 27 cm) for arranging a priming liquid container relative to an oxygenator.

Tenth to twelfth auxiliary requests - inventive step

Since none of the first, second, third and ninth auxiliary requests was allowable, the same applied also to the resulting combinations in which the features incorporated according to the first, second and third auxiliary requests were combined with those added in the ninth auxiliary request.

Reasons for the Decision

Technical background

1. The invention defined in granted claim 1 of the opposed patent relates to a method for priming an extracorporeal blood circuit. Before connecting a patient to the extracorporeal blood circuit to perform the extracorporeal blood treatment, the extracorporeal blood circuit must be primed to remove all air and possible fragments of remaining sterilising agents or

other residuals from the disposable elements from all the components constituting the blood circuit, including the treatment units, tubing, valves, connectors, etc. For this purpose, the extracorporeal blood circuit is filled with a priming solution, e.g. saline. The claimed invention is directed to the removal of air in an extracorporeal blood circuit which comprises a membrane gas exchanger having a gas-permeable membrane. A membrane gas exchanger may be used for the purpose of oxygenation or CO2 removal of the patient blood (see also paragraphs 1 and 2 of the patent). Due to their membrane properties, membrane gas exchangers require specific precautions during and after priming to prevent air intake through the membrane and the formation of bubbles during the following blood treatment.

Main request - novelty

2. The Board confirms the conclusion reached by the opposition division that the ground for opposition pursuant to Articles 100(a) and 54 EPC prejudices maintenance of the patent. The subject-matter of claim 1 of the opposed patent indeed lacks novelty in view of D1. The arguments submitted by the appellant-proprietor could not convince the Board to the contrary for the reasons given below.

2.1 As stated in point 2.1 of the impugned decision, D1 discloses (for example, in Figure 1) a system and a method for priming an extracorporeal blood circuit 6, (see also paragraphs 1 and 7). A blood pump 5 and an oxygenator 4, corresponding to a membrane gas exchanger according to claim 1 of the opposed patent, are provided in the extracorporeal blood circuit. To prime the circuit, a priming liquid is fed into the circuit

and into the blood side of the oxygenator (paragraphs 42 to 46). When the oxygenator is filled with priming liquid, the blood pump is started and driven in a pulsatile mode (paragraph 47). A transitory pressurisation step is thus generated in the blood circuit and in the oxygenator (see also paragraph 10). According to paragraph 10, the transitory pressurisation step dislodges air bubbles from the tubing and the oxygenator. According to paragraph 47, the air is removed from the oxygenator while the blood pump is driven in the pulsatile mode.

2.2 The appellant-proprietor contested the disclosure of feature 2.1 of granted claim 1 in D1, i.e. that generating the transitory pressurisation step in the priming fluid flowing in the blood circuit and on the blood side of the membrane gas exchanger (oxygenator 4), by means of operating the blood pump in the pulsatile mode, was effected to prevent the release of air bubbles at a blood outlet of the membrane gas exchanger.

2.3 In its notification pursuant to Article 15(1) RPBA, the Board stated the following in regard to the appellant-proprietor's arguments presented in writing so far (see also point VII. above):

"*1.2.1 These arguments correspond essentially to those already presented by the appellant-proprietor before the opposition division and considered in section 2.1 on page 7 of the impugned decision. The Board cannot see that the appellant-proprietor brought up any consideration which convincingly refutes the reasoning of the opposition division in the two paragraphs on page 7, following the statement "[t]he Opposition Division cannot agree with this reasoning".*

The Board notably concurs with the opposition division that feature 2.1 of granted claim 1 should be interpreted broader than what is implied by the appellant-proprietor's arguments. The feature indeed only requires the transitory pressurisation step to prevent release of air bubbles at the blood outlet of the membrane gas exchanger. Neither the individual feature 2.1, nor the combinations of all features of independent claim 1 exclude that the transitory pressurisation step loosens air bubbles before they are removed or that the bubbles are removed by the oxygenator, as also argued by the appellant-opponent on page 9 of its reply to the appeal grounds of the appellant-proprietor.

1.2.2 Moreover, the appellant-proprietor's statement that air bubbles are moved to the oxygenator by the normal pump flow rate appears to be contradicted by the final sentence of paragraph 47 of D1.

