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**Datasheet for the decision
of 27 February 2025**

Case Number: T 0183/23 - 3.3.08

Application Number: 09161982.5

Publication Number: 2141224

IPC: C12M1/10, C12M1/24

Language of the proceedings: EN

Title of invention:

Stirred tank bioreactor

Patent Proprietor:

EMD Millipore Corporation

Opponent:

Sartorius Stedim Biotech GmbH

Headword:

Stirred tank bioreactor/EMD MILLIPORE CORPORATION

Relevant legal provisions:

EPC Art. 123(2)

RPBA 2020 Art. 12(4), 12(6)

Keyword:

Amendments - allowable (no)

Amendment to case - amendment within meaning of Art. 12(4) RPBA
2020 (yes) - reasons for submitting amendment in appeal
proceedings (no)

Decisions cited:

G 0002/10, T 1919/17, T 1776/18, T 1913/19, T 2843/19,
T 1692/21, T 1295/22



Beschwerdekammern

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Case Number: T 0183/23 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 27 February 2025

Appellant: EMD Millipore Corporation
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
18 November 2022 concerning maintenance of the
European Patent No. 2141224 in amended form**

Composition of the Board:

Chair R. Winkelhofer
Members: R. Morawetz
M. Montrone

Summary of Facts and Submissions

- I. European patent No. 2 141 224 B1 ("the patent") was granted for European patent application No. 09 161 982.5, published as EP 2 141 224 A1.
- II. An opposition was filed against the granted patent. The patent was opposed in its entirety under Article 100(a) EPC on the ground of lack of inventive step (Article 56 EPC) and under Article 100(c) EPC.
- III. By an interlocutory decision, the opposition division decided that the patent in amended form on the basis of the set of claims of auxiliary request 4, filed as auxiliary request 3a with the submission dated 11 August 2022, and the invention to which it relates met the requirements of the EPC. With respect to the higher-ranking claim requests, the opposition division held, *inter alia*, that claim 1 of the main request and of auxiliary requests 1 and 2 contravened Article 123(2) EPC.
- IV. The patent proprietor ("appellant") appealed this decision. With their statement setting out the grounds of appeal ("SGA"), they submitted sets of claims of a main request and auxiliary requests 1 and 2 and replacement pages of the description for the main request/auxiliary request 1 and for auxiliary request 2, with the main request and auxiliary request 1 corresponding to auxiliary requests 1 and 2 before the opposition division and with auxiliary request 2 being new.

V. Claim 1 of the main request reads as follows (labels [F1] to [F7a] have been added to indicate the individual feature groups of claim 1):

[F1] "A bioreactor (2) for culturing, fermenting or processing a biomass comprising:
[F2] a presterilized, disposable housing
[F3] having a top (16;16a) and a body (22), the body (22) having an interior space,
[F4a] wherein the housing is rigid in that it is made of a molded plastic
[F4b] or is semi-rigid in that the top (16a) and a bottom (28a) are made of molded plastic and a side wall (26a) is made of a flexible plastic;
and
[F5] one or more ports (30,32) formed in the top (16;16a) and/or the body (22) respectively of the housing and in fluid communication with the interior space of the body (22);
[F7] wherein the body (22) is sealably attached to the top (16;16a)
[F7a] by a mechanical seal formed by a rubber seal, in the form of a rubber gasket, and clips, and
[F6] wherein at least one port (30,32) is provided in the body (22) at a level below a normal liquid/air interface of the housing."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the "or" alternative in the expression "*and/or the body (22)*" in feature F5 is deleted.

Claim 1 of auxiliary requests 2 differs from claim 1 of auxiliary request 1 in that feature F4b is also deleted.

- VI. The opponent ("respondent") filed a reply to the appeal.
- VII. The board issued a communication under Article 15(1) RPBA and held oral proceedings in accordance with the parties' requests.
- VIII. The arguments of the parties relevant for the decision are dealt with in detail in the reasons for the decision.
- IX. On substance, the appellant requests that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the main request or one of auxiliary requests 1 and 2.
- X. The respondent requests that the appeal be dismissed.

Reasons for the Decision

Main request

Amendments (Articles 100(c) and 123(2) EPC) - claim 1

- 1. Reference is made below to the page and line numbering of the A1 publication (section I., above), referred to as the "application as filed".
- 2. The opposition division held that claim 1 (of then auxiliary request 1) contravened Article 123(2) EPC because feature F4b of claim 1 had no basis in the application as filed.
- 3. On appeal, the appellant maintained that feature F4b of claim 1 met the requirements of Article 123(2) EPC.

