

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 12 November 2021**

Case Number: T 1367/19 - 3.3.05

Application Number: 10736633.8

Publication Number: 2456547

IPC: B01F7/00, C12M1/02, C12M1/06

Language of the proceedings: EN

Title of invention:
STIRRER SYSTEM

Patent Proprietor:
F. Hoffmann-La Roche AG

Opponent:
SARTORIUS STEDIM BIOTECH GMBH

Headword:
Stirrer/Hoffmann la Roche

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - main request (no) - suitable for different use -
second auxiliary request (yes)
Inventive step - (yes) - second auxiliary request

Decisions cited:

T 2702/18

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1367/19 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 12 November 2021

Appellant: SARTORIUS STEDIM BIOTECH GMBH
(Opponent) August-Spindler-Strasse 11
37079 Göttingen (DE)

Representative: Michalski Hüttermann & Partner
Patentanwälte mbB
Speditionstraße 21
40221 Düsseldorf (DE)

Respondent: F. Hoffmann-La Roche AG
(Patent Proprietor) Grenzacherstrasse 124
4070 Basel (CH)

Representative: Bösl, Raphael Konrad
Patentanwälte
Isenbruck Bösl Hörschler PartG mbB
Postfach 86 08 80
81635 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 11 March 2019
rejecting the opposition filed against European
patent No. 2456547 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman E. Bendl
Members: G. Glod
P. Guntz
T. Burkhardt
O. Loizou

Summary of Facts and Submissions

I. The appellant's (opponent's) appeal lies from the opposition division's decision rejecting the opposition against European patent EP 2 456 547 B1.

II. The following documents cited in the impugned decision are of relevance here:

D18: Product leaflet Biostat[®] D, Sartorius

D22: Flow chart of the fermenter system
delivered to Ecover

D23: Equipment list for the fermenter delivered

D24: Operation and Maintenance Instructions, and
certifications of the stirring unit of the
fermenter system delivered

D48: Product Information Biostat[®] D50/D100, as
distributed by B. Braun Biotech International

D49: Product leaflet for the Biostat[®] D50/D100, as
made available online by B. Braun Biotech
International

III. Oral proceedings in the appeal procedure took place on 12 November 2021, during which the appellant withdrew its objection under Article 113(1) EPC.

IV. The main request (patent as granted) comprises 18 claims, of which claim 11 reads as follows:

"Device for culturing animal cells, characterized in that the device comprises:

a) a cultivation vessel,

b) a vertical shaft along the middle axis of the cultivation vessel,

- c) a stirrer system consisting of two radially-conveying stirrer elements and one axially-conveying stirrer element arranged above one another on a vertical stirrer shaft, wherein the axially-conveying stirrer element is arranged above the radially-conveying stirrer elements,
- d) a gas feed at the bottom of the cultivation vessel, and
- e) at least one inlet in the area above the liquid surface for adding correcting and/or feeding solutions."

Claim 10 of the first auxiliary request is identical to claim 11 of the main request.

In the second auxiliary request, claims 10 to 18 of the patent as granted have been deleted. Claims 1 and 2 of the second auxiliary request read as follows:

"1. Method for culturing mammalian cells, characterized in that the mammalian cells are cultured in a device comprising a stirrer system and a cultivation vessel, wherein the stirrer system is consisting of two radially-conveying stirrer elements and one axially-conveying stirrer element arranged above one another on a vertical stirrer shaft, wherein the axially-conveying stirrer element is arranged above the radially-conveying stirrer elements."

"2. Method for producing a polypeptide comprising the following steps:

- a) culturing a mammalian cell comprising a nucleic acid encoding the polypeptide in a device comprising a stirrer system and a cultivation vessel,

wherein the stirrer system is consisting of two radially-conveying stirrer elements and one axially-conveying stirrer element arranged above one another on a vertical stirrer shaft, wherein the axially-conveying stirrer element is arranged above the radially-conveying stirrer elements,

b) recovering the polypeptide from the cultivation medium or from the cells,

c) purifying the polypeptide and thereby producing the polypeptide."

Claims 3 to 9 relate to preferred embodiments.