1.2.3 The Board is thus of the opinion that feature 2.1 is also disclosed in D1."

2.4 In its subsequent written submission and in the oral proceedings, the appellant-proprietor did not present any further arguments in regard to the main request and confirmed that it relied only on its previous written submissions. Consequently, the Board had no reason to deviate from its provisional opinion, which is therefore confirmed.

It has not been argued that any other non-optional feature of granted claim 1 lacked disclosure in D1, and the Board also does not see this to be the case. The Board concludes that the subject-matter of granted claim 1 is not novel over D1 (Article 54 (1) and (2)

EPC).

2.5 The request of the appellant-proprietor that the patent be maintained as granted could therefore not be allowed.

First auxiliary request - novelty

3. The amendment made in amended claim 1 according to the first auxiliary request does not change the Board's conclusion on lack of novelty over D1 reached for granted claim 1 (Article 54(1) and (2) EPC).

3.1 The following feature has been added to the end of granted claim 1:

> "*whereby the apparatus for extracorporeal treatment of blood is configured to prevent formation of bubbles in the extracorporeal blood circuit due to the presence of the membrane gas exchanger*".

3.2 Based on the principles arising from G 1/24 on claim interpretation, the Board cannot see that the claim's wording should be interpreted as having any meaning other than its literal meaning. The effects sought by the invention of the patent as expressed in paragraphs 12 and 13 of the specification are essentially defined by feature 2.1 and the feature added in claim 1 of the first auxiliary request.

As further noted by the appellant-opponent (and by the opposition division in point 6.2 of the impugned decision), the claim does not define any specific conditions for the transitory pressurisation step, let alone an interval during which formation of bubbles should be prevented. Indeed, the experimental data

disclosed in the patent and referred to also by the appellant-proprietor also show that new bubbles form after some time. The fact that such bubble-free intervals may under certain conditions last relatively long, even under low mean pressure levels on the blood side, is not reflected by any structural or functional feature in amended claim 1 of the first auxiliary request.

3.3 The Board agrees with the reasoning given by the opposition division in point 6.2 of the impugned decision that the added feature is considered to be disclosed in D1.

3.4 The arguments presented by the appellant-proprietor could not convince the Board to overturn the decision on this aspect for the following reasons.

3.4.1 As acknowledged by the appellant-proprietor, the priming method according to D1 relies on the oxygenator, embodying a membrane gas exchanger, to evacuate air from the priming fluid in the extracorporeal blood circuit when the blood pump is operated in the pulsatile mode. This is disclosed in paragraph 47 of D1. However, the conclusion of the appellant-proprietor that due to the passage of air through the oxygenator's membrane being allowed during this step of the method, the formation of new air bubbles in the oxygenator could not be prevented cannot be accepted by the Board. The technical effect of a pressure increase during the pulsatile mode, compared to the normal pressure during normal circulation in the blood circuit of D1, is inevitably an increase of the pressure on the blood side of the oxygenator's membrane, forcing liquid to block its pores and temporarily altering the permeability properties of the

membrane, at least to a certain extent, thereby leading to a reduction of gas transfer from the gas side to the blood side. Since air is undisputedly evacuated through the oxygenator's membrane according to D1 (see above), the pressure differential across the membrane must necessarily be such that air flows from its blood side to the gas side. Otherwise, air could not be evacuated by the oxygenator. Therefore, air cannot flow against this pressure differential to form new bubbles on the blood side of the oxygenator's membrane.

3.4.2 The fact that the description of the patent (paragraphs 10 and 11), that has to be consulted to interpret the claim (G 1/24, headnote), states that effect of the added feature would not be achieved in D1 does not lead to a different interpretation of the claim but is merely a matter of assessment of the disclosure of D1. This assessment is however to be performed by the competent body of the EPO on the basis of the disclosure of the relevant item of the prior art.

3.4.3 Hence, contrary to the appellant-proprietor's contention concerning the assessment of the disclosure of D1 given in the patent in suit (paragraphs 10 and 11) the release of air bubbles at the membrane's blood outlet is prevented, as also stated by the opposition division (see section 6.2 of the impugned decision).

