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Datasheet for the decision of 11 January 2022

Case Number: T 0269/20 - 3.3.05

Application Number: 07795356.0

Publication Number: 2046941

IPC: C12M1/36

Language of the proceedings: EN

Title of invention:
IMPROVED DISPOSABLE BIOREACTOR VESSEL PORT

Patent Proprietor:
Finesse Solutions, Inc.

Opponents:
SARTORIUS STEDIM BIOTECH GMBH
Mettler-Toledo GmbH

Headword:
Bioreactor vessel port/FINESSE

Relevant legal provisions:
EPC Art. 54(1), 54(2), 56, 123(2)
RPBA 2020 Art. 12, 13

Keyword:
Novelty - main request (no)
Amendments - first auxiliary request - allowable (no)
Inventive step - second auxiliary request (yes) - non-obvious modification

Decisions cited:
T 0892/05, T 2159/17

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0269/20 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 11 January 2022

Appellant: (Opponent 2)	Mettler-Toledo GmbH Im Langacher 44 8606 Greifensee (CH)
Representative:	Leinweber & Zimmermann Patentanwalts-PartG mbB European Patent Attorneys Viktualienmarkt 8 80331 München (DE)
Respondent: (Patent Proprietor)	Finesse Solutions, Inc. 3501 Leonard Ct. Santa Clara, CA 95054 (US)
Representative:	J A Kemp LLP 80 Turnmill Street London EC1M 5QU (GB)
Party as of right: (Opponent 1)	SARTORIUS STEDIM BIOTECH GMBH August-Spindler-Strasse 11 37079 Göttingen (DE)
Representative:	Müller-Boré & Partner Patentanwälte PartG mbB Friedenheimer Brücke 21 80639 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 December 2019 rejecting the opposition filed against European patent No. 2046941 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	E. Bendl
Members:	T. Burkhardt
	P. Guntz

Summary of Facts and Submissions

I. The appeal filed by opponent 2 (appellant) lies from the opposition division's decision to reject the oppositions against European patent EP 2 046 941 B.

II. The following documents were among those discussed at the opposition stage:

F1 WO 2005/068059 A1

F3 US 4,163,903 A

F5 US 2006/0240546 A1

F7 US 2006/0131765 A1

F20 T.A. Osswald, G. Menges, "Material Science of Polymers for Engineers", 3rd edition, 2010, pages 13-14

III. The opposition division had come to the conclusion, among other things, that the claims as granted fulfil the requirements of Article 54 EPC in view of documents F1/F7.

IV. With its submission dated 13 April 2021, the appellant additionally filed, *inter alia,* document B1:

B1 T.A. Osswald, G. Menges, "Materials Science of Polymers for Engineers", 2nd edition, 2003, pages 10-12

V. Opponent 1 has not filed any submission as to the substance of the appeal and is a party as of right.

VI. With its submission dated 10 January 2022, the appellant further submitted the following document:

B5 B. Elliott, M. Gilmore, "Fiber Optic Cabling", 2nd edition, Newnes, 2002, pages 102-103

VII. With the reply to the grounds of appeal the respondent (patent proprietor) maintained the claims as granted as its main request and submitted seven auxiliary requests.

VIII. The independent claim of the main request reads as follows:

"1. A port for use with a disposable bioreactor vessel, said port comprising:

i) a flexible base member comprising a hollow tubular portion and a base plate configured to be sealingly affixed to a hole in the wall of said bioreactor vessel;
ii) a hollow, generally tubular bushing member for containing electrical, and/or optical, and/or acoustic and/or magnetic and/or microfluidic and/or chemical monitoring components which bushing member fits inside the bore of the tubular portion of said base member, both said base member and said bushing member providing access to the contents of said bioreactor vessel;
iii) a monitoring assembly inserted into said bushing member which assembly comprises means for providing incoming optical and/or electrical signals and means for collecting and transmitting measurement signals resulting from the interaction of said incoming optical and/or electrical signals with the contents of said bioreactor; and

iv) a cover which maintains the position and alignment of components ii) and iii) relative to said base member."

