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**Datasheet for the decision  
of 20 April 2021**

**Case Number:** T 2233/15 - 3.2.03

**Application Number:** 08161344.0

**Publication Number:** 2020433

**IPC:** C12M1/00

**Language of the proceedings:** EN

**Title of invention:**

Continuous perfusion bioreactor system

**Patent Proprietor:**

Global Life Sciences Solutions USA LLC

**Opponent:**

INNOVINCIA

**Headword:**

**Relevant legal provisions:**

EPC Art. 56, 123(2)

**Keyword:**

Inventive step - (yes)

Amendments - added subject-matter (no)

**Decisions cited:**

T 0611/90, T 1002/92, T 1705/07, T 1067/08, G 0003/14,  
G 0009/91

**Catchword:**



**Beschwerdekammern**

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Case Number: T 2233/15 - 3.2.03

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.03**  
**of 20 April 2021**

**Appellant:** INNOVINCIA  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 8 October 2015  
rejecting the opposition filed against European  
patent No. 2020433 pursuant to Article 101(2)  
EPC.**

**Composition of the Board:**

**Chairman** G. Patton  
**Members:** C. Donnelly  
N. Obrovski

## **Summary of Facts and Submissions**

- I. The present appeal was lodged by the opponent (the "appellant") against the decision of the opposition division rejecting the opposition against European Patent No. EP-B-2 020 433.
- II. By letter of 22 June 2016 the patent-proprietor (the "respondent") set out its response to the grounds of appeal and submitted auxiliary requests 1 to 9. By letter of 23 November 2016, the appellant submitted further arguments, in particular with respect to the auxiliary requests.
- III. The following documents cited by the appellant in the notice of opposition and the grounds of appeal are relevant to the present decision:
- E1: US 6 544 788 B;  
E3: US 2005/0272146 A;  
E6: US 6 596 521 B; and  
E7: WO 2005/108546 A.
- The appellant also made reference to the following document cited for the first time with the grounds of appeal:
- E25: US 2005/0158851 A1.
- IV. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA 2020), annexed to the summons to oral proceedings, the Board informed the parties of its provisional opinion.

V. With the consent of both parties, oral proceedings were held by video-conference on 20 April 2021. The presentation and withdrawal of requests is detailed in the minutes of the oral proceedings. At the end of the debate the parties confirmed the following requests:

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

The respondent requested that the patent be maintained in amended form on the basis of the sole request filed as auxiliary request 7 with letter dated 22 June 2016.

VI. Claim 1 of the respondent's sole request reads as follows:

"A system (10) for containing and manipulating fluid substances, comprising:

- a first apparatus (14), comprising:
  - a first collapsible bag (118) adapted for containing a fluid, the first collapsible bag (118) including a first inlet, a first outlet, and a base plate (400) that is attached to the first collapsible bag (118);
  - an impeller (509) associated with the base plate (400);
  - a first reusable support structure (114) adapted for surrounding and supporting the first collapsible bag (118); and
  - a second apparatus (18) in fluid communication with the first apparatus (14), the second apparatus (18) including a second inlet and a second outlet, wherein

the second apparatus (18) is disposed external to the first collapsible bag (118) or disposed inside of the first collapsible bag (118), wherein

(a) when the second apparatus (18) is disposed external to the first collapsible bag (118), the first outlet of the first collapsible bag (118) is in fluid communication with the second inlet of the second apparatus (18), and the second outlet of the second apparatus (18) is in fluid communication with the first inlet of the first collapsible bag (118); and

(b) when the second apparatus (18) is disposed inside of the first collapsible bag (118), the first outlet of the first collapsible bag (118) is in fluid communication with the second outlet of the second apparatus (18), and the second inlet of the second apparatus (18) is in direct fluid communication with the fluid inside the first collapsible bag (118), wherein

said first apparatus (14) is in fluid communication with an apparatus (40) including a storage tank adapted for containing media, buffer, reactants, and/or other fluids, and including a collapsible bag adapted for containing a liquid."