3.4.4 The apparatus of D1 is thus "*configured*" to prevent, at least during these steps of pulsatile pump operation, formation of bubbles in the extracorporeal blood circuit due to the presence of the membrane gas exchanger (oxygenator). The technical effect according to the added feature of amended claim 1 is thus a necessary and inevitable consequence of the pressure increase during the pulsatile operation of the blood

pump. The skilled person would realise this fact on the basis of their common general knowledge. Hence, the added feature is directly and unambiguously disclosed to the person skilled in the art.

3.5 The request of the appellant-proprietor that the patent be maintained in amended form according to the first auxiliary request could therefore not be allowed.

Second and third auxiliary requests - novelty

4. The amendments made to claim 1 of the second and third auxiliary requests also do not change the conclusion on lack of novelty over D1 reached for the higher-ranking requests (Article 54(1) and (2) EPC).

4.1 In claim 1 of the second auxiliary request, the following features have been inserted before the feature added in claim 1 of the first auxiliary request :

> "*wherein the transitory pressurization step results:*
> *o in the forcing of some priming fluid into hydrophobic pores of a membrane of the membrane gas exchanger (18) leading to a reduction of gas transfer, and*
> *o in a removal of micro-air bubbles, accumulated at a wall of the membrane, through the membrane and before their aggregation into macro-bubbles*"

4.2 As stated in the Board's provisional opinion, the additional features added in the second auxiliary request do not give rise to a structural or functional limitation for the claimed method over the method disclosed in D1.

As also noted by the appellant-opponent, the claim does not define any particular gas exchanger membrane properties or any particular pressure conditions. Membrane properties, let alone necessarily modified membrane properties, are not disclosed as such in the patent specification either.

The Board therefore considers that the skilled person, having consulted the entire patent specification (G 1/24), would not read into the wording of claim 1 any limiting structural or functional technical feature beyond what is literally defined.

The Board further concurs with the appellant-opponent that amended claim 1 does not define to what extent priming fluid would be forced into the membrane pores. As noted above, the patent specification does not give any details in this context. Furthermore, the skilled person would understand from the patent specification that gas transfer from the gas side to the blood side must be reduced, by some undefined amount, whereas no information can be found in the patent specification that gas transfer from the blood side to the gas side should also be reduced. Such an assumption would oppose the requirement in feature 2.1 of claim 1 according to which air bubbles were prevented from being released at the blood outlet of the membrane gas exchanger, meaning that if bubbles were present on the membrane, they would have to be evacuated through the membrane

4.3 Despite D1 indeed being silent on the effect of the transitory pressurisation step at the membrane, the Board cannot see any technical reason why the corresponding intermittent pressurisation step ("*speed increase of the blood pump*") in D1 would not

necessarily and inevitably lead to the claimed effects, as also convincingly explained by the opposition division in the first and second full paragraphs on page 16 of the impugned decision. Thus, also in this case the skilled person would realise on the basis of their common general knowledge that the process of D1 achieves the claimed effects. The added features is therefore directly and unambiguously disclosed by D1.

4.3.1 The appellant-proprietor's arguments concerning the lack of an implicit disclosure of the additional features by the known method of D1 are also not persuasive.

While the appellant-proprietor is correct that an implicit disclosure requires that the respective features arise as the inevitable consequence of what is disclosed in the prior art, the Board is satisfied that this condition is met in the current case.

It is the very purpose of a priming method, including the one disclosed in D1 (see paragraphs 4 and 6), to remove all air, generally present in the form of bubbles of varying size, including micro bubbles, from an extracorporeal blood circuit, as pointed out by the appellant-opponent. It is common ground that the oxygenator is used in the priming method of D1 to vent the air in the blood circuit (paragraph 47). No other way of evacuating air from the blood circuit is described in D1. It is furthermore undisputed that D1 does not explicitly disclose any detail of the membrane or the operating conditions during priming. Nevertheless, as the only way to vent air bubbles is through the oxygenator's membrane and since the priming liquid will necessarily be in contact with the membrane after the circuit has been filled with the priming

liquid (see paragraph 46 of D1), even before the pulsatile mode is initiated, a pressure increase must inevitably force some of the priming liquid, at least to some extent, into the pores of the membrane's blood side. Under this condition, the gas transfer at least in the direction from the membrane's air side to its blood side is necessarily reduced, otherwise air could not be meaningfully vented through the oxygenator in the other direction, i.e. from the blood side to the air side. The appellant-proprietor, when asked by the Board during the oral proceedings, could not explain why, as a consequence of a pressure increase for the mentioned purpose, priming fluid would not be forced into the membrane pores at least to a certain extent or why gas transfer would not be reduced. The Board therefore considers these effects to be inevitable consequences arising when the method according to D1 is carried out, rather than merely hypothetical assumptions.

