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Datasheet for the decision of 30 July 2025

Case Number: T 0637/23 - 3.2.03

Application Number: 19756029.5

Publication Number: 3728550

IPC: C12M1/00

Language of the proceedings: EN

Title of invention:
LID CONFIGURATION FOR A BIOREACTOR

Patent Proprietor:
APPLIKON BIOTECHNOLOGY B.V.

Opponent:
SARTORIUS STEDIM BIOTECH GMBH

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
RPBA 2020 Art. 12(4), 12(6)

Keyword:

Novelty - main request (no) - auxiliary request (yes)
Inventive step - after amendment - non-obvious modification
Sufficiency of disclosure - after amendment
Amendments - allowable (no)
Amendment to case - suitability of amendment to address issues (no)
Late-filed request - should have been submitted in first-instance proceedings (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0637/23 - 3.2.03

D E C I S I O N
of Technical Board of Appeal 3.2.03
of 30 July 2025

Appellant: (Patent Proprietor)	APPLIKON BIOTECHNOLOGY B.V. Heertjeslaan 2 2629 JG Delft (NL)
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Appellant: (Opponent)	SARTORIUS STEDIM BIOTECH GMBH August-Spindler-Strasse 11 37079 Göttingen (DE)
Representative:	Prinz & Partner mbB Patent- und Rechtsanwälte Rundfunkplatz 2 80335 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 27 February 2023 concerning maintenance of the European Patent No. 3728550 in amended form.**

Composition of the Board:

Chairman	C. Herberhold
Members:	B. Miller
	J. Hoppe

Summary of Facts and Submissions

I. European patent EP 3 728 550 B1 ("the patent") relates to a lid configuration for a bioreactor comprising one or more 3D-printed sensor (5) or controller (6) elements, and to a bioreactor and bioreactor configuration kit comprising such a lid configuration, as well as to a method for producing such a lid configuration.

II. An opposition against the patent was filed on the grounds of Article 100(b) EPC and Article 100(a) EPC together with Articles 54 and 56 EPC.

The opposition division concluded that
- the main request (claims as granted) and auxiliary requests 1 and 8 did not meet the requirements of Article 54 EPC,
- auxiliary requests 2 and 3 did not meet the requirements of Article 56 EPC and
- auxiliary requests 4 to 7 did not meet the requirements of Article 123(2) EPC.

The opposition division ultimately decided that the patent in amended form met the requirements of the EPC, on the basis of the then-pending auxiliary request 9 submitted with a letter dated 6 April 2022 (corresponding to auxiliary request 10 of the present appeal proceedings).

III. The interlocutory decision was appealed by both parties. As the patent proprietor and the opponent are both appellants and respondents in the appeal proceedings, for the sake of simplicity the Board will

continue to refer to the parties as the patent proprietor and the opponent in the present decision.

IV. Cited evidence

(a) The following documents already cited during the opposition proceedings are of particular importance for the present decision:

D1: WO 2017/083705 A1

D2: US 2017/0349874 A1

D3: US 2017/0369828 A1

D5: US 2017/0321178 A1

D9: US 2016/0053213 A1

D12: T.H. Lücking et al.: "3D-printed individual labware in biosciences by rapid prototyping: A proof of principle", Eng. Life Sci. 2015, 15, pages 51-6

D13: L. Raddatz et al.: "Additive manufactured customizable labware for biotechnological purposes", Eng. Life Sci. 2017, 17, pages 931-9

D15: CN 106693873 A

D15a: English machine translation of D15

D16: JP 2015-221002 A

D16a: English machine translation of D16

V. Wording of the claims of the requests at issue in this decision

(a) Claim 1 as granted including feature numbering as used by the parties reads:

F1.1 "Lid configuration (1) for a bioreactor (2), comprising:

F1.2 - a lid (3) configured for connection with a vessel (4) of the bioreactor (2),

F1.3 the vessel (4) during use containing a bioreactor fluid (7),

F1.4 the lid (3) being provided with one or more 3D-printed sensor (5) or controller (6) elements for, during use, sensing or controlling one or more parameters of the bioreactor (2), in particular the bioreactor fluid (7),
characterized, in that

F1.5 the one or more 3D-printed sensor (5) or controller (6) elements comprise one or more 3D-printed inlets (11) or outlets (12)."

(b) Claim 1 of auxiliary request 1 corresponds to claim 1 as granted wherein feature F1.4 has been amended as follows:

F1.4' "the lid (3) being provided with one or more 3D-printed sensor (5) or controller (6) elements for, during use, sensing or controlling one or more parameters of the **bioreactor fluid (7) in the** bioreactor (2), ~~in particular the bioreactor fluid (7),~~ characterized, in that"

(c) Claim 1 of auxiliary request 2 corresponds to claim 1 of auxiliary request 1 wherein the following features have been added after F1.5:

"wherein the one or more 3D-printed sensor (5) or controller (6) elements comprise a 3D-printed agitation element (8), wherein the agitation element (8) comprises a 3D-printed impeller, such as a screw (9)."

(d) Claim 1 of auxiliary request 3 reads:

"Method for producing a lid configuration (1) comprising a lid (3) configured for connection with a vessel (4) of a bioreactor (2), the vessel (4) during use containing a bioreactor fluid (7), the lid (3) being provided with one or more 3D-printed controller (6) elements for, during use, controlling one or more parameters of the bioreactor (2), in particular the bioreactor fluid (7), wherein the one or more 3D-printed controller (6) elements comprise one or more 3D-printed inlets (11) or outlets (12), comprising the steps of:

- providing the lid (3) configured for connection with the vessel (4) of the bioreactor (2),
- 3D-printing the one or more controller (6) elements for, during use, controlling the one or more parameters of the bioreactor (2), in particular the bioreactor fluid (7), and
- connecting the one or more controller (6) elements to the lid (3)."

(e) Claim 1 of auxiliary request 4 corresponds to claim 1 of auxiliary request 3 wherein the following features have been added at the end of claim 1:

"further comprising the steps of:

- determining the process or experiment to be carried out with the bioreactor (2),
- determining the 3D-printed controller (6) elements, in particular the 3D-printed inlets (11) or outlets (12) required for carrying out the experiment or process, and
- 3D-printing only those controller (6) elements

required for carrying out the experiment or process."

(f) Claim 1 of auxiliary request 5 corresponds to claim 1 of auxiliary request 4 wherein the following features have been added at the end of claim 1:

"wherein, prior to determining the 3D-printed controller (6) elements required for carrying out the experiment or process, a design is made of the bioreactor (2) for carrying out the process or experiment, and the 3D-printed controller (6) elements required for carrying out the experiment or process are determined from the design."

(g) Claim 1 of auxiliary request 6 corresponds to claim 1 of auxiliary request 2 wherein the following features have been added:

"wherein the lid (3) is a 3D-printed lid (3)".

(h) Claim 1 of each of auxiliary requests 7 to 9 is directed to a "Single use" of a bioreactor as defined in claim 1 according to auxiliary requests 1, 2 and 6.

(i) Claim 1 of auxiliary request 10 corresponds to claim 1 as granted wherein the alternatives "sensor (5)" elements and "inlets (11)" have been deleted and a further feature has been added at the end. It reads as follows:

"Lid configuration (1) for a bioreactor (2), comprising:

- a lid (3) configured for connection with a vessel (4) of the bioreactor (2),
the vessel (4) during use containing a bioreactor fluid (7),
the lid (3) being provided with one or more 3D-printed controller (6) elements for, during use, controlling one or more parameters of the bioreactor (2), in particular the bioreactor fluid (7),
characterized, in that
the one or more 3D-printed controller (6) elements comprise one or more 3D-printed outlets (12),
wherein an inlet end (121, 122) of an outlet (12) has a circumferential wall and one or more openings in its circumferential wall."

Auxiliary request 10 corresponds to the previously pending auxiliary request 9 which the opposition division considered as meeting the requirements of the EPC.

(j) Claim 1 of auxiliary request 11 corresponds to claim 1 of auxiliary request 10 wherein the following features have been added at the end of claim 1:

"wherein a top portion of the circumferential wall facing the lid (3) or a bottom portion of the circumferential wall facing a bottom of the vessel (4) comprises the one or more openings."

(k) Auxiliary requests 12 to 14 are based on the claims as granted, auxiliary request 10 and auxiliary request 11 wherein in claim 1 the following feature has been added at the end of claim 1:

"wherein the one or more 3D-printed sensor elements (5) comprise a temperature sensor (5)"

(l) Claim 1 of auxiliary request 15 reads:

"Lid configuration (1) for a bioreactor (2),
comprising:
- a lid (3) configured for connection with a vessel (4) of the bioreactor (2),
the vessel (4) during use containing a bioreactor fluid (7),
the lid (3) being provided with one or more 3D-printed controller (6) elements for, during use, controlling one or more parameters of the bioreactor (2), in particular the bioreactor fluid (7),
characterized, in that
the vessel has a volume of less than 3 liters,
wherein the one or more 3D-printed controller (6) elements comprise one or more 3D-printed inlets (11) or outlets (12)
comprising 3D-printed coaxial inlet (11) and/or outlet (12) tubes extending into the vessel."