As compared with claim 1 of the main request:

- claim 1 of the first auxiliary request additionally contains in item iii), after "... with the contents of said bioreactor,", the feature "wherein the monitoring assembly does not come in contact with the contents of said bioreactor", and

- claim 1 of the second auxiliary request contains, instead of the passage inserted into claim 1 of the first auxiliary request, the feature "wherein said monitoring assembly or the components thereof are keyed so as to permit insertion into said bushing in only one orientation".

Claims 2 to 12 of the second auxiliary request relate to preferred embodiments of claim 1.

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

Document B1 should be considered, since it was an earlier edition of F20, which illustrated the common general knowledge of the skilled person.

B5 was only found just before the oral proceedings at the appeal stage. However, it should be considered since it illustrated the common general knowledge of the skilled person.

The main request did not fulfil the requirements of Article 54 EPC.

The first auxiliary request did not meet the requirements of Article 123(2) EPC. Indeed, the "reader" on page 10 as originally filed was different from the "monitoring assembly" in claim 1. Without a specification of the material used for the reader in claim 1, moreover, the modification amounted to an intermediate generalisation.

The second auxiliary request should not be considered, since it diverged from the first auxiliary request.

Moreover, the second auxiliary request did not meet the requirements of Article 123(2) EPC. Specifically:
- the deletion of the alternative of a rigid base member shifted the meaning of the remaining option of a flexible base member,
- the result of the use of a flexible material was not inserted into claim 1 as well, and
- the use of a flexible material did not necessarily yield a flexible base member.

The second auxiliary request did not meet the requirements of Article 54 EPC.

The second auxiliary request did not meet the requirements of Article 56 EPC in view of each of F1/F7 and F5 in combination with the common general knowledge as illustrated by B5.

X. The respondent's arguments as far as relevant to the present decision can be summarised as follows:

The appellant should have looked for B5 at an earlier stage of the proceedings. Additionally, F20 and B1 were

late-filed. These three documents should be disregarded.

The main request met the requirements of Article 54 EPC in view of F1/F7 since a rigid receiver could not anticipate a flexible base member. This was in line with T 892/05. Moreover, the sealing tube in Figure 11 had only a sealing function and did not maintain the position and alignment of the components of the port.

Regarding the first auxiliary request, the skilled person would understand that the "reader" of page 10 as originally filed was identical to the "monitoring assembly" of claim 1.

The second auxiliary request met the requirements of the EPC.

XI. The appellant requests that the decision be set aside and the patent be revoked.

The respondent requests that the oppositions be rejected.

As an auxiliary measure it requests that the patent be maintained in amended form on the basis of one of seven auxiliary requests as filed with the reply to the statement setting out the grounds of appeal.

Reasons for the Decision

1. Consideration of documents

The respondent requests, *inter alia*, that documents B1, F20 and B5 be disregarded.

F20 was submitted at the opposition stage (at that time as E12). However, it was published after the effective date of the patent in suit and thus does not form part of the state of the art according to Article 54(2) EPC.

1.1 The appellant filed B1 with its submission dated 13 April 2021, i.e. after the initial phase of the appeal. B1 is a textbook and an earlier edition of F20. It illustrates the common general knowledge of the skilled person before the effective date of the patent in suit.

The submission of B1 is a direct response to the fact that the respondent raised the issue of the publication date of F20 in its reply to the grounds of appeal.

It has not been disputed that the respective passages of B1 and of F20 are identical, in particular Figure 1.6 of F20 and Table 1.3 of B1, both labelled "Plastics Identification Attributes". Therefore, the disclosure of B1 cannot come as a surprise.

For these reasons, B1 is taken into consideration (Article 13(1) RPBA 2020).

1.2 The question of whether F20 is to be considered in the appeal proceedings has no bearing on the present decision and may be left open.

1.3 The appellant submitted B5 the day before the oral proceedings at the appeal stage to prove that the "keying" of components of a monitoring assembly (i.e. the new feature of the second auxiliary request) belonged to the common general knowledge of the skilled person, and thus constituted the application of routine measures.