Method claim 13 of the respondent's sole request reads as follows:

"A method of recovering and recycling solutes or cells from a bioreactor comprising the first collapsible bag (118) of the system (10) of any of claims 1 to 12 while maintaining a substantially constant volume of fluid in the bioreactor, the method comprising:

- allowing a cell culture suspension in a fluid medium in the first collapsible bag (118) to grow to a first concentration of solutes or cells;

- continuously allowing a portion of the fluid medium comprising the solute or cell culture suspension having the first concentration of solutes or cells to flow out of the first outlet of the first collapsible bag (118) and into the second inlet of the second external apparatus (18) comprising the separation device or through the second internal separation device to the outlet of the first apparatus (14);

- allowing the separation device of the second apparatus (18) to separate out at least a portion of the solutes or cells from the fluid medium flowing into the second apparatus (18) from the first collapsible bag (118), while simultaneously causing a fluid to flow from the second apparatus (18) out of the second outlet of the second apparatus (18) and into the first inlet of the first collapsible bag (118); and

- recycling at least a portion of the solutes or cells separated out by the second apparatus (18) by flowing some or all of the separated solutes or cells back into the collapsible bag (118), or directly back into the fluid within the first apparatus (14),

while continuously maintaining a substantially constant volume within the collapsible bag (118) during the outflowing, inflowing, and recycling steps, thereby recovering and recycling solutes or cells from the bioreactor while maintaining a substantially constant volume of fluid in the bioreactor or pharmaceutical device."

**VII. Appellant's submissions**

*Admissibility of E25*

E25 should be admitted into the proceedings since it was filed at the earliest possible opportunity with the grounds of appeal in response to certain interpretations made by the opposition division, in particular point 11.9 of the decision under appeal.

*Added subject-matter, Article 123(2) EPC*

The subject-matter of claim 1 comprises added subject-matter since it fails to specify that "different media, buffer, reactants, and/or other liquids to be transferred to apparatus 14" as originally disclosed in paragraph [0062] of the patent application as published.

*Inventive step*

The subject-matter of claim 1 lacks an inventive step starting out from E6 in combination with E3 or E7, and taking into account general knowledge as taught in E1.

The subject-matter of claim 13 lacks an inventive step starting out from E6 in combination with E3 or E7.

**VIII. Respondent's submissions**

*Admissibility of E25*

E25 should not be admitted into the proceedings since there have been no exceptional circumstances to justify its late filing. In particular, the reasoning in the



contested decision does not comprise anything which the appellant could not have expected.

Should E25 be admitted, it is requested that the case be remitted to the opposition division for further prosecution.

*Added subject-matter*

The supplementary feature with respect to claim 1 is based on paragraph [0062] of the patent application as published. Each of the aspects mentioned in this paragraph are optional and not inextricably linked. Therefore, there is no added subject-matter.

*Inventive step*

The skilled person would not have taken E6 as the closest prior art since it relates to continuous large-scale fermentation of lactic acid whereas the patent relates to the production of high value complex biological products. However, even if E6 were considered to be the closest prior art, the subject-matter of claim 1 is any case inventive since the skilled person would not combine the teachings of E6 with E3 and E1 without the benefit of hindsight and, even if they did, it would not lead to the subject matter of claim 1 without exercising an inventive step. The same applies for the combination of E6 with E7.

Claim 13 comprises all the features of system claim 1 since otherwise it would not make any technical sense and would be unclear. Therefore, the subject-matter of claim 13 also involves an inventive step.

## **Reasons for the Decision**

### *1. Admissibility of E25*

1.1 Document E25 was cited for the first time in the grounds of appeal. The board shares the opinion expressed in T 1002/92, referred to by the respondent, that new material should only very exceptionally be admitted into the proceedings since the essential purpose of the appeal procedure inter partes is to give the losing party the possibility of challenging the decision of the first instance rather than to repeat the opposition proceedings.

In that respect, the appeal proceedings are not about bringing an entirely fresh case to the board. This means that a party is not at liberty to bring about the shifting of its case to the appeal proceedings as it pleases, and so compel the board either to give a first ruling on the critical issues or to remit the case to the opposition division. Conceding such freedom to a party would run counter to orderly and efficient appeal proceedings. In effect, it would allow a kind of "forum shopping" which would jeopardise the proper distribution of functions between the departments of first instance and the boards of appeal and would be absolutely unacceptable for procedural economy generally (G 9/91, OJ EPO 1993, 408, point 6 and 18; T 1705/07, not published, point 8.4 of the reasons; T 1067/08, not published, points 7.1 to 7.2).