As a further inevitable consequence, the Board considers that since all bubbles have to be vented through the oxygenator's membrane according D1, it is excluded that micro bubbles aggregate on the membrane to form macro bubbles.

4.3.2 Hence, the skilled person would directly and unambiguously recognise, on the basis of their common general knowledge that the added features are present in the process of D1.

4.4 Since the amended claims of the third auxiliary request are only distinguished from those of the second auxiliary request in that the final feature is deleted (i.e. the feature previously added to claim 1 in the first auxiliary request), the conclusion on novelty

cannot differ from that for the second auxiliary request, as stated by the Board in its provisional opinion. This has not been contested by the appellant-proprietor, so the provisional opinion can only be confirmed.

4.5 The request of the appellant-proprietor that the patent be maintained in amended form according to the second or third auxiliary request could therefore not be allowed.

Fourth auxiliary request - inventive step

5. Claim 1 of the fourth auxiliary request, which was found to meet the requirements of the EPC by the opposition division, does not involve an inventive step (Article 56 EPC) when starting from the method known from D1 in combination with the teaching of D24.

5.1 Claim 1 is based on granted claim 1, with the following feature added to it:

"*wherein generating the transitory pressurization step comprises:*
restricting or occluding transiently a portion of the extracorporeal blood circuit placed downstream of the membrane gas exchanger (18) with respect to a flow direction of the priming fluid"

5.2 It was common ground that the added feature was not disclosed in D1.

5.3 The technical effect achieved by the distinguishing feature has to be determined to establish an objective technical problem solved by the subject-matter of amended claim 1 over D1.

5.3.1 The problem considered by the appellant-proprietor, i.e. "*how to generate, during priming and using existing circuit components, a localised pressure build-up at the blood side of the membrane gas exchanger, i.e. acting locally on the blood side of the membrane, rather than merely a global flow pulsation in the extracorporeal circuit*", is not an objective problem.

This problem introduces limiting requirements not based on the established distinguishing feature. There is nothing in amended claim 1 which allowed limiting the considerations by the skilled person to use only existing circuit components.

Contrary to the view of the appellant-proprietor, the Board cannot find the problem in the patent specification. Paragraph 42, referred to by the appellant-proprietor, discloses a pressurisation step "*in the priming fluid and in the blood side of the membrane gas exchanger*" and describes the hypothetical mechanisms possibly ("*may result*") preventing the release of air bubbles at the gas exchanger's outlet. Paragraph 43 gives an example of generating the transitory pressurisation step by intermittently closing a return clamp, which is located at the downstream end of the blood line.

The Board accepts that D1 does not explicitly disclose a pressure build-up to be required on the blood side of the oxygenator's membrane. However, the generation of the transitory pressurisation step according to the method of D1 is achieved by the pulsatile operation of the blood pump arranged upstream of the oxygenator. The pressure pulses created by the blood pump according to D1 inevitably lead to a pressure build-up on the blood

side of the oxygenator's membrane. As a consequence, no difference in view of a technical effect attributed to the position where the pressure build-up occurs can be identified between the added feature of amended claim 1 and the method according to D1.

5.3.2 Rather, as stated in the Board's provisional opinion, the patent itself does not disclose any advantage of that particular mode of generating transitory pressurisation steps. Compared to the method disclosed in D1, no further technical effect is achieved by the claimed method. Instead, it constitutes one of several alternative ways of generating transitory pressurisation steps (see also granted claims 5 to 8).

5.3.3 For these reasons, the Board rejects the technical problem formulated by the appellant-proprietor.

5.3.4 An objective technical problem can therefore be seen in providing an alternative way of generating transitory pressurisation steps in the method of D1.