4. The standard for assessing compliance with the requirement of Article 123(2) EPC is the standard set out in decision G 2/10 (OJ EPO 2012, 376, Reasons 4.3), also known as the gold standard. Amendments are only permitted within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed. After the amendment, the skilled person may not be presented with new technical information (ibid., Reasons 4.5.1).

5. It is undisputed that claim 1 of the main request is based on claim 1 as filed. That claim reads as follows:

"1. A bioreactor (2) for culturing, fermenting or processing a biomass comprising:
a presterilized, disposable housing made of semi-rigid or rigid plastic, said housing having a top (16) and a body (22), the body (22) having an interior space; and one or more ports (30,32) formed in the top (16) and/or the body (22) respectively of the housing and in fluid communication with the interior of the body (22)."

6. The feature relating to the housing of the bioreactor was amended and reads as follows in claim 1 of the main request:

"1. A bioreactor ... comprising:
a presterilized, disposable housing ~~made of semi-rigid or rigid plastic, said housing~~ having a top (16;16a) and a body (22), the body (22) having an interior space, wherein the housing is rigid in that it is made of a molded plastic or is semi-rigid in that the top (16a) and a bottom (28a) are made of molded plastic and a side wall (26a) is made of a flexible

plastic;..." (Amendments compared to claim 1 as filed are shown by underlining and strike-through.)

7. The appellant conceded that claim 1 as filed assigns the attributes "*rigid*" and "*semi-rigid*" to the plastic material and not to the housing of the bioreactor. However, they submitted, based on paragraphs [0008] and [0054] of the application, that the terms "*rigid*" and "*semi-rigid*" were also used to describe the resulting property of the bioreactor/housing as a result of it being formed from plastic material and that the terms "*molded*" and "*rigid*" were used as synonyms to describe the properties of the plastic body or its parts that form the housing. Therefore, they submitted, paragraph [0034] of the application as filed referred to an example of a "*rigid*" bioreactor/housing whereas paragraph [0035] of the application as filed referred to an example of a "*semi-rigid*" bioreactor/housing.
8. This is not persuasive for the reasons set out below.
9. Paragraph [0008] of the application as filed discloses that "*[t]he present invention is a disposable bioreactor formed of molded plastic so that it can be rigid or at least semi-rigid ...*", and paragraph [0010] of the application as filed - which corresponds to claim 1 as filed - discloses that the disposable housing is "*made of a plastic selected from the group consisting of semi-rigid and rigid plastic*". The terms "*molded*" and "*rigid*" are evidently not used as synonyms in paragraphs [0008] and [0010] of the application as filed.
10. Paragraph [0054] of the application as filed states that "*[a]n additional advantage to a molded or rigid formed plastic body is that heating or cooling blankets*

can be easily attached to them". Even if "molded" and "rigid" in paragraph [0054] were presented as synonyms, and not merely as alternatives, the appellant could not explain why the skilled person would ignore the teaching in paragraph [0008] of the application as filed. Therefore, the skilled person would not derive directly and unambiguously from the application as filed as a whole that the terms "molded" and "rigid" are used as synonyms to describe the properties of the bioreactor housing.

11. Contrary to the appellant's assertion, paragraph [0034] of the application does not refer to an example of a "rigid" bioreactor/housing. Instead, that paragraph merely discloses that "[p]referably, the body is made of a single piece of molded plastic". Paragraph [0034] of the application as filed is silent as to whether the body is rigid or semi-rigid. It cannot, therefore, be derived directly and unambiguously from paragraph [0034] of the application that the bioreactor/housing would be necessarily rigid. Consideration of the application as a whole further confirms this assessment as paragraph [0008] of the application as filed discloses that a bioreactor formed from molded plastic can be either rigid or semi-rigid.

12. Paragraph [0035] of the application does not refer to a "semi-rigid" bioreactor/housing either. Instead, it discloses that "[i]n another alternative arrangement shown in Figure 5, only the top 16a and bottom 28a are made of molded plastic and the one side wall 26a in this embodiment is formed of flexible plastic such as a plastic film". Like paragraph [0034], paragraph [0035] of the application as filed is silent as to whether the top and bottom are rigid or semi-rigid. The arrangement as a whole is also not described as being semi-rigid.