VI. Oral proceedings were held on 30 July 2025.

VII. At the end of the oral proceedings, the following requests were maintained by the parties.

The patent proprietor requested that the decision under appeal be set aside and the patent be maintained on the basis of the claims as granted (main request) or, as an auxiliary measure, that the patent be maintained in amended form according to one of auxiliary requests 1 to 15 as submitted with the statement setting out the grounds of appeal (including an adapted description for

auxiliary request 15, as filed during the oral proceedings on 30 July 2025).

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

Procedurally, the opponent requested *inter alia* that auxiliary requests 5 and 7 to 9 not be admitted.

VIII. It is noted that in addition the patent proprietor requested that several submissions filed by the opponent not be allowed into the appeal proceedings even though they were a subject of the first-instance proceedings because they were filed too late in said first-instance proceedings and were incorrectly allowed into said proceedings by the opposition division. These submissions relate to documents and arguments which are not relevant to the present decision and hence do not need to be listed and discussed herein.

IX. The patent proprietor's arguments, as far as they are relevant to this decision, can be summarised as follows.

(a) Main request - claim construction

The skilled person was aware that sensors, such as temperature or pH sensors, required additional functional parts, such as electronic components. Accordingly, they would interpret claim 1 in a technically sensible manner as referring to sensor elements and controller elements, both of which simply provided access to the bioreactor and could be supplemented by additional components (3D-printed or otherwise manufactured) to form a final controller or sensor.

The claimed 3D-printed sensor and controller elements were positively identifiable component parts of the lid configuration, providing access to the bioreactor via inlets and outlets.

The skilled person would also understand that these parts were essentially tubes which extended into the interior of the bioreactor. Moreover, it was clear that inlets and outlets needed to be present in the lid.

(b) Main request - sufficiency of disclosure

The sensor and controller elements addressed by claim 1 were simply elements which were part of the final sensor (e.g. a tube into which a concentration sensor, or a detector of any kind, could be inserted) or part of the final controller (e.g. a sleeve, into which an impeller could be inserted). The skilled person could provide such an element without undue burden since 3D printing was a known manufacturing process.

(c) Main request - novelty/inventive step in view of D9

D9 was not an enabling disclosure, since it did not provide specific details of the 3D-printing manufacturing method. In particular, D9 did not disclose a lid configuration with identifiable 3D-printed sensor or controller elements. Indeed, D9 merely disclosed that the starting material for forming the lid was obtained by 3D printing.

Furthermore, D9 did not disclose that all parts of the bioreactor were produced using 3D printing. The high temperatures mentioned in paragraph [0008] which the material could sustain were indicative of

autoclavation, which was impossible for a 3D-printable material.

Therefore claim 1 differed from the disclosure of D9 in that the lid comprised 3D-printed sensor or controller elements comprising one or more 3D-printed inlets or outlets.

D9 related to a vessel for cultivating an organ, with a lid that was provided with a support structure for supporting the organ, rather than to a bioreactor. Hence D9 was an accidental anticipation, not an appropriate starting point for assessing inventive step. Moreover, D1 was more pertinent than D9 because D1 came structurally closer to the subject-matter of claim 1. The patent focused on disposable, custom-made bioreactors that could be manufactured on demand. D9 did not address the disposability of the lid configuration at all and did not provide the end user with a lid configuration having a higher degree of configurability and customisability.

The objective technical problem had to be formulated as being to provide a lid configuration for a bioreactor,
where the sensor or controller elements are substantially disposable, and/or
where the end user is provided with a higher degree of configurability and customisability than with present-day lid configurations, and/or
where the shaping of inlets or outlets can be optimally tailored to a specific function since with 3D printing shapes and designs which were previously impossible to manufacture become obtainable, and/or
where sufficient miniaturisation of all components can be obtained.

The advantages of using 3D printing for producing bioreactors or components thereof were not derivable from D9 or the other cited prior art such as D1, D2, D3, D12, D13, D15 and D16. Documents D12 and D13 related to mass-produced shake flasks, not individualised bioreactors. Shake flasks were for an entirely different process without any controlling. Therefore the skilled person would not consult these documents when starting from D9.

The skilled person would not consider manufacturing sensor or controller elements by 3D printing obvious, since 3D printing was not a cheaper or faster production method. It also required careful redesign of the element to render it suitable for 3D printing. Moreover, 3D-printed lid configurations were not known to be airtight, biocompatible or autoclavable.

(d) Main request - novelty/inventive step in view of D1

D1 disclosed in Figures 1 and 8 a 3D-printed lid configuration that lacked controller and sensor elements within the meaning of claim 1. The protrusions in cover plate 50 (see Figures 1 and 8) did not represent inlets or outlets within the meaning of claim 1 because they did not extend into the interior of the bioreactor. Furthermore, the lid according to D1 did not have inlets and outlets, but rather a simple hole for inserting the impeller shaft.

(e) Auxiliary requests 1 and 2

In relation to D1 the same arguments applied as for claim 1 as granted.

(f) Auxiliary request 3

D1 did not disclose 3D-printed elements that comprised an inlet or outlet that could be connected to the lid.

Concerning D9, the arguments as presented for claim 1 as granted applied. D9 did not suggest using 3D printing to manufacture the fluid conduits of the bioreactor of D9.

(g) Auxiliary request 4

The method steps introduced in claim 1 defined the invention underlying the patent more precisely, according to which custom-made bioreactors could be produced with a high degree of individualisation. None of the cited documents suggested that single-use bioreactors could be produced on demand using 3D printing. The cited prior art related to standardised labware.

Therefore it was not obvious to perform the method steps defined in claim 1 to manufacture a custom-made bioreactor.

(h) Auxiliary request 5 - admittance

Auxiliary request 5 built on auxiliary request 4 and was based on granted claims. Moreover, it constituted a reaction to the reasoning in the contested decision.

(i) Auxiliary request 5 - inventive step

The method steps introduced into claim 1 further tailored the scope of protection to the invention underlying the patent, according to which the method

provided the possibility of manufacturing custom-made bioreactors on demand with a high degree of individualisation.

(j) Auxiliary request 6

In relation to D1 the same arguments applied for the lid configuration according to claim 1 as for the lid configuration according to claim 1 as granted.

(k) Auxiliary requests 7 to 9 - admittance

Claim 1 of each of auxiliary requests 7 to 9 was based on the use according to claim 14 as granted, except that it was further specified as a "single" use. This implied the method step of throwing away the bioreactor after its first and only use. The remaining amendments corresponded to those in claim 1 according to auxiliary requests 1, 2 and 6. Adding the term "single" and changing the claim category did not alter the subject-matter under discussion, since the patent as a whole was directed toward manufacturing single-use bioreactors.

(l) Auxiliary request 10

D9 did not disclose a lid configuration with a controller element (i.e. the tubes of the bioreactor of D9) wherein an inlet end of an outlet had a circumferential wall and one or more openings in its circumferential wall.

The objective technical problem could be formulated as being to facilitate the production through 3D printing of complex outlet shapes that allow for the suction of

specific fluids, such as supernatant liquids, from the bioreactor fluid.

None of the cited documents disclosed a bioreactor or lid configuration with an outlet comprising openings in its circumferential wall.

(m) Auxiliary request 11

The amendments to claim 1 were based on the disclosure on page 5, lines 9 to 12 of the application as originally filed, where the two alternatives added to claim 1 were generally disclosed as exemplary options due to the use of the term "e.g.".

(n) Auxiliary requests 12 to 14

The skilled person would interpret claim 1 with a mind willing to understand. Thus the skilled person would understand that amended claim 1 referred to sensor elements, not complete temperature sensors.

(o) Auxiliary request 15

The subject-matter of claim 1 differed from the disclosure of D9 in that the lid comprised 3D-printed controller elements comprising one or more 3D-printed inlets or outlets comprising 3D-printed coaxial inlet (11) and/or outlet (12) tubes extending into the vessel.

The patent stated in paragraph [0020] that coaxial tubes provided more functionality inside a vessel.

The skilled person had no motivation to use coaxial tubes as fluid conduits in the bioreactor of D9.

Furthermore, none of the documents on file disclosed the use of coaxial tubes in bioreactors or their manufacture using 3D printing.