1.2 In the present case, the attacks based on E25 are completely new. Therefore, their admittance would necessitate either examination of new objections or remittance to the first instance for further

prosecution (see for example T 611/90) as requested by the respondent.

- 1.3 In view of the case-law mentioned above, E25 is not admitted into the proceedings (Article 12(4) RPBA 2007).

Hence, the respondent's request to remit the case to the opposition division should E25 be admitted into the proceedings is moot.

2. *Added subject-matter*

- 2.1 In comparison with claim 1 as granted, the subject-matter of claim 1 comprises the supplemental feature according to which:

"said first apparatus (14) is in fluid communication with apparatus (40) including a storage tank adapted for containing media, buffer, reactants and/or other fluids, and including a collapsible plastic bag for containing a liquid".

- 2.2 This feature is based on paragraph [0062] of the patent application as published which states:

"Optionally, in some embodiments apparatus 14 is in fluid communication with one or more apparatuses 40. For instance, liquid may be transferred 42 continuously or periodically from apparatus 40 to apparatus 14. Apparatus 40 may include, for example, a vessel such as a storage tank adapted for containing media, buffer, reactants, and/or other fluids. A plurality of apparatuses 40 may each contain different media, buffer reactants, and/or other liquids to be transferred to apparatus 14. One or more apparatuses 40 may include

disposable components such as a collapsible bag adapted for containing a liquid, the collapsible bag optionally being supported and contained by a reusable support structure."

2.3 Contrary to the opinion of the appellant, it is apparent from this paragraph that the designation of the different media, buffer, reactants, and/or other liquids as being "to be transferred to apparatus 14" is optional since it is stated that "For instance, liquid maybe transferred 42 continuously or periodically from apparatus 40 to apparatus 14". The terms "For instance" and "may be" used in this sentence both indicate the optional nature of this specification.

2.4 Therefore, the requirement in the first sentence that "in some embodiments apparatus 14 is in fluid communication with one or more apparatuses 40" is not inextricably linked to the designation of the liquids as being "to be transferred to apparatus 14.

2.5 Consequently, the subject-matter of claim 1 does not comprise added subject-matter and meets the requirement of Article 123(2) EPC.

### 3. *Inventive step, claim 1*

3.1 The Board agrees with the appellant that E6 is a realistic starting out point for assessing the inventive step of claim 1 since it also relates to a system for containing and manipulating fluid substances in a biological process (see E6, abstract).

3.2 The Board agrees with the parties that E6 fails to disclose at least:

(i) a first collapsible bag; and

(ii) a first reusable support structure, adapted for surrounding and supporting the first collapsible bag; and

(iii) an apparatus which is in fluid communication with the first apparatus and which includes a storage tank adapted for containing media, buffer, reactants and/or other fluids, and including a collapsible plastic bag for containing a liquid.

3.3 The technical effect of these distinguishing features is to provide a system which can be set up quickly, without the need for sterilisation and certification of the standard stainless steel or glass bioreactors.

3.4 Therefore, the objective technical problem can be seen as one of how to increase efficiency of a system for containing and manipulating fluid substances in a biological process. Notwithstanding the fact that it would not be related to the technical effects, any attempt to define the technical problem more narrowly by referring to replacing stainless steel or glass containers would be inappropriate since it gives a hint to the solution.

3.5 The respondent submitted that the skilled person would not combine the teachings of E6 and E3 because E6 refers to large scale fermentation whereas E3 is concerned with smaller scale operations. However, this is not persuasive since the apparatus of E3 can also be dimensioned for large scale operations (see E3, paragraph [0031] "The design may also be scalable down to small bench bioreactors volumes and up in excess of 1000 L working volumes").