It cannot therefore be derived directly and unambiguously from paragraph [0035] of the application that the disclosed arrangement constitutes a semi-rigid housing. Consideration of the application as a whole confirms this assessment.

13. Therefore, the respondent is right that nothing in the application as filed connects the term "*semi-rigid*" to a combination of a top and bottom made of a molded plastic and a side wall made of a flexible plastic.
14. At the oral proceedings before the board, the appellant put forward a further line of argument in support of feature F4b. They argued that the expression "*in that*" had been used only once in the description of the application, namely in paragraph [0046]. In the context of paragraph [0046] of the application, this expression meant "*wherein*" and not "*as a result of*" (corresponding to the German terms "*wobei*" and "*dadurch, dass*" as used by the appellant in the oral proceedings). Therefore, in the context of feature F4b, the expression "*in that*" also had to be understood as "*wherein*". Feature F4b thus related to a semi-rigid housing, irrespective of how it was manufactured. Such a semi-rigid housing was disclosed in paragraph [0008] of the application. Paragraph [0035] of the application as filed disclosed the arrangement shown in Figure 5, which had a rigid top and bottom and a flexible side wall and which was therefore semi-rigid.
15. For the reasons set out below, this is not persuasive either.
16. First, as correctly outlined by the respondent, feature F4b, read alone, is clear and means that the bioreactor is semi-rigid as a result of, i.e. because, the top

(16a) and a bottom (28a) are made of molded plastic and a side wall (26a) is made of a flexible plastic.

17. Second, paragraph [0046] does not concern a semi-rigid bioreactor or an arrangement comprising a top (16a) and a bottom (28a) made of molded plastic and a side wall (26a) made of a flexible plastic. In fact, feature F4b is not based on paragraph [0046] of the application. Although the application as a whole must be considered in assessing the requirements of Article 123(2) EPC (point 4. above), the respondent is also right that the skilled person has no reason to turn specifically to paragraph [0046] of the application, let alone re-interpret feature F4b in light of the use of the conjunction "*in that*" in the context of that paragraph.

18. Third, contrary to the appellant's assertion, paragraph [0008] of the application does not disclose a semi-rigid bioreactor as such (see point 9. above). The appellant could also not explain why the disclosure in paragraph [0008] should be generalised to a semi-rigid bioreactor as such, regardless of how it is made. This is all the more so as the appellant also considered that paragraph [0008] of the application "*assigns the attributes 'rigid and semi-rigid' to properties of the **resulting** bioreactor (i.e. the housing) as a result of it being formed of molded plastic*" (SGA, page 9, second paragraph, emphases in the original).

19. Finally, paragraph [0035] of the application as filed discloses that the arrangement shown in Figure 5 has a molded - not a rigid - top and bottom and a side wall formed of flexible plastic and does not associate this arrangement with semi-rigid properties (see also point 12. above).

20. To conclude, it cannot be derived directly and unambiguously from the whole of the application as filed that a bioreactor housing in which *"the top (16a) and a bottom (28a) are made of molded plastic and a side wall (26a) is made of a flexible plastic"* has *"semi-rigid"* properties. Feature F4b therefore presents the skilled person with new technical information which they cannot directly and unambiguously derive from the application as filed.
21. The subject-matter of claim 1 extends beyond the content of the application as filed, and, as correctly found by the opposition division, the claim thus contravenes Article 123(2) EPC.

Auxiliary request 1 - claim 1

Amendments (Articles 100(c) and 123(2) EPC) - claim 1

22. Claim 1 likewise comprises feature F4b. The conclusions set out above for claim 1 of the main request apply equally to claim 1 of auxiliary request 1, which thus also contravenes Article 123(2) EPC.

Auxiliary request 2

Admittance and consideration

23. Auxiliary request 2 was first submitted with the appeal. Its admission and consideration was disputed by the respondent.
24. The appellant argued that the submission of auxiliary request 2 was not an amendment within the meaning of Article 12(4) RPBA because it was essentially the same as auxiliary request 3b submitted on 11 August 2022, which had been admissibly raised and maintained in the

proceedings leading to the decision under appeal.