Documents D29 and D30 were irrelevant, since they pertained to rocket engines and air-blast nozzles, which the skilled person would not have considered when aiming at providing more functionality in a bioreactor.

Moreover, the opponent had not identified any exceptional circumstances for filing D29 and D30 for the first time only about one month before the oral proceedings before the Board. Therefore D29 and D30 should not be admitted into the proceedings.

X. The opponent's arguments can be summarised as follows.

(a) Main request - claim construction

The skilled person would interpret claim 1 based on its wording, not on speculations about what had been intended when drafting the claim.
The claimed 3D-printed sensor and controller elements were not defined by their structure or specific function. Claim 1 only required that they comprised an inlet or outlet, not that these parts extended into the interior of the bioreactor.

(b) Main request - sufficiency of disclosure

The skilled person could not produce a complete sensor or controller addressed by claim 1 through 3D printing because it was impossible to obtain for example the necessary electronic components by that route.

(c) Main request - novelty/inventive step in view of D9

D9 explicitly disclosed the possibility of using 3D printing to manufacture the bioreactor. The skilled person did not require any further information from D9 to rework its disclosure since 3D printing was a known manufacturing method. As evidenced for example by D1 or D12, it was also a well-known method for obtaining customised labware. 3D printing was a method for shaping the material into a desired form, not for obtaining a base material which then underwent a forming or machining process.

D9 disclosed that bioreactors could generally be made by 3D printing. This included any part thereof.

D9 explicitly disclosed a bioreactor and hence was an appropriate starting point for assessing inventive step.

Claim 1 was directed to a lid configuration *per se*. Claim 1 did not contain any features that made the claimed lid configuration particularly suitable for disposal. The alleged advantages referred to by the patent proprietor were related to the specific manufacturing method but not to the lid configuration itself. No advantages were demonstrated of using a 3D-printed controller element or sensor element, such as a simple tube, instead of the same element obtained by a different manufacturing method, such as e.g. injection moulding.

The objective technical problem had to be formulated as being to provide an alternative lid configuration for a bioreactor.

3D printing was a well-known manufacturing process for prototyping and for producing individualised or customised labware, as evidenced by D1, D2, D3, D12, D13 and D15.

Following D9's teaching to use 3D printing to manufacture bioreactors, the skilled person would also consider this method for individual parts, such as tubes, as well.

(d) Main request - novelty/inventive step in view of D1

D1 disclosed a 3D-printed lid configuration with protrusions in Figures 1 and 8. These protrusions constituted controller and sensor elements within the meaning of claim 1. Therefore no distinguishing feature could be identified between the disclosure of D1 and the subject-matter defined by claim 1.

(e) Auxiliary requests 1 and 2

In relation to D1, the same arguments applied as for claim 1 as granted.

(f) Auxiliary request 3

D9 suggested using 3D printing to manufacture the bioreactor. Therefore the method according to claim 1 of auxiliary request 3 was obvious for the reasons presented in relation to claim 1 as granted.

(g) Auxiliary request 4

The additional method steps further introduced into claim 1 described the routine work for the skilled person when developing a bioreactor for a given

bioprocess. This work included considering alternative production methods for the required components.

(h) Auxiliary request 5 - admittance

Auxiliary request 5 could and should have been filed during the opposition proceedings.

(i) Auxiliary request 5 - inventive step

The method steps introduced in claim 1 were trivial and fell within the routine work of the skilled person when developing a bioreactor for a given bioprocess using 3D printing, see D12, section 3.1 and page 55, "Practical application", or D13, chapter 3 and page 938, "Practical application".

(j) Auxiliary request 6

In relation to D1, the same arguments applied for the lid configuration according to claim 1 of auxiliary request 6 as for the lid configuration according to claim 1 as granted.

(k) Auxiliary requests 7 to 9 - admittance

Claim 1 of auxiliary requests 7 to 9 was not directly based on the use according to claim 14 as granted but had been further specified as a "single" use of a bioreactor. This amendment fundamentally changed the subject-matter to be discussed compared with the previous requests, which were directed to a lid or a manufacturing method for a lid. These requests were also not convergent with the previous ones and *prima facie* not allowable in view of D1. In this context, the fact that D1 mentioned sterilisation of the bioreactor

was immaterial, sterilisation of a bioreactor before use being necessary whether this bioreactor is disposed of after a single use or not.

(l) Auxiliary request 10

D9 disclosed a lid configuration with a controller element (i.e. the fluid conduits of the bioreactor of D9), wherein an inlet end of an outlet had a circumferential wall and one or more openings in its circumferential wall elements 103 as depicted in the figures of D9 by darker/shaded zones, which the skilled person would identify as frits (filters) or spargers.

Claim 1 did not define the number, size or shape of the openings. Figure 5 of the patent demonstrated that the inlet end 121 in the circumferential wall at the end of the controller element did not need to be separate from the conventional opening at the end of a tube.

The objective technical problem could thus at best be formulated as being to provide an alternative lid configuration which allowed fluid to be sucked out.

The variation in the shape of the suction hole(s) (terminal and/or in the circumferential wall) fell within the experimental routine of the skilled person.

(m) Auxiliary request 11

The amendment to claim 1 extended beyond the disclosure on page 5, lines 9 to 12 of the application as originally filed.

By omitting the restriction "only" in both alternatives, claim 1 encompassed configurations in

which not all, but only some of the openings were provided in the top portion or in the bottom portion, respectively, contrary to the disclosure on page 5, lines 9 to 12.

(n) Auxiliary requests 12 to 14

The amendment to claim 1 altered its interpretation. According to amended claim 1, the entire temperature sensor, not just an element thereof, had to be 3D-printed. However, the application did not disclose how a temperature sensor could be obtained by 3D printing, contrary to Article 83 EPC.

(o) Auxiliary request 15

The subject-matter of claim 1 differed from the disclosure of D9 in that the lid comprised 3D-printed controller elements comprising one or more 3D-printed inlets or outlets comprising 3D-printed coaxial inlet (11) and/or outlet (12) tubes extending into the vessel.

The objective technical problem to be solved could again be regarded as being to provide an alternative lid configuration.

Documents D29 and D30 confirmed that coaxial tubes could be manufactured by 3D printing, which was common general knowledge of the skilled person.

D29 and D30 were found by chance and were *prima facie* relevant to the assessment of inventive step of claim 1 of auxiliary request 15. These documents should be admitted into the proceedings.

The skilled person also knew that coaxial tubes required less space than two individual tubes.

Therefore, starting from D9, it was obvious to use a coaxial tube to provide an alternative lid configuration for a small bioreactor with limited space, given its well-known benefits.

Reasons for the Decision

1. Main request - claim construction

1.1 Claim 1 requires that the lid be provided with "3D-printed sensor (5) or controller (6) elements for, during use, sensing or controlling one or more parameters of the bioreactor (2), in particular the bioreactor fluid (7)".

According to the literal wording of claim 1 the 3D-printed elements must be suitable for sensing or controlling one or more parameters of the bioreactor.

The skilled person knows that complete sensors, such as temperature or pH sensors, require additional functional parts, such as electronic components, and that complete controllers need a control unit (e.g. a control unit and an engine to control the speed of an impeller or means to control the transport of gas or fluid through the inlets and outlets). Thus it is clear to the skilled person that sensors (5) and controllers (6) cannot be completely manufactured by 3D printing. Therefore the skilled person will interpret claim 1 in a technically sensible manner as referring

to sensor elements and controller elements that simply provide access to the bioreactor and can be supplemented by additional components (3D-printed or not) to form a final controller or sensor.

This interpretation is confirmed by the disclosure in the patent, see for example:

- paragraph [0014]:

"*In other words, the lid configuration for a bioreactor is characterized by the lid being provided with one or more 3D-printed inlets or outlets.*"

- Figure 1 in combination with paragraphs [0059] and [0049] (last two words) "sensor element"

- Figures 4 and 5:
The sensor and controller elements are gas or fluid inlets and outlets. Therefore they do not sense or control a parameter, but rather provide access to do so.

- paragraph [0017]:

"*the inlets or outlets may be spargers, water inlets, gas outlets, nutrient inlets, anti-foam inlets, steam inlets, inoculant inlets, et cetera. Therein, both "fluids", such as gasses or liquids, as well as solid materials may be transported through the inlets or outlets.*"

1.2 The sensor and controlling elements of the lid configuration according to claim 1 are not defined by their shape, material or specific function.

Hence, in view of the general and non-specific wording of the claim, the sensor and controller elements can be any 3D-printed part of the lid with an inlet and outlet opening that is either integrated into or connected to the lid.

The Board considers the unspecific terms in claim 1 to include identifiable elements, such as a sleeve or tube, but not a simple hole, since a hole is not a 3D-printed, separate element.