5.4 Faced with this objective technical problem, the skilled person would turn to D24.

5.4.1 The method disclosed in D24 relates to priming or flushing extracorporeal blood circuits comprising a dialyser. D24 also mentions the applicability of the disclosed method to other extracorporeal blood treatment systems, including heart-lung machines (see, for example, page 3 or 9), without, however, giving any further detail of such an application.

Pressure pulses are created in the method known from D24 by temporarily increasing the pressure or the flow rate of the priming liquid in the blood circuit (see

the paragraphs bridging pages 2 and 3). The purpose of the generated pressure pulses is to reduce the amount of air bubbles in the extracorporeal blood circuit, thereby reducing the risk of infusing air bubbles into the patient.

D24 explicitly mentions in the passage beginning in the last paragraph on page 3 up the last paragraph of page 4 that pressure variations may be generated by either changing the speed of the blood pump or by actuating a clamp, for example the venous clamp, the arterial clamp, or a clamp at the inlet or outlet of the flushing liquid, as noted by the opposition division on page 22 of the impugned decision (see also the first two paragraphs on page 20, D24)

Dislodged air bubbles are then removed with the flushing or priming liquid through a discharge port downstream of the dialyser's blood outlet (see D24, page 11, second to fourth paragraphs).

As mentioned above, the method of D24 uses transitory pressurisation steps for dislodging air bubbles in extracorporeal blood circuits for the same purpose as intended, for example, in D1 (see also the third paragraph on page 32 of the statement of grounds of appeal of the appellant-opponent).

5.4.2 The skilled person is thus presented in D24 with alternative ways of creating transitory pressurisation steps. A first way corresponds to the method also used in D1, i.e. by modulating the operation of the blood pump. As an equivalent alternative way of generating the pressure variations, D24 indicates actuating a clamp in the blood circuit, such as a venous clamp, an arterial clamp or another clamp located in the

extracorporeal circuit that can affect the pressure of the priming liquid.

The skilled person, moreover, is prompted by D24 to consider applying its teaching to other extracorporeal blood treatment systems, including heart-lung machines, which commonly include oxygenators.

The skilled person would therefore have applied, without inventive skill, any of these alternative solutions of D24 to the method known from D1, directed to the priming of an extracorporeal blood circuit comprising an oxygenator. According to the schematic figures of D1, the extracorporeal blood circuits are illustrated in a closed loop configuration. They do not show any clamp, as argued by the appellant-proprietor. The Board, however, considers that such clamps are commonly used components in an extracorporeal blood circuit. They are required to securely open and close the circuit when, after priming, it has to be connected to the patient for the subsequent blood treatment. The skilled person therefore would have considered the use of corresponding clamps at the appropriate locations also in the extracorporeal blood circuit disclosed in D1. Based on the indications in D24, the skilled person would therefore have had no difficulty applying to the method of D1 any of the alternative ways of generating pressurisation steps by actuating a clamp.

Since all options suggested by D24 are considered to represent obvious solutions to the objective technical problem, the selection of one of these, namely the generation of pressurisation steps by actuating a venous clamp, which would be necessarily located downstream of the blood treatment unit (in D1, the oxygenator, in D24, the dialyser; see also the

penultimate paragraph of page 3 of D24) cannot involve an inventive step either (see also I.D.9.21.9(b) of the "*Case Law of the Boards of Appeal of the European Patent Office*", 11th edn., 2026 revision).

5.5 The arguments of the appellant-proprietor that the combination of D1 and D24 would not have been obvious for the skilled person could not convince the Board.

5.5.1 To the extent that the appellant-proprietor relied, notably in its written submissions, on the contention that dialysers and heart-lung machines or oxygenators relate to different technical or medical fields, such that the skilled person would not consider teachings from the field of dialysis to be applicable to heart-lung machines or oxygenators (see, for example, last paragraph on page 35 of the reply), the Board is not convinced by that argument. As stated in its provisional opinion, the Board considers that the skilled person in the field of extracorporeal blood treatment has common general knowledge on methods of operation, including priming, and apparatus for all types of possible blood treatments, including dialysis as well as oxygenators and heart-lung machines, despite the complexity which might be involved with the latter group of machines (see page 30 of the reply of the appellant-proprietor). These considerations were not contested by the appellant-proprietor.