25. However, as correctly set out by the respondent, claim 1 of auxiliary request 3b is different from claim 1 of auxiliary request 2. Claim 1 of auxiliary request 3b is directed to a bioreactor "*wherein the housing is rigid in that it is made of a molded semi-rigid or rigid plastic*", while claim 1 of auxiliary request 2 is directed to a bioreactor "*wherein the housing is rigid in that it is made of a molded plastic*". In addition, the feature "*and wherein the body (22) includes a port adjacent a portion of the body (22) farthest from the top (16) and the port farthest from the top include an air diffuser*" present in claim 1 of auxiliary request 3b has been deleted from claim 1 of auxiliary request 2.
26. Auxiliary request 2 therefore is not essentially the same as auxiliary request 3b. It constitutes an amendment of the appellant's case within the meaning of Article 12(4) RPBA which may be admitted into the proceedings only at the board's discretion. Pursuant to the non-exhaustive list of criteria in Article 12(4) RPBA, the boards are to exercise their discretion in view of, *inter alia*, the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal and the need for procedural economy.
27. Furthermore, pursuant to Article 12(6) RPBA, the boards must not admit requests, facts, objections or evidence which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

28. When they filed auxiliary request 2, the appellant did not provide any reasons as to why auxiliary request 2 could not have been filed during opposition proceedings, nor can any such reasons be inferred from the file.
29. Only at the oral proceedings before the board did the appellant explain that they had decided to submit auxiliary request 2 only on appeal because they had already submitted 15 claim requests in the opposition proceedings. In addition, auxiliary request 2 had been filed at the first opportunity in reaction to the decision under appeal. It should be admitted out of fairness towards the appellant as Article 12(6) RPBA was generally unfair to patent proprietors. Finally, no further examination was necessary since, with respect to auxiliary request 1, only an alternative had been deleted from claim 1.
30. None of these arguments are persuasive for the following reasons.
31. First, the appellant did not elaborate in what way auxiliary request 2 was a reaction to the decision under appeal. They did not argue that auxiliary request 2 was filed in response to a late turn of events in the opposition proceedings or a new reasoning of the opposition division in the decision under appeal to which they had not had time to react (see e.g. [T 1919/17](#), Reasons 25 and [T 1913/19](#), Reasons 16: Articles 12 and 13 RPBA mainly serve to allow account to be taken of changes of fact or the subject-matter of the appeal proceedings, within narrow limits; they do not allow the subsequent submission of essential elements of the appeal or the requests

filed).

32. Second, it is well established in the case law of the boards that Article 12(6), second sentence, RPBA expresses and codifies the principle that each party should submit all facts, evidence, arguments and requests that appear relevant as early as possible to ensure a fair, speedy and efficient procedure (e.g. see [T 1692/21](#), Reasons 53; [T 1776/18](#), Reasons 4.5.7; [T 2843/19](#), Reasons 3.3; [T 1295/22](#), Reasons 3.34). An appellant is not at liberty to bring about the shifting of the case to the appeal proceedings as they please and so compel the board either to give a first ruling on the critical issues or to remit the case to the opposition division (Case Law of the Boards of Appeal, 10th edn., 2022, V.A.4.3.1). Accordingly, Article 12(6) RPBA applies equally to all parties, and fairness towards all parties (i.e. a fair trial) is a cornerstone of the RPBA, just as is procedural economy, and thus is something already built into the system of the RPBA to fairly balance these principles.
33. Third, claim 1 of auxiliary request 2 lacks the feature "*wherein the body (22) includes a port adjacent a portion of the body (22) farthest from the top (16) and the port farthest from the top includes an air diffuser*" and is therefore broader than claim 1 of auxiliary request 4, which was held allowable in the decision under appeal.
34. Contrary to the appellant's assertion, the fact that with respect to auxiliary request 1, only an alternative was deleted from claim 1 does not mean that no further examination is required. Inventive step and sufficiency of disclosure of auxiliary request 1 were not examined by the opposition division. Only auxiliary

request 4 was fully examined by the opposition division, but auxiliary request 2 is broader than auxiliary request 4 (see previous point).

35. The appellant has foregone an examination by the opposition division of the subject-matter pursued in auxiliary request 2, and examination of that subject-matter on appeal is at odds with the purpose of appeal proceedings as set out in Article 12(2) RPBA, namely to review the decision under appeal in a judicial manner.

36. There is therefore no reason to admit and consider auxiliary request 2 in the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



C. Rodríguez Rodríguez

R. Winkelhofer

Decision electronically authenticated