This broad interpretation ("an identifiable element") adopted by the Board corresponds to the patent proprietor's claim construction as proposed in point B.3 of its statement setting out the grounds of appeal:

"*The claimed 3D-printed inlets or outlets are thus positively identifiable component parts of the lid configuration.*"

1.3 During the oral proceedings before the Board, the patent proprietor further argued that the 3D-printed sensor or controller elements must be interpreted as elongated parts, i.e. tubes that extend into the interior of the bioreactor vessel.

The Board does not agree with this narrow interpretation.

Claim 1 does not contain any specific features, nor could the patent proprietor identify any, which imply a specific function, form, orientation or dimension of the controller and sensor elements, or of their 3D-printed inlets and outlets.

Furthermore, the accompanying patent specification does not support the patent proprietor's narrow interpretation. Paragraph [0017] of the patent explains that the inlets and outlets may be gas outlets, and solids may also be transported through them. Therefore the patent confirms that the 3D-printed sensor and controller elements are not limited to elements that have to reach into the fluid-comprising interior of the vessel. Paragraph [0018] of the patent confirms this teaching by stating that, in only one possible embodiment, the 3D-printed inlets (or outlets) are tubes which extend into the vessel of a bioreactor ("***especially*** *when the inlet has a tube that extends into the vessel of a bioreactor, is that fluids may be injected directly into the liquid (instead of being dripped onto the foam)*", highlighting in bold by the Board).

Hence the narrower and restricted interpretation of claim 1 proposed by the patent proprietor is not based on the wording of the claim and is further contradicted by the general specification of the patent.

2. Main request - sufficiency of disclosure

In view of the above claim interpretation, the sensor and controller elements in the definition of claim 1 are simply parts of the final sensor (such as a tube into which a concentration sensor, or a detector of any kind, can be inserted, or a tube through which gas etc. can reach the detector) or parts of the final controller (such as a sleeve into which an impeller can be inserted, or a tube through which the addition or removal of gas or fluid can be achieved and controlled). The skilled person can provide such an element without undue burden because 3D printing is a

known manufacturing process, as discussed below in the context of inventive step.

The same applies to the subject-matter of claims 2 to 4.

In view of the above, the Board concludes that the invention as defined in the claims as granted can be reproduced by a skilled person, and that the ground for opposition under Article 100(b) EPC does not prejudice maintenance of the patent.

3. Main request - novelty in view of D9

3.1 D9 - enabling disclosure

3.1.1 D9 discloses in the figures a bioreactor (which is explicitly referred to as a "bioreactor" throughout the specification of D9) comprising a lid. Regarding the manufacturing process for the bioreactor, D9 discloses the following in paragraph [0026]:

"*It should be appreciated that bioreactors can be made of any suitable material (including a printed material from a 3D printer).*"

3.1.2 The patent proprietor argued that the disclosure of D9 was not enabling since it did not provide specific details about the 3D-printing manufacturing method.

This argument is not convincing.

3.1.3 Providing a CAD model of the article to be manufactured is standard practice for the skilled person when constructing an article, regardless of the final manufacturing method. Converting the CAD file to an STL

file, which is commonly used by 3D printers, and setting the appropriate 3D-printing parameters also falls within the experimental routine of the skilled person, since 3D printing is a well-known manufacturing process, even in the biosciences (see, for example, D13, Fig. 1, and the last paragraphs, highlighted in grey, in each of D12 and D13).

3.1.4 Therefore the Board considers the reference to 3D-printed material in D9 sufficient for the skilled person to obtain a bioreactor as disclosed in D9 using additive manufacturing methods (see also point 3.2.2 below).

3.2 Disclosure of D9

3.2.1 D9 discloses in Figure 4 a lid for a bioreactor, which is shown in its entirety in Figure 1.

The bioreactor of D9 can be used for culturing, cellularising, decellularising and/or conditioning biological or synthetic objects, such as engineered tissues or organs (see paragraphs [0003], [0021] and [0022]). Thus D9 explicitly discloses not only a bioreactor, but also the typical application of such a vessel. It is therefore by no means an accidental anticipation, but a disclosure within the very field of the application.

To conclude, D9 discloses a lid suitable for the purpose according to claim 1.

Paragraph [0029] of D9 discloses that the lid comprises "*a plurality of ports (e.g., supports various options including locking mechanisms, plugs, bubble traps, right angle); and holes (e.g., for fastening cover*

assembly to vessel). Ports may contain O-rings, for example. Fluid conduits (e.g., cannula, drain etc.) are attached to and transverse ports [sic] *and are shown in configuration for attachment to a biological object.*"

Therefore D9 distinguishes between holes and ports. Holes are intended for fastening the lid to the vessel (see paragraph [0032]), whereas ports comprise for example an O-ring or a locking mechanism, etc. (see paragraphs [0032], [0033] and Fig. 4).

In the words of claim 1 of the patent, D9 thus discloses a lid configuration wherein the lid is provided with sensor and controller elements (e.g. fluid conduits) comprising an inlet and an outlet.

3.2.2 Paragraph [0026] of D9 states that the bioreactor can be made of a printed material from a 3D printer.

The patent proprietor argued that the skilled person would understand from D9 that the starting material is obtained through 3D printing and could then be used to manufacture the bioreactor.

However, this interpretation of D9's disclosure is not convincing, as 3D printing is a method of shaping and forming material into a particular 3D shape, not a method for obtaining a base material for a subsequent forming or machining process.

Furthermore, the patent proprietor argued that the skilled person would not consider the reference to 3D printing in paragraph [0026] of D9 because it was not known in the field that parts of or entire bioreactors could be manufactured using 3D printing. Therefore the skilled person would interpret the single reference as

speculative or even incorrect and would not seriously take it into account.

However, this argument is not convincing, as 3D printing was a well-known manufacturing method at the patent's priority date and was already well-known to be applicable to manufacturing labware, as evidenced by the following documents:

D1: Figures 1, 2c, 6, 7,
paragraphs [0047], [0098], [0101], [0164];
D2: Figures 1a, 1b, paragraphs [0155], [0167], [0168];
D3: Figure 11, paragraphs [0061], [0064], [0066],
claim 12;
D12: abstract, Figure 1, paragraph highlighted in grey
on page 55, left-hand column
D13: abstract, Figure 1, paragraph highlighted in grey
on page 938, left-hand column
D15: Figure 2, paragraphs [0010], [0020]
D16: paragraphs [0086], [0087]

In particular, D1, paragraph [0056] shows that 3D-printing materials may well be autoclavable materials which can be easily sterilised. The argument that the temperatures mentioned in paragraph [0008] of D9 were teaching away from using 3D printing for the bioreactor lid of D9 is thus not convincing.

Furthermore, the general scientific article D12 proves that it was known that 3D printing can be used for manufacturing individually configurable labware (see paragraph highlighted in grey on page 55, left-hand column), such as a lid configuration for a shaking flask (see Figure 1A: CAD model and Figure 1D: printed part). A bioreactor can have a more complex structure than a shaking flask. However, claim 1 does not require

that the lid configuration be configured for a complex biological task, and simply requires one inlet or outlet element comprising an inlet and outlet. Hence, if the main focus of D12 may be seen to be directed to a shaking flask, as argued by the patent proprietor, the skilled person would still consider D12 because a shaking flask is a vessel holding biological material with control/sensor elements (in the broad sense of the patent, see e.g. the inlets/outlets in D12, Fig. 1) and thus a type of bioreactor. Moreover, the teaching concerning the individualisation possibilities for manufacturing caps and lids is not limited to shaking flasks, see paragraph highlighted in grey on page 55, left-hand column.

The patent proprietor argued that the skilled person would not consider the disclosure in D12 (and correspondingly in D13) since it related to mass-produced shaking flasks, not individualised, customised bioreactors produced on demand. Furthermore, D12 was only a theoretical concept paper.

This argument is not convincing.

Claim 1 is directed to a lid configuration comprising at least one 3D-printed element: it is not directed to custom-made bioreactors. According to the features of claim 1, the remaining parts of the lid, as well as the other parts of the bioreactor, such as the vessel, can be mass-produced. Therefore the wording of the claim does not justify disregarding D12.
Contrary to the patent proprietor's view, D12 is not a theoretical concept paper but clearly demonstrates in Figure 1 that a lid for a shaking flask has been 3D-printed. Moreover, D12 repeatedly refers to individualised labware, see introduction, Figure 1,

Example 1 and the "Concluding remarks", in particular the paragraph highlighted in grey on page 55 in the left-hand column.
Hence D12 leaves no doubt that the skilled person would be aware of the fact that 3D printing can be used to manufacture individualised, customised labware, such as a lid configuration.