5.5.2 The further arguments submitted by the appellant-proprietor rely to a great extent on the assumption of a further technical effect and a different technical problem. The technical effect was attributed to the fact that the transient occlusion or restriction had to occur downstream from the membrane gas exchanger according to amended claim 1. However, as explained

above, the Board does not accept such an effect to be achieved compared to the effects inevitably already achieved in D1. Also in D1, the pressure increase is necessarily also present on the membrane's blood side. The claimed method does not define any feature which excluded that the pressure increase is "*merely a global flow pulsation in the extracorporeal circuit*".

It follows that all arguments of the appellant-proprietor based on an alleged localised pressure increase or a specific transitory modification of membrane properties are not relevant for the assessment of inventive step based on the objective technical problem formulated in point 5.3.4 above.

5.5.3 The argument that D1 already employed the preferred method of generating transitory pressurisation steps taught in D24, i.e. by modulating the operation of the blood pump, is irrelevant in view of the objective technical problem the skilled person is asked to solve. By disclosing different alternatives, D24 shows that even where one method is preferred, alternative methods may still be considered.

5.5.4 Concerning the appellant-proprietor's contention directed to an alleged risk of damage incurred when priming a heart-lung machine including a centrifugal pump by a clamp arranged downstream of a membrane gas exchanger, the Board finds this argument to be based on speculation. The method of D1, which constitutes the starting point for the objective technical problem to be solved, does not disclose the type of pump to be used in the blood circuit. D1 only suggests using a roller pump or a centrifugal pump for the priming circuit (see paragraphs 14 and 15). D24 refers to pumps in general and makes only a cursory reference to

peristaltic pumps (page 9) and schematically illustrates a roller pump in its only figure. The skilled person is aware of the advantages and technical challenges linked to the different pump types. Considerations involved in adopting the method used in D1 to the teaching of D24, in view of the pumps and the methods to control their operation, do not exceed the common practice of the skilled person.

5.6 The request of the appellant-proprietor that the patent be maintained in amended form according to the fourth auxiliary request was consequently not allowed.

Fifth to twelfth auxiliary requests - remittal

6. The Board decided to reject the request of the appellant-proprietor, submitted for the first time at the oral proceedings, that the case be remitted to the opposition division (Article 111(1) EPC).

6.1 Whether or not to remit the case according to Article 111(1) EPC is a discretionary decision of the Board. In accordance with Article 11 RPBA, the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. In line with the explanatory remarks on Article 11 RPBA (Supplementary publication 2, OJ 2020), the aim of this provision is to reduce the likelihood of a ping-pong effect between the boards and the departments of first instance and a consequent undue prolongation of the proceedings before the EPO. If all issues can be decided without an undue burden, a Board should normally not remit the case.

6.2 The appellant-proprietor submitted that the subject-matter of the corresponding amended claim 1 involved new technical features which had not been considered before and would have required a substantial first-instance examination by the Board. The Board, however, considered that the issue of inventive step starting from D1 had already been considered for the higher ranking requests. Moreover, at least in as far as the objections under Article 56 EPC against these requests are based only on documents D1, D24 and common general knowledge, no substantial further fact finding or complex considerations were likely to arise. The written arguments submitted by the parties before the oral proceedings indicated that the questions and considerations likely to arise during the oral proceedings to reach a decision on these requests, at least in as far as the objections were based only on D1, D24 and common general knowledge, could be expected to be dealt with appropriately by the parties and the Board. In the communication under Article 15(1) RPBA the Board took into account the parties submissions on the fifth to twelfth auxiliary requests to reach a preliminary opinion on said requests. Indeed the appellant-proprietor requested to remit the case for further prosecution at the latest possible stage of the proceedings, at the oral proceedings. Under these circumstances, the Board decided to reject the request for remittal.