- V. The appellant's arguments relating to the main and first auxiliary request, as far as relevant to the present decision, are reflected in the reasoning below. Those concerning the second auxiliary request are as follows:

The subject-matter of claims 1 and 2 lacked inventive step in view of the prior use of the Ecover fermenter. The problem to be solved was simply to provide a new use for the known fermenter. This fermenter was suitable for culturing animal cells. The skilled person therefore knew that it could also be used for that purpose. In addition, the skilled person intended to provide a broad spectrum of uses for a fermenter, so that it was easier to sell on the secondhand market.

- VI. The respondent's (proprietor's) arguments concerning claim 11 of the main request are summarised as follows:

It was not shown beyond reasonable doubt that no confidentiality agreement between Ecover and Sartorius existed. Ecover had an interest in keeping the combination of the specific stirrer with the D100

fermenter, which could be considered as a pilot system, confidential. Although the witnesses at the oral proceedings in the opposition procedure indicated that they were not aware of any confidentiality agreement, this could simply mean that they did not know of one. Therefore the Ecover fermenter was not publicly available.

The Ecover fermenter was not suitable for culturing animal cells. It had to be considered as a whole, meaning that the whole system that was delivered, including the control elements, had to be taken into consideration when evaluating novelty. It had to be analysed whether that system as such was suitable for culturing animal cells without any changes. A change included either a replacement, an addition or an omission of a technical feature.

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

The respondent requested that the appeal be dismissed, or alternatively that the patent be maintained in amended form on the basis of the first or second auxiliary request, both as submitted with the reply to the grounds of appeal.

Reasons for the Decision

Main request (patent as granted)

1. Article 54 EPC - Claim 11

Claim 11 relates to a device for culturing animal cells characterised by features a) to e). This means that the

scope of the claim is a device having these five features which is suitable for culturing animal cells.

It needs to be determined whether a device having the five features is part of the state of the art and is suitable for culturing animal cells.

The so-called Ecover fermenter is the system as shown in D22 with the equipment as listed in D23, including the stirrer of D24.

There are two points of debate, namely

(i) whether the Ecover fermenter was publicly available, and,

(ii) if so, whether the Ecover fermenter was suitable for culturing animal cells.

1.1 in relation to (i)

As indicated in the impugned decision (point 19.1.3), this system was installed on site in Malle/Belgium in 2004 and was not subject to confidentiality. This conclusion is endorsed by the Board.

Both witnesses heard before the opposition division indicated that there was nothing to be kept confidential (see the minutes of the taking of evidence by hearing of Mr. Demaret, page 4, bottom and minutes of the taking of evidence by hearing of Mr. Laue, bottom of page 6 and top of page 7). There is no reason to doubt the credibility of these statements. If there was a confidentiality agreement between Braun Biotech and Ecover, then all the employees working on the project related to both companies would surely have

been informed of it in order to guarantee that they were bound by it and the secret was actually kept. There is no information from Ecover contradicting the witnesses' statements.

The appellant argues that an implicit non-disclosure agreement is to be assumed because the fermenter sold was customized at the request of Ecover, therefore making it special. However, the mere customization of an otherwise commonly sold product is not sufficient to assume that parties would have a common interest in keeping the features of such product confidential and a binding mutual will to do so (see T 2702/18, Reasons 3.2.2). Although the stirrer is not the standard stirrer of the Biostat D100 fermenter, there is no indication that the combination of stirrer and fermenter was part of a pilot project or other joint venture between the two companies for its development that might have implied confidentiality between the parties.

1.2 in relation to (ii)

The next contested point is whether this Ecover fermenter discloses all the features of claim 11 and is suitable for culturing animal cells. It is undisputed that the vessel No. 1370 of D22 is a cultivation vessel (corresponding to feature a) of the present claim 11) and contains the stirrer system as shown on page 33 of D24. This system corresponds to features b) and c). It is also immediately apparent from D22 that the vessel has a gas feed at the bottom and an inlet at the top. Thus features d) and e) of claim 1 are also present.

It is important to distinguish between:

- the vessel containing the five features a) to e), and

- the remaining peripheral equipment of the whole Ecover fermenter system as well as the buffer solution and the gases actually used.