Therefore the Board considers the statement in paragraph [0026] of D9, which discloses the possibility of making bioreactors using 3D printing, to be significant.

3.2.3 However, the question arises as to whether this general statement of D9 can be used to conclude that all parts of the bioreactor are made using 3D printing.

The Board considers that this is not the case, contrary to the assumption adopted by the opposition division, see point 28 of the contested decision.

According to paragraphs [0026] and [0027] of D9, the bioreactor can be made of various alternative materials, and specific parts can be made of specific materials. For example, the support base can be made of Kevlar or stainless steel.

While D9 generally suggests that the bioreactor can be formed using 3D printing, it does not directly and unambiguously specify that all parts of the bioreactor, including the tubes connected to the lid, are formed by 3D printing.

3.2.4 In view of the above, the Board concludes that the subject-matter of claim 1 differs from the disclosure of D9 in that the lid comprises 3D-printed sensor

elements or controller elements with one or more 3D-printed inlets or outlets.

3.2.5 The same reasoning applies to the remaining claims of the main request.

4. Main request - novelty in view of D1

4.1 In point B.6.1 of the statement setting out the grounds of appeal, the patent proprietor argued that D9 was not the closest prior art. It repeatedly stated that D1 was far more relevant, see letter dated 5 February 2023, point III.4:

"*D9 is on 3 accounts less specific than D1*"
"*D1 is therefore the document that has the most features in common with the claimed subject-matter and thus is more relevant than D9.*"

and point III.6.2:

"*the proprietor most certainly has provided alternative closest prior art documents. In the introduction of the description of the granted Patent explicit reference is made to three closest prior art documents, of which D1 actually describes a 3D-printed bioreactor (in contrast to D9) but without inlets/outlets, let alone 3D-printed inlets or outlets.*"

According to the additional statement in the letter dated 3 May 2024 (page 3, penultimate paragraph), the patent proprietor is of the opinion that

"*To assess novelty and inventive step over D1 can thus not be seen to constitute a new line of argumentation*".

In line with the line of argument presented by the patent proprietor, novelty and inventive step are therefore to be discussed on the basis of D1.

4.2 In point 16.3.1 of its communication under Article 15(1) RPBA the Board informed the parties that inventive step would be discussed during the oral proceedings starting from D1, and that it would be necessary to identify which features of claim 1 distinguished it from the lid configuration of D1.

During the oral proceedings, none of the parties objected to evaluating claim 1 with respect to D1.

4.3 D1 discloses in Figures 1 and 8 a 3D-printed lid configuration, see paragraph [0047].

The 3D-printed lid (50) comprises multiple openings through which the Teflon sleeve bearings and spin shafts of the impellers (likewise 3D-printed) are inserted, see paragraph [0047].

The lid is provided with identifiable cylindrically shaped protrusions supporting the Teflon sleeve bearings as shown in Figures 1 and 8.

These protrusions in the cover plate 50 (see e.g. Figures 1 and 8) represent inlets or outlets comprised by the controller elements within the meaning of claim 1 (identifiable elements integrated in the lid, taking up the bearing and shafts or the motor and being more than just a port or hole).

The patent proprietor argued that the protrusions of the lid according to D1 did not extend into the interior of the bioreactor. However, as discussed above

in point 1.2, claim 1 encompasses an inlet and an outlet opening that is either integrated into or connected to the lid but does not contain any features that define the dimensions, shape or orientation of the controller and sensor elements.
Therefore the patent proprietor's arguments are not convincing.

The patent proprietor further argued that the lid configuration of D1 did not comprise inlets and outlets according to the intention underlying claim 1.

However, this argument is not convincing when considering the wording of claim 1. Claim 1 does not require the presence of inlets and outlets, but rather merely requires the presence of at least one inlet or outlet. In particular, claim 1 does not require an additional inlet for liquids in the lid configuration, in addition to the controller element comprising an inlet for an agitation element.

4.4 In view of the above, the Board concluded that no distinguishing features could be identified in claim 1 in relation to D1 (Article 54 EPC).

5. Main request - inventive step

5.1 Selection/suitability of the starting point

5.1.1 D9 relates to a bioreactor used for culturing, cellularising, decellularising and/or conditioning biological or synthetic objects (see D9, paragraphs [0003], [0021], [0022]) and belongs to the same technical field as the contested patent (see also point 3.2.1 above). Therefore it is a realistic

starting point for developing a lid for a bioreactor as defined in claim 1.

5.1.2 However, the patent proprietor argued that D9 was not an appropriate starting point for assessing inventive step because it did not relate to a bioreactor and did not address the disposability of the lid configuration, let alone provide the end user with a lid configuration having a higher degree of configurability and customisability. Indeed, it focused on a bioreactor for cultivating an organ with a lid that provided a support structure for holding the organ.

This argument is not convincing.

5.1.3 D9 repeatedly and consistently refers *expressis verbis* to a bioreactor throughout its entire description. Therefore the patent proprietor's argument that D9 relates to a different type of labware is unfounded and not justified in view of the broad and unspecific definition of the claims of the patent.

Furthermore, claim 1 of the patent is directed to a lid configuration, does not address its disposability and, in particular, does not contain any feature that would make the lid configuration particularly suitable for disposal. In any case, a lid configuration and its components, as shown in D9, can also be disposed of like any other lid.

The same applies to arguments relating to the manufacturing method. For a claim directed to the product itself, certain advantages relating to specific manufacturing methods are not relevant. Moreover, the lid of D9 can be varied and customised because it comprises ports into which various elements can be

inserted. The statements in the patent description referring to particular advantages or opportunities enabled by 3D printing (see, for example, paragraph [0057]) relate to specific embodiments and do not apply to the claimed subject-matter in general.

Moreover, sensor elements and controller elements of various shapes and designs can be produced using methods such as injection moulding and connected to a lid such as shown in Figure 4 of D9. Thus D9 also provides a certain configurability and customisability during the manufacturing of the final lid configuration.

5.1.4 The patent proprietor further argued that D9 was not the closest prior art, since it was less pertinent than D1, which was more structurally similar to the subject-matter of claim 1.

The Board is of the opinion that the question of whether D1 or D9 is a more relevant document can be left unanswered.

As summarised in Case Law of the Boards of Appeal, 11th edition, 2025 ["Case Law"], Chapter I.D.2, the evaluation of inventive step is usually based on problem-solution approach. This approach does not consist of a forum in which an opponent can freely develop various attacks based on diverse prior-art documents in the hope that one of them will succeed. However, this approach does not exclude more than one document being used as a possible starting point for assessing inventive step. It is, rather, established case law that, if the skilled person has several workable routes to choose from, i.e. routes starting from different documents that might lead to the

invention, the rationale of the problem-solution approach requires that the invention be assessed relative to all these possible routes before an inventive step can be acknowledged, see Case Law, Chapter I.D.3.1.

Therefore the Board concluded that D1 and D9 were both reasonable starting points for assessing inventive step.

5.2 D9 as the starting point

5.2.1 D9 discloses in Figure 4 a lid for a bioreactor, which is shown in Figure 1.

As discussed above, D9 generally suggests in paragraph [0026] that the bioreactor can be formed by 3D printing, but does not specify which parts are 3D-printed.

5.2.2 The subject-matter of claim 1 therefore differs from D9's disclosure in that the lid comprises 3D-printed sensor elements or controller elements comprising one or more 3D-printed inlets or outlets.

5.2.3 The 3D-printed sensor and controller elements according to claim 1 are not defined in detail regarding their shape or function, and may be simple tubes or sleeves as discussed above in point 1.2.

Moreover, no advantages have been demonstrated in using a 3D-printed sensor or controller element, such as a simple tube or sleeve, as opposed to the same element obtained by a different manufacturing method, such as injection moulding.

5.2.4 Nevertheless, the patent proprietor argued that the objective technical problem had to be formulated as being to provide a lid configuration for a bioreactor,

a) wherein the sensor or controller elements are substantially disposable (paragraph [0012] of the patent) and/or
b) wherein the end user is provided with a higher degree of configurability and customisability than what present-day lid configurations offer (paragraph [0013] of the patent) and/or
c) wherein the shaping of inlets or outlets can be optimally tailored to a specific function, as shapes and designs become obtainable that were previously impossible to manufacture (paragraph [0019] of the patent) and/or
d) wherein sufficient miniaturisation of all components can be achieved (paragraph [0020] of the patent).

This argument is not convincing.

5.2.5 A lid configuration and its components can always be disposed of, regardless of the manufacturing method used to produce them.