Fifth to seventh auxiliary requests - inventive step

7. The amendments to the independent method claim of the fifth to seventh auxiliary requests cannot overcome the outstanding objection under Article 56 EPC which is considered prejudicial to the maintenance of the patent in the amended form according to the fourth auxiliary

request (see point 5. and sub-points). As set out in points 3. and 4. above, the amendments made to the claims of the first to third auxiliary requests which are likewise made to the fourth auxiliary request, resulting in the corresponding fifth to seventh auxiliary requests, do not further distinguish the claimed subject-matter from the method disclosed in D1. Therefore, these features cannot add any further distinguishing feature over D1, and the finding on lack of inventive for the fourth auxiliary request also applies to the fifth to seventh auxiliary requests (Article 56 EPC).

The appellant-proprietor did not contest this consideration of the Board.

The request of the appellant-proprietor that the patent be maintained in amended form according to any of the fifth to seventh auxiliary requests was consequently not allowed.

Eighth auxiliary request - inventive step

8. The subject-matter of amended claim 1 of the eighth auxiliary request does not involve an inventive step (Article 56 EPC).

8.1 The independent method claim of the eighth auxiliary request is again based on granted claim 1 to which the following feature has been added:

> "*wherein, at the end of the priming and before patient connection, a pressure in the blood circuit and in the blood side of the membrane gas exchanger (18) is kept between 20mmHg and 400mmHg*"

8.2 As stated in its provisional opinion, the Board was not persuaded that the claimed broad pressure interval had any technical effect that the skilled person would not have expected. Instead, the Board agreed with the appellant-opponent that the lower and upper limits appeared to arise from common considerations of the skilled person (see the arguments presented in the paragraph bridging pages 14 and 15 of the appellant-opponent's letter dated 24 February 2025, with the exclusion of the passages on page 15 referring to documents D32 and D33).

8.3 The appellant-proprietor did not submit any further argument in regard to the Board's consideration. The Board therefore had no reason to change its provisional opinion, which is thus confirmed.

The request of the appellant-proprietor that the patent be maintained in amended form according to the eighth auxiliary request was consequently not allowed.

Ninth auxiliary request - inventive step

9. The subject-matter of amended claim 1 of the ninth auxiliary request does not involve an inventive step (Article 56 EPC).

9.1 Amended independent claim 1 of the ninth auxiliary request is based on claim 1 of the fourth auxiliary request, with the following additional features (feature numbering in square brackets added by the Board):

"[5] *wherein the transitory pressurization step in the priming fluid is generated once the priming fluid fills the blood side of the membrane gas exchanger (18), and*

[4'] *wherein, at the end of the priming and before patient connection:*

[4''] *the blood pump is stopped while a return clamp or valve placed on a blood return line and downstream of the membrane gas exchanger is kept closed;*

and

[4'''] *a pressure in the blood circuit and in the blood side of the membrane gas exchanger (18) is kept between 20mmHg and 400mmHg*"

9.2 No synergy can be seen between these further distinguishing features and the feature added in auxiliary request 4 which, as explained above, solves the (partial) problem of providing an alternative way of generating transitory pressurisation steps in the method of D1 in an obvious way.

The Board agrees with the appellant-opponent that the first of the added features, feature 5, defines a necessary condition for starting the priming method of D1. The filling condition defined by this feature, which applies before the start of the transitory pressurisation step, is not linked to the end-of-priming condition defined by the other distinguishing features 4', 4'' and 4''', as also stated by the appellant-opponent. The appellant-proprietor did not refute this argument.

The skilled person would recognise that it makes no sense to initiate the priming process step of generating a transitory pressurisation step before the membrane gas exchanger is entirely filled with priming liquid. It instead constitutes a necessary condition for the subsequent transitory pressurisation step. Otherwise, air could never be prevented from diffusing

from the gas side to the blood side of the membrane. Therefore, the distinguishing feature 5 does not involve any inventive activity in view of the known method of D1 and the common general knowledge.

9.3 Starting from the known method of D1, the further distinguishing features 4', 4'' and 4''' may be seen to solve the following (partial) objective technical problem, as suggested by the appellant-proprietor:

"*how to provide an extracorporeal blood circuit comprising a membrane gas exchanger that is reliably ready for safe patient connection following an interval after completion of the priming.*"

9.4 The Board cannot see that any of these additional distinguishing features involved considerations going beyond the common practice of the skilled person.