The appellant argued that it could not have submitted B5 earlier because this document had only just been found. Moreover, common general knowledge should always be admitted in the appellant's view.

According to Article 13(2) RPBA 2020, "any amendment to a party's appeal case made after ... notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned".

The submission of B5 constitutes an amendment to the appellant's case as it is an attempt to provide evidence for an assertion unproven hitherto. However, the fact that this document had been found at a very late stage in the proceedings cannot justify the presence of "exceptional circumstances".

Indeed, the opposition division had already indicated in its summons to oral proceedings, with regard to the then fourth auxiliary request, that the document F3 - which had been invoked by opponent 1 to show that the keyed nature of the components of the monitoring

assembly could not confer inventive step - related to a "field totally unrelated".

In the reply to the statement setting out the grounds of appeal (i.e. when the current second auxiliary request was submitted), the respondent indicated that none of the prior-art documents disclosed keyed components of a monitoring device.

To counter this, the appellant alleged that the use of keyed components of the monitoring assembly represented merely the application of routine measures ("eine lediglich handwerkliche Ausgestaltung"), yet without any proof. The appellant should have made the effort to look for evidence at least at that moment.

Furthermore, the possibility that even evidence of alleged common general knowledge is not necessarily admitted at any moment of the appeal proceedings is in line with established case law (see e.g. T 2159/17, reasons 2).

If this were not the case, the other party would be deprived of an opportunity to evaluate the newly submitted evidence and counter it with evidence and arguments to the contrary where necessary.

Document B5 is therefore disregarded (Article 13(2) RPBA 2020).

Main request

The main request corresponds to the claims as granted.

2. Article 54 EPC

For the reasons set out below, the subject-matter of claim 1 is anticipated by F1/F7, contrary to the opposition division's conclusion.

2.1 The features of claim 1 are identified in Figure 11 of F1 (see also page 17, lines 14 to 28) as follows:

- The "rigid receiver 200" with the sections 202a and 202b in Figure 11 is construed as the "flexible base member" i).
- "Bushing 204" is construed as the "bushing member" ii).
- The system comprising both the "fiber optic cable L" and the "transparent tube G" is construed as the "monitoring assembly" iii).
- The "sealing tube 206" is construed as the "cover" iv).

2.2 In the respondent's view, the embodiment of Figure 11 of F1 discloses

- neither a *flexible* "base member"
- nor a "cover" which maintains the position and alignment of the bushing member and the monitoring assembly relative to the base member; in particular since the fibre optic cable L had some spatial tolerance inside the glass tube G.

2.3 At first glance it might indeed appear surprising to construe the *rigid* receiver 200 of F1 (page 17, line 17) as the *flexible* base member of claim 1.

However, the term "flexible" in claim 1 is a relative term and has to be construed broadly. In addition, it refers to different aspects: while it designates the ability of the base member to "generally maintai[n] its

shape under the weight of fluid introduced in the bag" in F1 (page 6, lines 18/19), it means the ability to "conform to a more delicate subsystem that does not require support" in the patent in suit (patent in suit, column 7, lines 12/13). Indeed, the base member of F1 can be rigid enough to maintain its shape under the weight of fluid, while at the same time being flexible enough to conform to a more delicate subsystem.

Moreover, F1 indicates on page 6, lines 13 to 17, that rigid materials in this context may be "high density polyethylene (HDPE), ultrahigh molecular weight (UHMW) polyethylene, or like materials" and that these materials inevitably "have some inherent flexibility when used to form relatively thin components or when a moderate amount of bending force is applied thereto".

The flexible nature of (low- and high-density) polyethylene is also confirmed in B1 (first lines of Table 1.3 on page 12: "PE-LD" and "PE-HD"), which illustrates the common general knowledge of the skilled person.

The situation in T 892/05, referred to by the respondent, is not comparable: in that case the feature in dispute was a temperature, not a relative term as in the present case.

For these reasons, F1 is considered to disclose a *flexible* base member.