Moreover, claim 1 is directed to a lid configuration itself. The lid of D9 can be varied and customised because it comprises ports into which various elements can be inserted. Any arguments presented by the patent proprietor that refer to particular advantages or opportunities enabled by 3D printing (e.g. the ability to produce custom-made bioreactors on demand) are not relevant to the claimed subject-matter, i.e. the lid configuration itself. Additionally, any advantages

relating to manufacturing very specific embodiments (e.g. costs involved in producing specific parts, as discussed in paragraph [0057] of the patent) cannot be taken into account, as these embodiments are not defined in claim 1.

Furthermore, sensor and controller elements of various shapes and designs can also be produced using methods such as injection moulding and connected to a lid as shown in Figure 4 of D9. Hence using 3D printing for any type of sensor or controller element, such as tubes or sleeves, does not provide an advantage to the claimed lid configuration itself. Regarding claims directed to the corresponding manufacturing method, see the following point 8.

Tailoring the shape of an inlet or an outlet to a specific function is also possible with accurate injection-moulding tools. Claim 1 does not define sensor or controller elements having a specific shape or design that can only be manufactured surprisingly by 3D printing. Rather, the lid configuration of claim 1 encompasses the simplest possible design of elements comprising an inlet and an outlet, such as tubes or sleeves, which can be easily manufactured using any conventional production method.

The same reasoning applies in principle to the miniaturisation problem allegedly solved by claim 1 since it does not define the size of the elements. Moreover, paragraph [0035] of the patent stipulates that the lid can be used in combination with vessels of "higher volumes, for instance volumes up to several 1000's of liters". Hence the formulation of the objective technical problem concerning miniaturisation

does not align with the patent's teaching and the definition in claim 1.

5.2.6 Therefore the Board takes the view that the objective technical problem has to be formulated in a less ambitious manner. It can be seen as providing an alternative lid, which is basically in line with the opponent's argument:

"*providing an alternative method for producing sensor and controller elements including inlets or outlets for a bioreactor lid*"
(see its reply to appeal, point III.6.3).

5.2.7 3D printing is a well-known flexible manufacturing method for all possible types of parts and elements.

Moreover, using 3D-printed parts in the field of biosciences, in particular for bioreactors, is also well-known in the art, as evidenced by D9 (paragraph [0026]) and the various documents on file disclosing 3D-printed labware, such as impellers or caps for bioreactors, see by way of example the following documents:

D1: Figures 1, 2c, 6, 7, paragraphs [0047], [0098], [0101], [0164];
D2: Figures 1a, 1b, paragraphs [0155], [0167], [0168];
D3: Figure 11, paragraphs [0061], [0064], [0066], claim 12;
D12: abstract, Figure 1, paragraph highlighted in grey on page 55, left-hand column;
D13: abstract, Figure 1, paragraph highlighted in grey on page 938, left-hand column;
D15: Figure 2, paragraphs [0010], [0020].

Providing the required CAD drawing, converting the CAD file to an STL file, and setting the appropriate settings in a 3D-printing apparatus comes within the working routine of the skilled person, see D12 (see Figure 1 and section 3.1) and D13 (see chapter 3).

5.2.8 Starting from D9, and particularly considering the clear pointer in paragraph [0026] regarding 3D printing, the skilled person has a motivation to manufacture any part of the bioreactor of D9 by 3D printing. This includes parts such as tubes that constitute sensor and controller elements within the meaning of claim 1.

5.2.9 This assessment is independent of the definition of the skilled person, since a skilled person manufacturing bioreactor lids will be familiar with conventional manufacturing methods, such as injection moulding and 3D printing (see D12 and D13 as indicated above), as well as their respective advantages and disadvantages. Therefore the parties' discussions concerning the definition of the skilled person are not relevant in this regard.

5.2.10 The proprietor argued that the skilled person would not consider it obvious to manufacture sensor or controller elements by 3D printing, since

- 3D printing was not cheaper or faster
- 3D printing required careful redesign of the element to render it suitable for 3D printing, which the skilled person would definitely not do without proper motivation.

This argument is not convincing.

5.2.11 D9 already teaches that the bioreactor can be manufactured by 3D printing. Therefore the skilled person has an incentive to manufacture individual elements thereof by 3D printing, regardless of costs or time. Moreover, 3D printing is not so costly or time-consuming compared with injection moulding that the skilled person would be prevented from following the explicit teaching in D9. Indeed, D12 discloses that 3D printing is very cost-effective, see page 55, left-hand column, paragraph highlighted in grey.

Since the sensor and controller elements are not defined at all in claim 1, it is not clear why it is necessary to redesign the elements, such as a tube, before manufacturing them using 3D printing.

5.2.12 In summary, the Board considers that the subject-matter of claim 1 of the patent is obvious in view of D9.

6. Auxiliary request 1

6.1 In claim 1 of auxiliary request 1, the wording "sensor (5) or controller (6) elements for, during use, sensing or controlling one or more parameters of the bioreactor (2), in particular the bioreactor fluid (7)" has been replaced by "sensor (5) or controller (6) elements for, during use, sensing or controlling one or more parameters of the bioreactor fluid (7) in the bioreactor (2)".

6.2 As discussed above in point 1.2 under claim construction, the sensor and controller elements according to claim 1 are interpreted as identifiable elements that provide access to the bioreactor by providing inlets and outlets.

The amendment to claim 1 of auxiliary request 1 does not alter the line of argument presented regarding claim 1 as granted because the protrusions in the lid of D1 are suitable for the intended purpose of the sensor and controller elements according to claim 1 (i.e. sensing or controlling one or more parameters of the bioreactor fluid).

Furthermore, claim 1 relates to a lid configuration and is not limited by the shape or size of the reactor vessel, the level of its liquid content, or the length or shape of the further parts of the sensor and controller elements (even for a specific vessel with a specific liquid content, it is sufficient for the impeller, and not for the tube (controller element), into which the impeller is inserted, to reach the liquid).

6.3 Therefore the same arguments relating to D1 apply to claim 1 of auxiliary request 1 as to claim 1 as granted, and the Board concludes that the subject-matter of claim 1 of auxiliary request 1 lacks novelty over D1.

7. Auxiliary request 2

7.1 In addition to the amendments of auxiliary request 1, claim 1 according to auxiliary request 2 further includes the features of claims 2 and 3 as granted. That is, the 3D-printed sensor or controller elements comprise a 3D-printed agitation element, which, in turn, comprises a 3D-printed impeller.

7.2 D1 discloses a lid configuration into which 3D-printed shafts and 3D-printed impellers are inserted, see Figures 1, 2c, 6, 7, paragraphs [0098], [0101], [0164].

7.3 Therefore the same arguments relating to D1 apply to claim 1 of auxiliary request 2 as to claim 1 as granted, and the Board concludes that the subject-matter of claim 1 of auxiliary request 2 lacks novelty over D1.

8. Auxiliary request 3

8.1 Amendments

Claim 1 according to auxiliary request 3 is based on claim 15 as granted, with the option "sensor (5) or" deleted.

8.2 Novelty

Claim 1 defines a method of producing a lid configuration comprising the steps of connecting the one or more 3D-printed controller elements to the lid.

D1 discloses, with reference to Figure 8, a 3D-printed lid configuration comprising protrusions. These protrusions are formed during the 3D-printing step and are not connected to the lid after the printing step.

Therefore the subject-matter of claim 1 is novel over D1.

8.3 Inventive step

8.3.1 D9 is a suitable starting point for assessing inventive step of claim 1 since it discloses a bioreactor comprising a lid, and further indicates that it can be manufactured using 3D printing.

The lid configuration of D9 is formed by connecting various parts, such as connecting/inserting the fluid conduits 103 into the lid, see paragraphs [0033] and [0040].

8.3.2 The subject-matter of claim 1 differs from the manufacturing method implied by D9 in that controller elements are formed by 3D printing and comprise one or more 3D printed inlets or outlets.

8.3.3 As discussed above in point 5.2 with regard to claim 1 as granted, providing a lid configuration by using 3D-printed elements is obvious to a skilled person.

8.3.4 Even when considering the various advantages allegedly achieved through 3D printing according to the patent proprietor's arguments, such as a higher degree of configurability, customisability or freedom in labware design, the Board observes that these advantages are inherent and known for additive manufacturing methods, even in the field of bioscience and labware manufacturing, as evidenced, for example, by D12 on page 55, left-hand column in the paragraph highlighted in grey:

"*3D printing revolutionizes the way of working as it is in biotechnological laboratories today. It will enable scientists around the world to create* ***new individual labware*** *with ease and print them three dimensionally for direct use in the laboratory. This approach will lead to a* ***very time- and cost-efficient way*** *of optimizing already available labware or* ***create completely new designs.*** *This technical report presents practical examples that highlight the possibilities and reveal the great potential of using 3D printing in a dedicated biotechnology laboratory. Due to the fast*

progression of 3D printer technologies and their wider availability for laboratories, the labware consumable industry will start facing competition from ***self-developed labware****. Nevertheless, this industry can also benefit from* ***new, innovative designs*** *that will emerge from the science community*"
(highlighting by the Board).