- 3.6 Further, the respondent's reasoning that the skilled person would also be dissuaded from combining the teachings of E6 and E3 since the aim of E6 is to provide an environmentally friendly system which runs counter to the idea behind E3 of using disposable items such as plastic bags is not convincing. Whether something is "environmentally friendly" is open to debate. In some circumstances cleaning out tanks and creating waste water and/or solvents is less desirable than using containers which can be safely disposed of and/or recycled.
- 3.7 The respondent also suggested that since the system of E6 does not require stringent sterilisation there would be no point in modifying the system by employing disposable bags as used in the apparatus of E3. However, the system of E3 is also suitable for non-sterile applications (see E3, paragraph [0009]). Further, as submitted by the appellant the porous filtration element 401 of E3 is optional (see paragraph [0050]).
- 3.8 Therefore, faced with the above objective problem the skilled person would have consulted E3 and combined its teachings with E6 since it lies in the same technical area of processing biological materials (see paragraph [0002]) .
- 3.9 E3 also relates to bioreactors comprising a collapsible bag and a reusable support structure, adapted for surrounding and supporting the first collapsible bag (see paragraph [0028], figure 2 and claims 1 and 2). However, although both E6 and E3 indicate that there is a feed line to the system (see E6, figure 1, "Media" line m; and E3, paragraph [0032] "connections" 101e,

figure 1B), neither discloses any detail concerning the construction of the apparatus with which the feed line is in fluid communication.

3.10 The appellant submitted that the inclusion of a storage tank comprising a collapsible plastic bag for containing liquid in fluid communication with the first apparatus, as shown for example in E1 (see E1, figure 4, feed container 32), is merely common general knowledge. However, this argument is not persuasive since patent documents cannot normally be used as evidence of common general knowledge and E1 does not in any case disclose the nature of the feed container 32.

3.11 Therefore, the combination of E6 with E3, even taking into account the teaching of E1, does not lead to the subject-matter of claim 1 in an obvious manner.

3.12 E7 like E3, see point 3.9 above, does not disclose any detail concerning the construction of the apparatus which is in fluid communication with the first apparatus (feature (iii)). Hence, for the same reasons the combination of E6 with E7 does not lead to the subject-matter of claim 1 in an obvious manner.

3.13 In conclusion, the subject-matter of claim 1 meets the requirement of Article 56 EPC.

4. *Inventive step, method claim 13*

4.1 The introductory part of claim 13 reads:

"A method of recovering and recycling solutes or cells from a bioreactor comprising the first collapsible bag (118) of the system (10) of any of claims 1 to 12 while

maintaining a substantially constant volume of fluid in the bioreactor,....."

4.2 The appellant submitted that the claim is directed at a method employing any bioreactor comprising the first collapsible bag of any of the systems according to claims 1 to 12. The respondent on the other hand, argued during the oral proceedings, that the skilled person would immediately understand that the claim is for a method in which a system comprising all the features of any of claims 1 to 12 is used.

4.3 As evidenced by the parties' submissions, the introductory part of claim 1 could have perhaps been couched in clearer terms. However, since the wording of claim 13 is identical to claim 15 as granted, an objection of lack of clarity cannot be made (see G 3/14). Therefore, a technically sensible construction of the claim as a whole needs to be reached.

4.4 As argued by the respondent, it appears to the Board that the claim only makes technical sense if all the features of the system according to claim 1 are comprised in the claim. In particular, this is borne out by the use of the definite article when specifying *the* first apparatus and *the* second apparatus in the following features:

"allowing a portion of the fluid medium..... into *the* second inlet of *the* second external apparatus (18) ..... or through *the* second internal separation device to the outlet of *the* first apparatus (14; 66; 100); and

"allowing *the* separation device of *the* second apparatus (18) to separate out.....".



4.5 Thus, the skilled person interpreting claim 13 would set aside any purely grammatical construction of the introductory portion and understand that the claim comprises all the features of the system of any of claims 1 to 12 - and not only the first collapsible bag of these systems. In the oral proceedings before the Board, the respondent explicitly confirmed that in their view claim 13 had to be interpreted this way.

4.6 Accordingly, claim 13 also involves an inventive step.

## 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 with the following claims and a description to be adapted thereto:

#### Claims:

No. 1-13 filed as auxiliary request 7 with the submission dated 22 June 2016.

The Registrar:

The Chairman:



C. Spira

G. Patton

Decision electronically authenticated