2.4 The respondent also argues that F1 does not mention that the sealing tube 206 in Figure 11 maintains the position and the alignment of elements 200, 204, L and G, and that the function of maintaining the position

and alignment was fulfilled by the glass tube G rather than by the sealing tube 206.

However, any spatial tolerance of the fibre optic cable L inside the glass tube G is irrelevant since the "monitoring assembly" is construed as comprising both the fibre optic cable L and the glass tube G.

Moreover, the elements 200, 204, L and G are all mechanically connected with each other. Furthermore, the sealing tube 206 in Figure 11 of F1, which is fixed by cable ties 208, *inherently* maintains - at least to some degree - the position and alignment of bushing 204 as well as the subsystem comprising fibre optic cable L and transparent tube G relative to receiver 200. F1 therefore also discloses feature iv) of claim 1.

2.5 All the features of claim 1 are consequently anticipated by F1 (Article 54(1) and (2) EPC).

2.6 It has not been disputed that the disclosures of F1 and F7 are identical.

The subject-matter of claim 1 therefore lacks novelty also in view of F7 (Article 54(1) and (2) EPC).

First auxiliary request

The first auxiliary request is identical to the thirteenth auxiliary request of the opposition stage.

3. Article 123(2) EPC

The respondent indicates that the passage on page 10, lines 32 to 34, as originally filed is the basis for

the feature "*wherein the monitoring assembly does not come in contact with the contents of said bioreactor*" newly inserted into claim 1.

3.1 In contrast with claim 1, however, that passage of the description refers to a "reader" that "does not come in contact with the contents of the disposable bioreactor", not to a "monitoring assembly". The terms used are thus not identical.

Moreover, while the passage on page 10, lines 23 to 30, indicates some exemplary forms of a reader ("appropriate infrastructure for the measurement" which "*can* comprise an optical source and a photo-detector"), it does not state that the reader necessarily comprises:

- means for providing incoming optical and/or electrical signals, and
- means for collecting and transmitting measurement signals resulting from the interaction of said incoming optical and/or electrical signals with the contents of said bioreactor

as required by the "monitoring assembly" of claim 1.

It can thus not be directly and unambiguously deduced that the absence of contact with the contents of the disposable bioreactor is a characteristic of the "monitoring assembly" of claim 1.

3.2 Moreover, the feature "does not come in contact with the contents of the disposable bioreactor" on page 10 as originally filed is disclosed only in combination with the feature that the reader "can be constructed from metal or rigid plastics" (lines 32 to 34).

These features are inextricably linked since the absence of contact of the "reader" with the contents of the disposable bioreactor gives more freedom for the choice of materials for the reader.

The omission of the feature "can be constructed from metal or rigid plastics" from claim 1 hence represents an intermediate generalisation.

3.3 For the reasons set out above under points 3.1 and 3.2, the first auxiliary request does not meet the requirements of Article 123(2) EPC.

Second auxiliary request

For the reasons set out below, the second auxiliary request is considered/admitted and meets the requirements of the EPC.

4. Consideration/admissibility of the request

In the appellant's view, the second auxiliary request should not be considered since it diverges from the first auxiliary request.

However, the second auxiliary request corresponds to the fourth auxiliary request of the opposition stage. In other words, it is among those requests on the basis of which the opposition division had to decide. It was never withdrawn. Therefore, it does not constitute an amendment to the respondent's case within the meaning of Article 12(2) and (4) RPBA 2020. Any lack of convergence is thus irrelevant, as this as this would only be a relevant/applicable criterion when

considering procedural economy in the event of amendments to a party's case.

Therefore, the second auxiliary request is to be considered in the appeal proceedings (Article 12(4) RPBA 2020).

5. Article 123(2) EPC

For the reasons set out below, the second auxiliary request meets the requirements of Article 123(2) EPC.