8.4 In summary, the Board thus concludes that the subject-matter of claim 1 of auxiliary request 3 is obvious in view of D9 and does not meet the requirements of Article 56 EPC.

9. Auxiliary request 4

9.1 Auxiliary request 4 is based on a combination of claims 15 and 16 as granted (= claim 1 of auxiliary request 3 with the features of claim 2 of auxiliary request 3 incorporated into claim 1), i.e. the claimed method comprising the additional steps of

- determining the process or experiment to be carried out with the bioreactor (2),
- determining the 3D-printed controller (6) elements, in particular the 3D-printed inlets (11) or outlets (12) required for carrying out the experiment or process, and
- 3D-printing only those controller (6) elements required for carrying out the experiment or process.

9.2 The Board agrees with the opponent's argument that the additional steps in the method describe routine work for a skilled person when developing a bioreactor for a given bioprocess. This work includes considering alternative production methods for the required components. Moreover, it is also common practice in

prototyping and low-scale manufacturing processes to print only the parts needed for a particular task or project.

This common general knowledge in the context of 3D printing is briefly summarised and confirmed in D12, section 3.1, and in D13, chapter 3.

9.3 The subject-matter of claim 1 of auxiliary request 4 therefore lacks an inventive step in view of D9 and does not meet the requirements of Article 56 EPC.

10. Auxiliary request 5

10.1 Auxiliary request 5 is based on a combination of claims 15 to 17 as granted
(= claim 1 of auxiliary request 4 with the features of claim 2 of auxiliary request 4 incorporated into claim 1), i.e. the claimed method comprising the additional steps:

- wherein, prior to determining the 3D-printed controller (6) elements required for carrying out the experiment or process,
- a design is made of the bioreactor (2) for carrying out the process or experiment, and
- the 3D-printed controller (6) elements required for carrying out the experiment or process are determined from the design.

10.2 Admittance

Auxiliary request 5 was filed for the first time in the appeal proceedings together with the statement of grounds of appeal.

As mentioned above, the request follows on from auxiliary request 4 and is based on granted claims.

The Board considered the filing of auxiliary request 5 to constitute a response to the reasoning in the contested decision, and exercised its discretion to admit the auxiliary request under Article 12(4) RPBA.

10.3 Inventive step

The Board agrees with the opponent's argument that the additional method steps according to claim 1 of auxiliary request 5 also describe trivial method steps that fall within the routine work of the person skilled in the art when developing a bioreactor for a given bioprocess using 3D printing, see D12, section 3.1, and D13, chapter 3. In this context, the claimed method for developing a bioreactor for a given process is no different from the steps required for on-demand 3D printing. While the purpose and commercial interest may differ, this does not translate into the claimed subject-matter.

10.4 Therefore the subject-matter of claim 1 of auxiliary request 5 is obvious in view of D9 and does not meet the requirements of Article 56 EPC.

11. Auxiliary request 6

11.1 In addition to the amendments of auxiliary request 2, claim 1 according to auxiliary request 6 further includes the feature of claim 8 as granted, namely that the lid is 3D-printed.

11.2 D1 discloses that the cover plate 50 (a lid configuration) is 3D-printed, see paragraph [0164].

11.3 Therefore the same arguments relating to D1 apply to claim 1 of auxiliary request 6 as to claim 1 as granted, and the Board concludes that the subject-matter of claim 1 of auxiliary request 6 lacks novelty over D1 and does not meet the requirements of Article 54 EPC.

12. Auxiliary requests 7 to 9 - admittance

12.1 Claim 1 of each of auxiliary requests 7 to 9 is directed to a "Single use" of a bioreactor as defined in claim 1 according to auxiliary requests 1, 2 and 6. Hence claim 1 of each of auxiliary requests 7 to 9 is based on the use claim according to claim 14 as granted, with the amendments according to claim 1 of auxiliary requests 1, 2 and 6, wherein the term "Single" has been added.

12.2 Auxiliary requests 7 to 9 were filed for the first time in the appeal proceedings together with the statement of grounds of appeal.

The admission of these requests falls within the discretion of the Board, see Article 12(4) RPBA.

12.2.1 Due to the change in claim category from a lid configuration (claim 1 of auxiliary requests 1, 2 and 6) to a method (claim 1 of auxiliary requests 3 to 5) and finally to a "Single use", these requests are not convergent with the previous requests.

Moreover, the topic to be discussed shifts completely from the obviousness of a specific lid configuration and its manufacturing process to the intended use of an entire bioreactor.

This change of topic is not predictable from the patent as a whole. The intended "single use" of the bioreactor is not disclosed in either the "object of the invention" (paragraphs [0012] and [0013] of the patent) or in the "detailed description" (paragraphs [0048] to [0059] of the patent), nor in the claims as granted. Also in the remaining description, such as in paragraph [0017], it is only specified that the bioreactor components that are continuously or frequently exposed to a gas or fluid can be advantageously made "single-use".

Therefore changing claim category and making further amendments creates a completely fresh case. This is not the purpose of the appeal proceedings, see Article 12(2) RPBA. Auxiliary requests 7 to 9 should have been filed and discussed in opposition proceedings (Article 12(6) RPBA) to allow for a decision of the opposition division that could be reviewed by the Board.

12.2.2 Moreover, auxiliary requests 7 to 9 are *prima facie* not suitable for changing the assessment of novelty in view of D1, since any bioreactor can be disposed of after a single use.

D1 discloses a 3D-printed lid configuration for a bioreactor and thus makes use of the same type of materials as implied by claim 1 of auxiliary requests 7 to 9 (3D-printable plastics). Moreover, the bioreactor as defined in claim 1 comprises 3D-printed parts to the same extent as the bioreactor in D1, i.e. for the lid configuration. Therefore the features defined in claim 1 of auxiliary requests 7 to 9 do not provide a distinction over the possible single use of the

bioreactor according to D1. Interpreting the wording of claim 1 in a technically sensible manner, the skilled person would consider disposing of the bioreactor as far as 3D-printed parts are involved. A skilled person would not consider that any part of the bioreactor such as motor, bearings, sensors and further analytic equipment would have to be single-use. The same applies when interpreting D1, regardless of the teaching in paragraph [0008] of D1 that certain parts of the bioreactor can also be autoclaved, the initial sterilisation of a bioreactor before use being necessary no matter whether this bioreactor (or its lid) is disposed of after a single use or not.

12.2.3 In view of the change of focus to be discussed and the *prima facie* lack of success in overcoming the outstanding objections, the Board exercised its discretion not to admit auxiliary requests 7 to 9 (Article 12(4) and (6) RPBA).

13. Auxiliary request 10

13.1 Auxiliary request 10 corresponds to auxiliary request 9, which underlies the contested decision and was found by the opposition division to meet the requirements of the EPC.

In addition to the amendment of auxiliary request 1, claim 1 according to auxiliary request 10 further includes the feature disclosed on page 5, line 10 of the application as filed (paragraph [0019] of the patent):

"*wherein an inlet end (121, 122) of an outlet (12) has a circumferential wall and one or more openings in its circumferential wall.*"

13.2 This feature further distinguishes the claimed subject-matter from D9, since D9 does not describe an opening in the circumferential wall of the fluid conduits depicted in its figures.

13.3 The opponent argued that the added feature was known from D9, since elements 103 ("fluid conduits", see paragraphs [0033], [0040] and [0045]) as depicted in the figures of D9 comprised darker/shaded zones, which the skilled person would interpret as frits (filters) or spargers.

However, this argument is not convincing, since hypothetical alternatives and possible embodiments based on an assessment of probability are not taken into account for assessing novelty. Neither the cited paragraphs of D9 nor its figures disclose that the darker/shaded zones of the fluid conduits comprise openings. Indeed, the shading may just indicate a roughened surface. The additional question of whether any type of opening such as the pores in a sparger for introducing gas into the bioreactor's liquid are also suitable as outlets as required by claim 1 can thus be left unanswered.

13.4 Therefore the subject-matter of claim 1 differs from that of D9 in that the lid configuration comprises a 3D-printed controller element, wherein the inlet end of a 3D-printed outlet has a circumferential wall and one or more openings in that circumferential wall.

13.5 The patent proprietor identified the objective technical problem as facilitating the production of complex outlet shapes through 3D printing to enable the suction of specific fluids, such as supernatant

liquids, from the bioreactor fluid, see paragraph [0019] of the patent.

However, this formulation of the objective technical problem seems to be too ambitious in view of the broad scope of claim 1.