The vessel containing the five features a) to e) is considered to be an independent device within the whole Ecover fermenter system. It can be connected to pipes and a control system as desired. It therefore corresponds to a device according to claim 11. This device is suitable as such, i.e. without any modification, for culturing animal cells.

On the other hand, the rest of the peripheral equipment, including the control system and corresponding input pipes as well as the fluids used, is not part of the device defined in claim 11. Any modifications thereto in order to render the entire system suitable for culturing animal cells (e.g. a pH control, the supply of CO₂, the use of a different buffer solution) are irrelevant to the evaluation of the question of novelty of the claimed device. Contrary to the opposition division's position, the Board is of the opinion that the intended purpose "for culturing animal cells" cannot be used to read into the claim features that are not present. If the intention was to protect the device including the whole control system, the corresponding features should have been included in the claim.

As a consequence, the respondent's arguments relating to the gas connections, the control system and the type of valves to be used to avoid carbon dioxide corrosion are irrelevant, since these features are not part of claim 11 and do not have to be taken into consideration for the question of novelty. The Biostat[®] D100 fermenter is presented in D48 and D49 as a system which

is preconfigured for the measurement and control of certain parameters such as temperature, pH etc. However, this does not mean that the vessel as such with the specific stirrer, which is the claimed device, could not be used (or would be unsuitable) with a different control and measurement system. Different controls allow the technical features such as the stirrer to be adapted to a different use, meaning that the stirrer as such is suitable for an alternative use. The preconfiguration only means that certain openings such as the ones shown in D22 are already present in the wall of the vessel. Although they are intended for connecting sensors for measuring temperature, pH, O₂ and CO₂ concentration (see numbers 3021 to 3024 in D22 and D23), it is possible to connect other sensors instead. This interpretation is also in line with the indication in D49 that accessories for cell culture applications are available upon request.

Therefore the vessel of D22 with the specific stirring system and the fluid inlets as set up in Malle/Belgium is considered to anticipate the novelty of the subject-matter of claim 11.

The main request must fail.

First auxiliary request

2. Claim 10 is identical to claim 11 of the main request. Therefore the same conclusion applies and the requirements of Article 54 EPC are not met. This request must also fail.

Second auxiliary request

3. Article 56

- 3.1 The invention according to claim 1 relates to a method for culturing animal cells.
- 3.2 The appellant based its inventive-step objection on the Ecover fermenter as closest prior art. The Ecover fermenter, including the whole control system, was set up in Malle and was used for microbial applications.
- 3.3 The problem to be solved is to provide a method for effectively culturing animal cells (see paragraph [0010] of the patent). The appellant's proposed problem of providing a different use for the known fermenter does not apply to the subject-matter of claim 1, which is a method claim. In addition, it is based on an *ex post facto* analysis, as it already implies that a different use is possible.
- 3.4 The problem is solved by a method according to claim 1, characterised in that animal cells are cultured in a device such as the Ecover fermenter.
- 3.5 There is no reason to doubt that the problem is successfully solved.
- 3.6 The solution to the problem is not obvious. The Ecover fermenter was installed with the sole aim of culturing bacteria. While the vessel, which as such is part of the overall system installed, is suitable for culturing animal cells as set out above, there was no indication or pointer to the skilled person leading them to use that fermenter for culturing animal cells. Rather, the skilled person would have understood that the fermenter was specifically provided for bacterial applications, as is also evident from D18, which distinguishes

between fermenters for microbial applications and fermenters for cell culture applications (page 7).

The skilled person trying to solve the problem posed knows that both types of fermenter are available on the market. There is no reason why they would take a fermenter that is used to cultivate bacterial cells and convert it into a different system when there is no indication that the conversion would lead to a successful result. The skilled person would rather turn to the Biostat DC series described in D18 (which does not comprise the stirrer system of D24) when trying to cultivate animal cells.

The argument that the secondhand market would trigger broad usability of fermenters is based on speculation, for which no proof has been provided in relation to the specific fermenter.

- 3.7 The subject-matter of claim 1 is considered to be based on an inventive step.

- 3.8 Similar reasoning applies to the subject-matter of claim 2, which also includes the culturing of animal cells. Claim 2 and claims 3 to 9, which directly or indirectly depend on claims 1 and 2, also involve 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 in amended form on the basis of the second auxiliary request, submitted 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