5.1 The newly inserted feature (keyed components of the monitoring assembly) is based on claim 3 as originally filed.

5.2 Already in view of the main request, the appellant raised the objection that the deletion of the first option ("rigid material") in paragraph [0018] of the patent in suit as compared with page 10, lines 19 to 21, in the description as originally filed:

> "This port component serves as a base plate and ~~can be made of either rigid material (e.g. polyethylene) in order to provide structural integrity of an inserted subsystem, or can be~~ is made of a flexible material (e.g.: a cyclo-olefin) to conform to a more delicate subsystem that does not require support" (omission indicated by the board)

changes the scope of what may be considered a "flexible [base member]" in claim 1 as compared with the passage on page 10.

However, the omission of this alternative does not shift the meaning of the remaining option, which is

still to be construed broadly, as explained above under point 2., and does not therefore go beyond the original disclosure.

5.3 The appellant also contests that only the term "flexible" from the passage on page 10, lines 21 to 22, was inserted into claim 1, and not the related consequence "to conform to a more delicate subsystem that does not require support".

However, the board shares the view of the opposition division that this effect is an inherent consequence of the flexible nature of the base member.

5.4 In the appellant's view, a flexible base member (claim 1) is not directly and unambiguously derivable from the use of a "flexible material" (page 10, line 21).

However, the passage on page 10, lines 21 to 22, indicates that the consequence of the use of a flexible material is the ability "to conform to a more delicate subsystem that does not require support". This implies that not only the material is flexible but also the resulting base member.

5.5 For these reasons, the second auxiliary request meets the requirements of Article 123(2) EPC.

6. Article 54 EPC

Formally, the appellant invoked Article 54 EPC against the second auxiliary request, but has failed to substantiate its objection. This has not been disputed.

The objection is therefore disregarded (Article 12(3) and (5) RPBA 2020).

7. Article 56 EPC

In the appellant's view, the subject-matter of claim 1 lacks an inventive step in view of each of F1/F7 and F5.

7.1 The invention relates to a port for use with a disposable bioreactor vessel.

7.2 In the appellant's view, F1 is possibly the closest prior art.

Since F1 relates indeed to the same technical field and since it has numerous features in common with claim 1 (see point 2. above), it is an appropriate starting point for assessing inventive step.

7.3 According to paragraph [0011] of the patent in suit, the problem to be solved is to provide a more reliable method of obtaining information in disposable bioreactors in a timely manner.

7.4 It is proposed that this problem be solved by the port of claim 1 of the second auxiliary request, characterised in that the monitoring assembly or the components thereof are keyed so as to permit insertion into the bushing in only one orientation.

7.5 It has not been disputed that this problem is successfully solved. Furthermore, the board cannot see a reason why a limitation of the relative movement between the monitoring assembly and the bushing member

would not result in a more reliable measurement. Thus, the problem has been successfully solved.

8. The appellant alleges that the use of such a keyed monitoring assembly is merely a routine measure. However, the respondent has contested this allegation.

The appellant also cites B5 to prove its allegation, but B5 is disregarded (see point 1.3 above).

It is undisputed at the appeal stage that no other available prior art discloses keyed components of a monitoring assembly. It is also undisputed that such a "keying" solves the technical problem.

The subject-matter of claim 1 therefore involves an inventive step in view of F1 (Article 56 EPC).

8.1 The same holds for the family member F7, in particular since it is undisputed that the disclosure of F7 is identical to that of F1 (Article 56 EPC).

8.2 Due to the claim dependencies, the same reasoning applies to dependent claims 2 to 12 of the second auxiliary request (Article 56 EPC).

8.3 A similar reasoning applies when document F5 is considered as the closest prior art (Article 56 EPC).

Indeed, it has not been disputed that F5 (e.g.: Figures 10 and 11 and paragraphs [0071] to [0074]) also at least fails to disclose the keyed nature of the "monitoring assembly" (which is construed as the rod-shaped temperature probe 238 in the upper right corner of Figure 11).

It can thus be left undecided whether the first priority of the patent in suit is valid and whether F5 is consequently prior art under Article 54(2) EPC or not.

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 on the basis of the second auxiliary request filed with the reply to the statement of grounds of appeal and a description to be adapted thereto.

The Registrar: The Chairman:

C. Vodz E. Bendl

Decision electronically authenticated