In order to enable the withdrawal of a specific liquid, the length of the controller element and the position of the hole must be adapted to the size of the vessel and its intended filling level, and so on.

However, neither the precise location of the opening in the inlet end of the 3D-printed outlet nor the length or shape of the controller element nor the corresponding size or height of the bioreactor or its intended filling level is defined in claim 1. Therefore it is not plausible that specific fluids, such as supernatant liquids, can be sucked from any bioreactor by a lid configuration comprising a controller element with one or more holes at its inlet end of an outlet.

Moreover, the problem of providing a method which facilitates the production of complex outlet shapes is linked to the 3D-printing process rather than to the actual shape of an inlet end of an outlet provided in the lid configuration according to claim 1.

13.6 Therefore the Board takes the view that the objective technical problem has to be formulated in a less ambitious manner. It can be seen as being to provide an alternative lid configuration which also allows fluid to be sucked in.

13.7 D9 discloses a lid configuration comprising fluid conduits (elements 103, see paragraphs [0033], [0040] and [0045]).

The general statement in paragraph [0026] of D9, which refers to the manufacture of the bioreactor by 3D printing, provides motivation for also forming tubes, such as the fluid conduits of D9, using 3D printing. The variation in the position of the suction hole(s) (terminal and/or in the circumferential wall) is considered to be within the skillset of the skilled person.

The skilled person would therefore routinely consider conventional designs of fluid outlets, which are also aimed at by the patent. As demonstrated by Figure 5 of the patent (see the opening 121 "inlet end of outlet"), the one or more openings defined in claim 1 can be formed by a single opening that extends partially from the bottom end of the tube into the circumferential wall.

Tubes with an opening as depicted in Figure 5 of the patent are well known and commonly used by the skilled person, e.g. to facilitate insertion into a tubular structure.

Therefore it is obvious to modify the lid configuration of the bioreactor of D9 by using a 3D-printed fluid conduit with an opening as demonstrated in Figure 5 of the patent in order to provide an alternative lid configuration.

The subject-matter of claim 1 of auxiliary request 10 is therefore considered obvious in view of D9 and does not meet the requirements of Article 56 EPC.

14. Auxiliary request 11 - amendments (Article 123(2) EPC)

14.1 In addition to the amendments of auxiliary request 10, the wording "w*herein a top portion of the circumferential wall facing the lid (3) or a bottom portion of the circumferential wall facing a bottom of the vessel (4) comprises the one or more openings*" has been added to claim 1.

14.1.1 This amendment extends beyond the teaching on page 5, lines 9 to 12 as originally filed (published as WO 2020/036489 A1), which reads:

"*As a further example, an inlet end of an outlet may have one or more openings in its circumferential wall, e.g. only at the top portion (the portion facing the lid) or only at the bottom portion (the portion facing a bottom of the vessel).*"

While the application does disclose the added features as examples (see the term "e.g." at the beginning of the sentence insertion), it nevertheless discloses an embodiment on page 5, lines 9 to 12 wherein the one or more openings are present **only** at either the top or bottom portion.

By omitting the restrictive word "only" from both alternatives, the newly generated subject-matter extends beyond the teaching of the application as filed, since claim 1 now covers lid configurations where not all, but only some, of the openings are located in the top or bottom portion, contrary to the disclosure on page 5, lines 9 to 12.

It is noted that Figure 4 shows openings only located in the bottom portion, but - moreover - only specifically in the upper side thereof. Hence the disclosure provided by Figure 4 and the accompanying specification does not provide a basis for the more general definition in amended claim 1 either.

14.1.2 The amendments to claim 1 therefore do not meet the requirement of Article 123(2) EPC.

15. Auxiliary requests 12 to 14

15.1 Claim 1 of each of auxiliary requests 12 to 14 has been amended to include the wording "*wherein the one or more 3D-printed sensor elements (5) comprise a temperature sensor (5)*".

It follows that claim 1 of each of auxiliary requests 12 to 14 requires the temperature sensor to be 3D-printed.

Hence the amendment to claim 1 of each of auxiliary requests 12 to 14 changes the claim interpretation because amended claim 1 requires that the complete temperature sensor must be 3D-printed, not only an element thereof.

However, the application does not disclose how an entire temperature sensor can be obtained by 3D printing.

Therefore the invention as defined by claim 1 of each of auxiliary requests 12 to 14 cannot be realised by the skilled person and does not meet the requirements of Article 83 EPC.

16. Auxiliary request 15

16.1 Claim 1 is based on claim 1 as granted and further specifies that "the vessel has a volume of less than 3 liters" (see page 5, lines 18 to 20 of the application, or paragraph [0020] of the patent) and that the one or more 3D-printed inlets (11) or outlets (12) comprise "3D-printed coaxial inlet (11) and/or outlet (12) tubes extending into the vessel" (see page 5, lines 16 to 27 of the application, paragraph [0020] of the patent).

16.2 Building on the discussion of inventive step starting from D9 with regard to the main request (claims as granted), it can be seen that the volume of the vessel does not provide a limitation to the claimed lid configuration since a lid of a specific size can be placed on a vessel of any height and thus varying volume.
Moreover, D9 discloses that the vessel of the bioreactor can have a volume of less than 3 liters, see paragraph [0049]:

"*A vessel may have any suitable size for containing a liquid, biological object, or other entity. For example, the vessel may have a volume from about 0.1 L and about 0.5 L, about 0.1 L and about 1 L, about 1 L and about 5 L, and from about 1 L and about 10 L. […] The volumes may depend on the particular use of the bioreactor*".

It follows that the definition of the vessel's volume does not distinguish the claimed subject-matter further from the disclosure of D9.

However, D9 does not disclose coaxial tubes extending into the vessel.

16.3 Therefore the subject-matter of claim 1 differs from the disclosure of D9 in that the lid comprises 3D-printed controller elements comprising one or more 3D-printed inlets or outlets comprising 3D-printed coaxial inlet (11) and/or outlet (12) tubes extending into the vessel.

16.4 Paragraph [0020] of the patent describes the effect that coaxial tubes provide more functionality inside a small bioreactor.

The Board therefore takes the view that the objective technical problem can be seen as being to provide a lid configuration that allows for greater functionality inside the bioreactor, which corresponds to the problem as formulated by the opponent of providing a lid configuration for a small bioreactor with limited space.

16.5 As discussed above in relation to claim 1 as granted, D9 already suggests 3D printing as a possible manufacturing method, and the advantages of 3D manufacturing are known to the skilled person, as evidenced, for example, by D12 and D13.

Nevertheless, the opponent has not identified a single document disclosing a lid configuration for a bioreactor comprising a coaxial tube.

The opponent submitted documents D29 and D30 in order to demonstrate that the skilled person was aware that coaxial tubes could be manufactured using 3D printing.

Even if it were accepted that the skilled person would expect that coaxial tubes can be manufactured by 3D printing, there is no reason why, starting from the lid configuration of D9, the skilled person would use coaxial tubes for the fluid conduits 103 as shown in Figure 3 of D9.

The conduits 103 are configured for attaching to a fluid conduit of a biological object (e.g. a trachea of a lung or a ventricle or aorta of a heart), as detailed in paragraph [0033] of D9. In this context, using a coaxial tube does not appear to be advantageous, since a fluid conduit of a biological object is not coaxial. Hence a coaxial tube would not provide any benefit in the context of D9.

Furthermore, the opponent has not provided any argument as to why the skilled person would consider using a coaxial tube in the context of D9 besides the rather general statement that coaxial tubes are not rocket science, but rather known components with predictable benefits.

However, no document discloses the common use of coaxial tubes in bioreactors. The further documents D29 and D30, cited by the opponent, do not disclose the use of a coaxial tube in a bioreactor either, but instead relate to a rocket engine (D29) and an air-blast microfluidic nozzle (D30).

Therefore the subject-matter of claim 1 of auxiliary request 15 is considered not to be obvious starting from D9 and meets the requirements of Article 56 EPC.

16.6 The same reasoning applies to the remaining claims of auxiliary request 15.

16.7 As documents D29 and D30 are not relevant to the present decision, it is not necessary to decide on the admittance of these late-filed documents under Article 13(2) RPBA.

17. Adapted description

The opponent did not object to the adapted description pages filed by the patent proprietor at the end of the oral proceedings.

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 in amended form based on
   - claims 1 to 17 of auxiliary request 15, filed with the proprietor's grounds of appeal on 26 June 2023
   - an adapted description, pages 1 to 14, filed during the oral proceedings on 30 July 2025
   and
   - figures 1 to 6 in the specification of the patent as granted.

The Registrar: The Chairman:

C. Spira C. Herberhold

Decision electronically authenticated