9.4.1 The Board appreciates that neither D1 or D24 addresses the above technical problem. Both prior-art documents are indeed limited to the priming method as such. It is nevertheless clear to the skilled person that the purpose of priming is only a preliminary step before the subsequent blood treatment of the patient. The skilled person is thus aware that the patient must be connected in some way to the primed extracorporeal blood circuit and that it is absolutely necessary for patient safety to maintain the primed condition up to connection to the patient and even until the actual treatment starts. Therefore, the technical problem suggested by the appellant-proprietor must be seen to emerge from common practical considerations arising after the method of D1 has been completed and the skilled person would try to solve this problem. The fact that D1 or D24 does not address this problem, let

alone a solution to it, is therefore not sufficient to conclude that an inventive step is involved.

9.4.2 Concerning the further distinguishing features 4', 4'' and 4''', which effectively respond to the above formulated objective technical problem, they also do not involve more than common practical considerations of the skilled person. As stated above, once the extracorporeal blood circuit is primed and free of air, the skilled person has to ensure that this primed state is maintained until blood treatment of the connected patient starts. Allowing re-occurrence of air bubbles in the period between completion of priming and patient connection or the start of the blood treatment would clearly cancel any previous effort of evacuating the air from the blood circuit.

The skilled person is aware of the relevance of each component of the blood circuit and the role of the oxygenator's membrane. The Board does not agree with the appellant-proprietor's contention that the skilled person would not have recognised that the membrane gas exchanger was a source of reintroducing air into the primed circuit after priming. The skilled person is aware of the main sources of air entry into this type of extracorporeal blood circuit. The skilled person knows the role and basic properties of gas-permeable membranes. The skilled person also knows the basic laws of thermodynamics and fluid mechanics, notably the consequences of pressure differentials across such permeable membranes. The skilled person therefore would have recognised, on the basis of common general knowledge alone, that to maintain an air-free condition in the primed blood circuit comprising a membrane gas exchanger, a higher pressure must be provided on the blood side of its membrane.

This higher pressure on the membrane's blood side is to be maintained at the end of the priming process when the patient has to be connected to the primed circuit. Connecting the patient to the primed circuit of D1 would require connecting a needle in the arterial line (which is the line segment upstream of the oxygenator and the blood pump) to the patient for blood intake and connecting a needle in the venous line (downstream from the oxygenator) to the patient for blood return. Connecting the venous line requires that a venous clamp or occlusion means be closed prior to this connection. Otherwise, with an open venous clamp, the higher pressure maintained on the blood side of the membrane would lead to a spill of the priming liquid. Steps 4' and 4'' therefore cannot be seen to involve any consideration going beyond common general knowledge. In as far as the pressure range according to feature 4''' is concerned, equivalent considerations as for the eighth auxiliary request apply.

9.4.3 The Board agrees that none of these considerations derive from D1 or D24. However, this is not sufficient for concluding that such considerations rely on hindsight. They simply rely on what a skilled person would have to do, based on their common general knowledge, to safely start blood treatment once priming is complete. The appellant-proprietor did not refute the arguments in this regard presented by the appellant-opponent in its submission of 24 February 2025 and further developed during the oral proceedings before the Board. In particular, the appellant-proprietor did not show that the considerations went beyond the common general knowledge.

9.5 The request of the appellant-proprietor for maintenance of the patent in amended form according to the ninth auxiliary request was consequently not allowed.

Tenth to twelfth auxiliary requests - inventive step

10. The considerations under point 7. directed to the fifth to seventh auxiliary requests apply by analogy to the tenth to twelfth auxiliary requests since the further amendments made in these latter requests, which are based on the non-inventive ninth auxiliary request, also correspond to those of the first to third auxiliary requests made in the fifth to seventh auxiliary requests. Consequently, no further distinguishing feature was added to the amended claim of the ninth auxiliary request.

The request of the appellant-proprietor for maintenance of the patent in amended form according to any of the tenth to twelfth auxiliary requests was consequently not allowed for lack of inventive step (Article 56 EPC).

11. In the absence of any request which meets the requirements of the EPC, the patent has to be revoked (Article 101(3)(b) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated